Pop-up Maktivism:
A Case Study of Organizational, Pharmaceutical, and Biohacker Narratives
by
Matthew C. J. Donovan

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Graduate Supervisory Committee:

Sarah J. Tracy, Chair
Alexander Halavais
Heewon Kim
Majia Nadesan

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ABSTRACT

The biohacker movement is an important and modern form of activism. This study broadly examines how positive-activist-oriented biohackers emerge, organize, and respond to social crises. Despite growing public awareness, few studies have examined biohacking's influence on prevailing notions of organizing and medicine in-context. Therefore, this study examines biohacking in the context of the 2016 EpiPen price-gouging crisis, and explores how biohackers communicatively attempted to constitute counter-narratives and counter-logics about medical access and price through do-it-yourself (DIY) medical device alternatives. Discourse tracing and critical case study analysis are useful methodological frameworks for mapping the historical discursive and material logics that led to the EpiPen pricing crisis, including the medicalization of allergy, the advancement of drug-device combination technologies, and role of public health policy, and pharmaceutical marketing tactics. Findings suggest two new interpretations for how non-traditional forms of organizing facilitate new modes of resistance in times of institutional crisis. First, the study considers the concept of "pop-up maktivism" to conceptualize activism as a type of connective activity rather than collective organizing. Second, findings illustrate how activities such as participation and co-production can function as meaningful forms of institutional resistance within dominant discourses. This study proposes “mirrored materiality” to describe how biohackers deploy certain dominant logics to contest others. Lastly, implications for contributions to the conceptual frameworks of biopower, sociomateriality, and alternative organizing are discussed.
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CHAPTER 1:

INTRODUCTION AND RATIONALE

The United States has not-so-affectionately been referred to as “Pill Nation” because of its complicated and unhealthy historical relationship with prescription drugs. According to a 2017 report, the number of prescriptions filled in the United States has risen by more than 85% since 1997 (Carr, 2017). In fact, the Centers for Disease Control and Prevention reports that almost a half of all Americans are taking at least one prescription drug, and almost a quarter take three or more prescription drugs each day (Centers for Disease Control and Prevention, 2017).

Despite the prevalence of medication dispensing, the price of pharmaceutical drugs in the U.S. is twice that of most other developed nations (Kesselheim, Avorn, & Sarpotdwari, 2016), and prices continue to rise. Not surprisingly, from 2013 to 2015, the amount of money Americans spent on pharmaceutical drugs rose by 20% (Kesselheim et al., 2016). In 2016, while sales for pharmaceuticals reached $450 billion in the United States, medical-related expenses were the greatest contributor to poverty in the country (U.S. Census Bureau, 2017). In fact, that same year more than 10 million Americans fell below the poverty line due to medical-related expenses. Increasing drug prices coupled with increased prescribing fill pharmaceutical bank accounts while draining those of everyday Americans. Given that the U.S. Federal Reserve (2018) reports that 44% of Americans do not have enough money in their savings accounts to cover an unexpected $400 expense, increased financial strain related to pharmaceutical costs can have a significant impact on individual life. Not only are Americans affected financially, many face the potential decision to forego purchasing a medication they rely on to survive.
Thus, the implications for access to affordable medicine truly can be the difference between life and death.

Despite growing public and legislative concern over pharmaceutical pricing in the U.S., power remains lopsided and routinely favoring pharmaceutical companies. Pharmaceutical companies have a long history of using clever marketing tactics and engaging in questionable ethical practices. Despite its prevalence, very little organizational communication research examines pharmaceutical (mis)behavior (for exceptions, see Davis, Cross, & Crowley, 2007; Lyon, 2007; Lyon & Mirivel, 2011). Given the social influence pharmaceutical companies have over individual life, more research is needed to explore how dominant discourses and logics of pharmaceuticals continue to recirculate and reemerge over time (Lyon, 2007).

Lyon and Mirivel (2011) note that “the convergence of medical care and financial profit is not entirely new nor without communicative consequence” (p. 53). Communication scholars have been called to more thoroughly “investigate public health issues,” including “problems of access, skyrocketing costs, and quality in medicine” (Zoller, 2010, p. 482). Healthcare policies and protocols impact a variety of social systems, including government agencies, organizations, economic systems, families, and individuals (Birkland, 2005). Despite the field of medicine having been originally developed for public welfare, access to care (including affordable access to necessary pharmaceuticals) is complicated by a variety of economic, regulatory, corporate, and sociohistorical pressures in the United States.

Medicine has become privileged; medical “professionals” are determined by specialties and granted certificates of knowledge authority; medical logics dictate how
and where the development of new medical knowledge can be produced (and by whom); and medical technologies shape how individuals think about and interact with their social and individual bodies. As a result, the discourse of medicine is strongly institutionalized (Barbour, 2010; Murphy & Eisenberg, 2010; Murphy, Eisenberg, Wears, & Perry, 2008; Scott, Ruef, Mendel, & Caronna, 2000; Thornton & Ocasio, 2008).

Further, health and medicine are political. Medicine today largely functions under capitalistic logics that preserve economic-political sovereignty (Nadesan, 2008). Government regulations and medical device oversight are intended to protect individuals from receiving care that could lead to greater harm or do not provide substantially better outcomes than having no care at all. The question of who gets to interpret policy-related systems and engender trust in the medical space is an important issue that organizational communication scholars should (re)consider (Canary & McPhee, 2009). Health should be considered political in nature in part because access to medicine and medical care has become privileged (Bambra, Fox, Scott-Samuel, 2005). In this study, I will closely examine how certain medical logics become preferred and how the medical and scientific discursive formation of allergy and allergy treatment become constituted. The power of knowledge and authority is political; it situates historical values, interests, and norms while hiding and silencing others (Lyon & Chesebro, 2011).

One of the most prominent recent examples of pharmaceutical price-gouging is Mylan’s EpiPen, an epinephrine auto-injector sold to millions of Americans each year as an emergency option for treating anaphylaxis. As the price of EpiPens reached over $600 in 2016, physicians, politicians, and everyday citizens demanded explanations. How could a drug-device combination (that had not fundamentally changed since its first
market release in the late 1980s) increase in price more than 500% in the nine years since Mylan had owned the distribution and marketing rights to the devices? Mylan assigned blame to the complexity of the healthcare marketplace and American healthcare system, while congress, the public, and investigative journalists placed blame on corporate greed. In the United States, EpiPen price increases through 2016 had legitimate financial implications for millions of Americans. Further, lack of affordability presented risks to Americans who came to rely on EpiPens as a simple medical alternative to death.

This case, however, is not simply about EpiPen pricing or pharmaceutical (mis)behavior. While the dominant socio-political conversation focused on which government agencies, organizations, and bad actors were to blame, a relatively unknown biohacker group responded to the growing crisis by creating an affordable and legal do-it-yourself (DIY) epinephrine auto-injector. The group named their device the EpiPencil. Soon, other at-home makers, hackers, and even members of the medical community began developing alternative kits and devices at a fraction of the price of EpiPens. As awareness spread, medical authorities, government agencies, patient advocacy groups, and journalists alike urged the public not to build their own DIY auto-injectors. In the end, individuals responded through creating/making, both as a way to solve a social problem and to challenge dominant institutional logics. As a result, they contributed to a counter-discourse around ownership of medical knowledge and notions of access and price.

A close examination of this case is interesting, in part, because it marks one of the first times that biohackers received broad mainstream media attention. The DIY activities and discursive practices of biohackers are interesting sites of observation for analyzing
both material resistance and discursive contestation. This study of biohacker making/producing illuminates the role of social connected action and alternative organizing during times of crisis. In doing so, it expands organizational communication literature on social action through material production by considering how making can constitute new counter-logics and new bio-political discursive practices to contest dominant discourses of power. Although notions of organizational resistance are central to previous scholarship in organizational communication, few studies have focused on a close analysis of alternative or resistive forms of organizing in action (Kuhn, 2010). Analysis of the relationality between discourses and new material meanings requires new methodological approaches that incorporate a variety of modes for examining the materiality of objects in action (Rose, 2012) across social, organizational, and (in this case) biological contexts.

Issues of power, including questions of “who gains and who loses?” (Flyvbjerg, 2001), are central to critical research. Case studies are especially well suited to situate issues of power within context-dependent knowledge (Flyvbjerg, 2001) and illustrate the ways in which situational social issues can both reveal hidden substances of the human experience and lead to theoretical generalization. Only then will an understanding of the politics of representation be useful. Because power is discursively situated, a story/case can allow the researcher to explore various discourses in rich context. Cases also create opportunities for focusing on multiple oft-competing discourses by drawing attention to counter-narratives and by acknowledging their existence, even if they are fragmented, quiet, or disrupt canonical stories (Lindeman-Nelson, 1996). Finally, critical narrative can
create space for discourses that are embedded, which gives a tangible and meaningful grasp to case aspects that are talked about but do not do the talking.

In sum, the EpiPen pricing crisis provides a rich scene for case study analysis. Examining how various narratives, competing logics, and material productions unfolded in time and place and across multiple levels of discourse is a problematic of practical and theoretical importance. Biohacking is a timely and relevant social movement that, in the context of the EpiPen crisis, presents a unique angle by which a critical analysis can demonstrate the role and function of large institutional logics, corporatized politics of everyday health, and implications about the modes of material resistance.

**Dissertation Preview**

The primary purpose of this study is to elucidate how the biohacking counter-movement in the EpiPen crisis served as a transformative force within entrenched ideologies of preferred knowledge and authority. This case illustrates various forms of resistance discourses through new material resources and discursive constructions. To understand these phenomena in context, I engaged in various types of data collection and analysis, including discourse tracing (LeGreco & Tracy, 2009).

Chapter 2 reviews past literatures related to biohacking, discourse, biopower, and critical organizational communication theory and presents the study’s focal research questions. Chapter 3 overviews data collection, organization, analysis methods, and procedures used in this study. Chapter 4 presents core findings from data analysis and answers the aforementioned research questions. Chapter 5 concludes with a discussion of implications for this research across theoretical and practical contexts, study limitations, and future research extensions and directions.
CHAPTER 2: LITERATURE REVIEW

CONTEXTUALIZING BIOHACKING WITHIN DISCOURSE, BIOPOWER, AND ORGANIZATIONAL COMMUNICATION THEORY

As discussed in the previous chapter, the goal of this research project is to examine and analyze biohacker responses to EpiPen price-gouging by considering how various forms of resistance potentially contest dominant discourses of health, medicine, and the governance of both. This study will examine notions of social action and resistance through a critical post-structural lens and focus on counter-narratives through both discursive and material logics. The following literature review first situates this case in the context of previous research on biohacker collectives and alternative organizations. Then, I contextualize biohackers in relation to frameworks of discourse, biopower, and communicatively constituted organizing.

This is primarily a study about biohacking. Thus, I begin this review by operationalizing biohacking. The rest of the chapter unfolds by situating biohacking and biohacker activities with various conceptual and theoretic frameworks that guide this research study.

**Biohacking and Discourse**

The advent of biohacking originated from a 1988 *Washington Post* op-ed titled “Playing God in your Basement” (Schrage, 1988). Schrage, then-professor at the Massachusetts Institute of Technology, penned that just as previous open-source subcultures grew around computer technologies like microchips and software, a future coterie of amateur “hackers” would also grow around the development of biologic science and technology. In the four decades since, biohacking has indeed emerged as a
global movement of “amateurs conducting life sciences outside of traditional professional settings such as university and corporate labs” (Delfanti, 2012, p. 163).

Today the movement consists of various permutations (e.g., garage biology, do-it-yourself biology, citizen biology, biopunk) that are not necessarily synonymous or consistent with each other (Meyer, 2016). However, biohacking generally subscribes to an ethos of promoting open and decentralized ownership of and access to scientific knowledge, technologies, and participation—tenants also shared among other hacker cultures (Levy, 2001). Not so different than your grandfather stitching up his own thumb after cutting it, biohackers maintain that many of today’s medical procedures could be more accessible and just as successful if individuals were empowered to play a larger role in their own care. For the purposes of this study, do-it-yourself (DIY) biology and biohacking are used interchangeably.

Pang (2016) notes that prior to the 19th century, “almost all science was done by amateurs” (p. i). Over time, however, as scientific knowledge became institutionalized, it centralized in universities, graduate training programs, and formal research institutions. The result was the formation of specialized knowledge sets and new systems of expertise that left the public separated from their care. Critical post-structuralism informs this specialization of knowledge. It does so by providing a discursive framework that explains which types of knowledge come to be constituted and institutionalized and, further, how power becomes historically situated within this knowledge.

**Discursive Constructions**

Discourse refers to enduring group-level thoughts, beliefs, assumptions, and systems of knowledge within social contexts (Alvesson & Karreman, 2000). Also
referred to as master narratives or grand narratives (Boje, 2001). Discourses (with a “Big D”) refer to historically embedded “constellations of talk, ideas, logics, and assumptions that [come to constitute] objects and subjects” (Fairhurst & Putnam, 2004, p. 8).

Organizational communication scholars distinguish between “small d” discourse (i.e., the localized talk, texts, and social practices of members of a group) and “big D” Discourse (i.e., broad and enduring systems of thought) (Alvesson & Karreman, 2000; Fairhurst & Putnam, 2004). Taken this way, discourse is the “medium” by which talk and text contribute to the (re)production of enduring Discursive forms. Therefore, discursive formations are inherently organizing and communication phenomena (Fairhurst & Putnam, 2004).

Discursive formations constitute certain social realities, privilege certain forms of knowledge, create social order and modes of discipline, and embed power through their (re)production (Foucault, 1994). First, discursive formations constitute and construct certain social meanings through their enactment and, therefore, essentially function as social “truths.” Critical scholars acknowledge that discourses have authority and agency, establish the internalization of certain norms, form various types of social order, and subject ways of “believing and behaving across social life” (Nadesan, 2014, n.p.). The power of discursive forms comes from the ways in which the norms and behaviors become taken-for-granted assumptions, normalized, and preferred (Foucault, 1978). Over time, enduring Discourses (re)constitute power and authority through their repeated deployments and, in doing so, constitute organizational and institutional rules (i.e., logics). Thus, Discourses are generative and productive and are substantiated through their naturalization and normalization. At the same time, they also constrain what is (seen
as) possible or alternative. That is, that which is “ruled in” also conversely determines
what norms, talk, and logics become “ruled out” (Hall, 1997). As certain forms of
knowledge gain legitimacy, they come to be unquestioned, appearing value-neutral and
apolitical, and make it unthinkable to do anything else (Deetz, 1992). Unlike traditional
notions of power as a repressive or constraining force, power lies in the (re)production
and enactment of knowledges (Nadesan, 2014). Discursive formations, therefore,
“subject and produce the world” (Deetz, 1992, p. 59). Thus, discursive formations gain
power through their invisibility.

This study is primarily concerned with Discourses of medicine, including medical
governance and regulation. Indeed, Discourses of medicine “transform our understanding
of self, knowledge, technology, and work as well as the larger institution of medicine”
(Deetz & McLellan, 2009, p. 125). The production of new medical knowledge functions
as a mechanism that orients and governs health in certain ways. Further, medicine has
become a for-profit endeavor that uses corporatized models of operation, where corporate
logics have come to function as clinical authority.

**Discourses of Medicine: The Medical Gaze and Medicalized Self**

Medical knowledge has become a pervasive form of discipline for how (social
and individual) bodies are treated, both medically and non-medically. Scientific
technologies and Discourses of the body created new body politics in the 19th century
(Nadesan, 2008). Industrialization led to greater population density in urban areas, which
led to urban squalor and the more-likely spread of infectious disease. To protect the labor
force (thereby ensuring industrialized efforts and productivity continued), new
governmentalities were enacted (e.g., the institution of new public health authorities,
sanitation measures, infrastructure). Urban medicine efforts soon accompanied urban sanitation efforts, which resulted in biopolitical conceptions of the body as a source of illness and potential site of contamination. Medical authorities became responsible for stopping the spread of disease, as well as serving as a form of societal health security. Scientific focus on infectious disease and epidemiology soon came to politically govern public health. As a result, public health officials and medical authorities engaged in medical policing (Foucault, 1978), creating public policy, and developing new health protocols.

Foucault (1978) proposes that 19th century biopower operated through a *medical gaze*, whereby medicine was seen as the “regime of truth” (p. 133). As such, medical knowledge became the preferred instrumentality for medical welfare; however, the discourse of medicine also came to frame issues of social and moral health and hygiene as well. For example, logics of immunity (i.e., a rationalized perspective focused on resistance to certain pathogens) as a medicalized concept has become politically naturalized and embedded beyond biomedical contexts (Jamieson, 2015). Scholars point to discursive logics of immunity that position the body as a battleground, a place by which to eradicate unwanted organisms, both political and biologic. For example, scholars like Martin (1990, 1994) and Napier (2003) suggest that logics of immunity are both biologic and political and that they situate the body in military metaphors of “war, defence [sic], battle and invasion,” which creates an image of the body as “only capable of interacting with others in violent or antagonistic ways” (Jamieson, 2015, p. 3). Immunity logics also evoke biopolitical enactments that begin to devalue certain lives, which, like disease, poses large-scale threats to the health or maintenance of a certain
way of life. For example, asylum seekers, refugees, and the brain dead have all historically been considered risks to social health and political freedom (Lemke, 2011).

The medical gaze, thus, contributed to a kind of “therapeutic state” whereby non-normative behaviors, desires, thoughts, habits, or emotions became the focus of intense institutional problematization (Nadesan, in press) and medicalized intervention. Notions of diagnoses and treatment also trickled into the identity of mainstream society and created a kind of “therapeutic state” in which anything not normalized was seen as a personal ailment in need of therapeutic governance and remedy to be fixed by individual discipline. Individualism, as a result, was stripped away and replaced with a social orientation toward an idealized individual. By identifying human behaviors and affect in terms of their pathologies, the medical community has created new technologies of the self to manage the psyche and attempt to eradicate unwanted social and individual behavior (Nadesan, 2008; Rose, 1990). Scholars have argued that pharmacology is a pervasive form of biopolitics. Biopower is thus disseminated through individual practices of mental hygiene (Nadesan, 2008).

Groups like biohackers are susceptible to immunity logics because they operate outside of the institutional norms of Western science and medicine and, thereby, present the possibility of a threat to national health, both physically and mentally. From this standpoint, their activities are categorized as social deviance rather than making for the social good. Biohackers find themselves labeled by a biologic dystopian mythos that frames them as infiltrators of society’s biological and technical hardware (bodies) and software (minds) (Thomas, 2004). For example, Google—the world’s most used search engine—defines biohacking as “the activity of exploiting genetic material experimentally
without regard to accepted ethical standards, or for criminal purposes” (Google, n.d.). This negative popular framing is not unique to biohacking; other techno-social logics have emerged through the same medicalized perception. Internet attacks and malware are primarily referred to as “viruses” and “worms”; computers become “infected.” Television, the internet, video gaming, and cell phone use have all generated discourse around their “addictive” properties and have been framed and treated as public health concerns (Thomas, 2004).

The rise of the medical gaze also brought the rise of pharmaceutical and medicinal self-regulation (Coombs & Holladay, 2011). In fact, “during the last two decades of the twentieth century, a cognitive and pharmaceutical discourse of engineering and optimizing one’s neurological state for optimization slowly supplemented, and then replaced, the psychological discourse of personal adjustment, fulfillment, and self-actualization” (p. 161). A growing dependency on medicalized logics has introduced new discursive forms that treat non-medical aspects of life in medicalized ways.

**Diffusing Knowledge: Distributing Authority and Expertise**

The biohacker movement in this case finds itself situated within the dominant Discourses of medicine and science, complete with the various forms of institutionally derived disciplines, enacted policies, constituted protocols, and preferred forms of expertise (Nadesan, 2014). One of the more powerful ways “professional” science demarcates itself from that of “amateur” science is through the mapping of scientific spaces and territories, especially where professional science happens and, by comparison, where amateur science is therefore relegated to (Meyer, 2013). Gieryn (1999) notes that science defines itself through cultural maps and boundaries of authority and power;
“white lab coats, laboratories, technical journals, norms of scientific practice, linear accelerators, statistical data, and expertise” (p. x) all draw edges around what constitutes science work. Thus, biohackers take up territories in domestic places like the home kitchen or garage and public places, like coffee houses, libraries, or online. Myer (2013) notes that the contiguities of “boundary work” create spaces for contestation about expertise and professional authority, value of contributions, and epistemic validity and quality. In other words, biohackers attempt to extend the physical and epistemological boundaries of science through their participation and production and, in doing so, also challenge privileged perspectives of scientific inquiry and engagement. To counter the formal organizing of “professional” science, in the past 10 years biohackers have attempted to draw new boundaries and forms through the creation of formal organizing bodies and collective organizing groups (e.g., DIYBio.org), the development of open-source community policies and codes of ethics, the establishment of physical community laboratories known as hackerspaces, and the use of virtual network collaborations.

Further, the DIY community produces technologies that function as strategies for emancipating closed systems of knowledge and production. This includes regulatory restrictions on the dissemination of certain information (e.g., the pirate radio collective movement attempted to “free the airwaves” through low frequency rogue radio outside of Federal Communications Commission licensure), countering corporate intellectual property protections (e.g., open-source code software like Linux/UNIX as an alternative to proprietary, corporate-owned computer operating systems protected by intellectual property patents), and contesting privileged forms of expertise (e.g., the “copyleft” movements that undergirded the development of technology platforms such as
Wikipedia, to oppose copyright content) (Ratto & Boler 2014, p. 36). Creating open technologies to more broadly decentralize and emancipate institutionally-held knowledge contests aspects of power and authority by redefining, reclaiming, or expanding the discursive and physical mechanisms that traditionally define or restrict participation. By resituating (or de-situating) the territories and boundaries of institutionalized and corporatized production and embracing values like open participation, biohackers engage in activities that attempt to (un)discipline technology and make alternative logics of ownership, participation, and expertise boundless (Ratto, 2014).

Through this study, I aim to consider how exclusionary practices of institutionalized knowledge and organizing are contested in a specific case of biohacking and, conversely, how inclusionary practices enacted by biohackers challenge certain institutional logics. In doing so, this examination will trace various contestable discursive and material boundaries and consider the mechanisms used to preserve or disrupt logics of institutional power. The study asks:

RQ1: What institutional logics and dominant discourses are present in this case? To answer this research question, I will consider how various historical corporate, institutional, and governmental discursive forms (and apparatuses) have contributed to certain embedded logics of power and authority.

Additionally, to be able to observe how discourses of power become hegemonic, I will consider:

RQ2: What discourses are contested by biohackers and, conversely, which are not?
In their quest to emancipate scientific knowledge and decentralize its power, biohackers practice a unique type of activism that blends positive social action with material intervention.

**Hacktivism, Critical Making, and Maktivism**

Due to its operation on the contiguities of “traditional” science and technology, biohacking exists on the fringe, “between traditional manufacturers and users, between policy makers and community members” (Dunbar-Hester, 2014, p. 77). Biohacking functions as a form of social activism that attempts to create social change through its “making,” in order to “increase egalitarian social relations by eroding boundaries between experts and laypeople” (Dunbar-Hester, 2014, p. 75). Hacktivism (a portmanteau that combines the word “hacking” with “activism”) (Milberry & Anderson, 2009) describes the act of hacking as a strategy for both technical/scientific and political engagement, as well as a mode of increasing political participation. Making is a form of political action that permeating new forms of agency through diffused technologies (Dunbar-Hester, 2014).

Contrary to other “black hat” (i.e., criminal or exploitative) forms of “hacking” (e.g., cyber terrorism) that are also politically motivated, biohackers largely engage in acts of positive social deviance by producing and developing new capabilities that function as artifacts of change for social good (Myer, 2013). DIY (or maker) culture also attempts to “intervene in dominant modes of social life” (Ratto, 2014, p. 228). Making as a form of positive social action and engagement is conceptualized as a kind of critical making (Ratto, 2014). For example, DIY feminists in the 1990s engaged in grassroots organizing, cultural activism, and resistance to the traditional information production and
commercialization through the production of feminist *zines*, print and digital publications that addressed topics that dominant culture typically avoided like domestic violence, sexual liberation, and female health. Zines functioned as discursive and material forms of resistance and participation against (and outside of) dominant forms of publishing, women’s oppression, commercialization, and institutional production mills of knowledge (Mann, 2014).

Critical making and hacktivism together reflect a unique type of social action that combines maker agency (human and material deployments) to function as forms of political participation. In other words, material production comes to represent social activism and resistance through the process of innovation and making in the public sphere. Taken together, scholars have proposed the concept of *maktivism* to represent the intersection of critical making that toes the lines between free and proprietary, open-source and closed-source, privileged and emancipated, and breaking down barriers through creation (Mann, 2014). Maktivists are broadly “white hat” because their activism ultimately strives to create solutions through their engagement, rather than exploit or destruct. To date, few studies have considered maktivism in context. Further, maktivism is primarily focused on the material agency of production and has not explored the discursive embeddedness of resistance through maktivism. This study aims to examine the ways maktivism, resistance, and collectivity emerge in the context of this case by considering how maktivism is enacted through political, technical, and discursive production.

Further, Ratto (2014) notes the “need for scholars to attend to the materiality of our sociotechnical environment” (p. 228) and calls for more research that considers the
production of technical work accompanied by critical social analysis. This study examines the production of new and alternative medical devices developed by biohackers. In doing so, this case illustrates how resistance may be enacted through material and discursive production, particularly as a form of organizing. Thus, this study asks:

RQ3a: How is material activism (i.e., maktivism) performed in the case of responses to the EpiPen crisis?

RQ3b: What does material resistance specifically look like in a case of biohacking?

**Alternative Organizing and Resistance**

Most organizational communication research on alternative forms of organizing focuses on the ways that alternative organizations resist traditional corporatized logics and practices. From this standpoint, alternative organizing rejects dominant organizational structures and promotes alternative approaches, such as distributing power, hierarchy, and resources (Buzannell, 1995; Cheney, 1995; Cheney & Cloud, 2006; Cheney & Munshi, 2017); resisting models of ownership in favor of greater cooperation; and rejecting traditional organizational values (e.g., profit making) (Koschmann, 2011). The literature on alternative organizations also emerges as a counterpoint to the status quo (Buzannell et al., 1997). Indeed, alternative organizing often defines itself “at least somewhat in opposition to the ‘mainstream’” (Cheney, 1995, p. 171). Organizational communication scholarship has attended to certain forms of alternative organizing, particularly organizations that are fringe, hidden, shadowed, and otherwise secret/underground, including analysis of militia organizations like ISIL (Islamic
State of Iraq and the Levant) and al-Qa’ida (Bean & Buikema, 2015; Bruscella & Bisel, 2018; Schoenborn & Scherer, 2012; Stohl & Sthol, 2011) and computer hacker groups like Anonymous (Dobusch & Schoeneborn, 2015).

For the purposes of this study, alternative organizing literature has explicated certain issues and mechanisms, including how institutional legitimacy has been attempted or achieved (Bean & Buikema, 2015), how communication artifacts and channels (e.g., mediated technologies) facilitate concealment and revealing, and how issues of visibility and invisibility of public image have been managed (Wolfe & Blithe, 2015). That said, as it stands, the existing literature has done less to explore broader territories of resistance and social action as a form of collective, or more ambiguous forms of loosely connected organizing, which this study has the potential to contribute to or extend.

Riad (2005) suggests that “resistance can operate from within power; individuals can exercise power to resist certain elements…but then appropriate other elements of it in different contexts” (p. 1533). Indeed, historical research on resistance in organizational communication has typically been examined at the organizational level and focused on how resistance is demonstrated within organizations (e.g., Alvesson & Willmott, 1992; Bain & Taylor, 2000; Ball, 2005; Contu, 2008; Courpasson, Dany, & Clegg, 2012). However, Munro (2016) notes “an emerging literature has begun to look outside the boundaries of the workplace for sources of resistance that are developing on the periphery,” particularly through “counter-hegemonic networks by social movement organizations” (p. 570). For example, in his study on how Wikileaks resists hegemonic surveillance systems and corporate secrecy, Munro (2016) concludes that Wikileaks was
able to resist certain systems of state and corporate power through its ability to mobilize and become constitutive through its rhizomatic networked structure.

Deetz (2008) suggests that resistance to social, corporate, or other institutionalized dominance can happen through various forms of contestation but posits that resistance is often conceptualized in terms of its pushing back against dominance. Indeed, resistance scholarship primarily presents resistance as tension: resist domination through “difference” and “otherness” or give into domination. Although some research has suggested that deployments like appropriation can function as resistance (Riad, 2005), participation and imitation continue to be seen largely as subjective to dominant modes and logics of power. Historically, scholarship paints resistance as a reaction to power, through in notions of “struggle” and “conflict” (Deetz, 2008). However, it would be interesting to see if biohacking might provide an example for how activities like imitation and participation from peripheral group actors (like biohacker communities) can function as meaningful and powerful forms of resistance. Therefore, I will consider:

RQ4: What does this case illuminate about participation (e.g., coopting, imitation) as a function of meaningful resistance?

Sensitizing Theoretical and Conceptual Frameworks

The previous section provided a background and context on relevant literature and scholarship on the biohacker movement. The next section overviews several guiding theoretical constructs and critical perspectives that help situate the research project more broadly in the context of medicine and pharmaceuticals in the United States. Although these areas of literature do not foreground specific research questions, they serve as
sensitizing theoretical-conceptual lenses through which the case was analyzed and explained.

**Biopower: Anatamo Politics and Biopolitics**

Rather than other manifestations of direct, absolute, or repressive form of power used throughout history, institutionalized power is instead indirect, “dispersed throughout daily life in the form of laws, social norms, and personal habits” (Nadesan, 2014, n.p.). He termed such anonymous forces *disciplines* to describe the ways institutionalized and ritualized practices orient or discipline certain types of thinking and behaving. Western liberalism, he contended, governed bodies and life through two forms of power: *biopolitics* and *anatamo politics*.

Biopolitics emerged as a concern for the “health and welfare of the population as a political and scientific problem space” (Nadesan, 2014, n.p.). Specifically, the development of medical and scientific knowledge in the 18th century became a dominant Discourse and resulted in the development of new technological, scientific, social, and medical innovations that constituted a medical and clinical view of life and the body. Biopolitics aimed to “optimize the vitality of the population through knowledge, technology, and interventions aimed at promoting life expectancies, health, reproduction, and mental hygiene” (Nadesan, 2014, n.p.). Biopolitics brought with it the institutionalization of new expert knowledges and health authorities, government policies, and broadly disseminated hygiene protocols (Foucault, 1963).

Anatamo politics, on the other hand, refer to “technologies of power” that discipline, orient, and/or normalize individual lives and bodies toward aims of capital accumulation and the maintenance of nation-state sovereignty. Anatamo politics exploit
humans for their productive means and orient bodies and behavior toward disciplines that attempt to optimize human output, primarily through educational, medical, and corporate forms (i.e., the shape certain objects take) and logics (i.e., the meanings and purposes from which they are formed). To date, little communication research has examined the role of biopower in specific medicines and/or medical devices, including examining how their material construction and discursive genealogy shape their governance and biopolitical power. This study will attempt to do this by focusing on epinephrine auto-injectors as both the archetype and artifact of analysis. I will consider the institutionalized disciplines and techno-logics present in the Discursive formation of anaphylaxis and anaphylaxis management.

**Biopower through corporate subjectivities.** Nineteenth century liberalism and 20th century neoliberalism ushered in new forms of economic and political sovereignty—where the economic, the political, and the cultural increasingly overlap and invest in one another (Lemke, 2011, p. 68). Capitalistic logics have thus become the prevailing Discourse in the 21st century Western world, with corporate entities replacing governmentalities as the primary holders of economic and biologic governance (Deetz, 1992; Nadesan, 2008). Corporate meanings, logics, and values come to direct the way everyday citizens understand, think about, and act in everyday life (McLellan, 2017). By influencing the ways people think, talk, and see themselves, corporations subtly shape the taken-for-granted knowledge and values of societies (Deetz, 1992). Over time, strategic corporate logics influence the way people experience the world and see themselves, particularly in private aspects of their lives. For example, organizational ideologies have become situated protocols for our lives. Organizational communication scholars have
primarily considered the ways corporate and industrial vocabularies, values, tools, technologies, and forms of organizing dominate the possible ways of knowing available to individuals and how the presence of corporate logics become unquestioned over time (McLellan, 2017). Indeed, as organizational logics become more ubiquitous, “everyday language gradually becomes commercialized” (Deetz, 1992, p. 18). For example, we regularly attempt to “manage” our personal time and perform cost-benefit analyses for personal decisions. Corporate logics have also come to shape our orientation toward work and health. For example, Nadesan and Trethewey (2000) argue that women shape themselves into enterprising subjects, constantly attempting to resolve competing tensions between enacting corporate traits that are historically masculinized while also maintaining their female identities. Other scholars point to the ways healthcare has become colonized by institutional systems of consumerism and consumption (du Gay, 1996; du Gay & Pryke, 2002).

Over time, corporations have come to replace other social institutions (e.g., religious, family, educational, community, and governmental) as the primary source of meaning and sensemaking. The larger corporate discursive form has contributed to techniques in self-management and orienting behavior toward a consistent and preferred way of being, thus expanding the reach of technologies of the self. For example, discourses of managerialism have contributed to new economies of management-related training and career ambitions, as well as new conceptions about how workers see themselves and “manage” themselves. Trethewey (2001) examined how women workers identify with the grand narrative of “midlife” and found that organizational discourses of
midlife are represented as something that must be “managed” effectively, rather than a natural part of one’s aging or career longevity.

The rise of the modern corporate form has created discourses of power that have resulted in various forms of disciplinary (or self-orienteering) control toward corporate logics, such as individual optimization (Nadesan, 2014). By viewing all biologic function in terms of its pathology, the medical community has created new technologies of the self to manage the psyche (Nadesan, 2008). Pharmaceuticals, for example, have become an easy way to normalize behavior via legally sanctioned products. In fact, “during the last two decades of the twentieth century, a cognitive and pharmaceutical discourse of engineering and optimizing neurological states slowly supplemented, and then replaced, the psychological discourse of personal adjustment, fulfillment, and self-actualization” (Nadesan, 2008, p. 161). Additionally, over-the-counter medications or prescription drugs are often discussed as ways to “manage” or mask sickness in order to return to work (McLellan, 2017). Pharmaceutical drugs and medical devices, therefore, provide benefits to public health, while simultaneously contributing to the corporate economic model. For example, new economies around biologic material, including the consumption of human tissue, blood, and organs (Waldby & Mitchell, 2006), promotes new forms of biocapital.

Scholars and medical professionals have suggested that “the social construction of illness” has been replaced by the “corporate construction of disease” (Moynihan, Heath, & Henry, 2002, p. 886). Further, pharmaceutical interests shape public health by engaging in practices like disease mongering, which is attempting to profit off of social fears about disease (Payer, 1992). Pharmaceutical companies specifically engage in attempts to broaden the boundaries of illness, both by amplifying certain illnesses to the
public through marketing tactics disguised as public awareness and also through pushing medicines to treat those illnesses. Disease mongering has converted individuals from patients to medical consumers (Applbaum, 2006). The effect is that society becomes conditioned to think in terms of medical treatments, which oftentimes leads to over-diagnosing and overtreatment driven by both medical professionals and patients (Moynihan et al., 2002).

Pharmaceutical biopower. Pharmaceutical companies have gained significant authority over American lives. Albeit limited, several communication scholars (e.g., Coombs & Holladay, 2011; Davis et al., 2007; Deetz, 1995; Johnson, Sellnow, Seeger, Barret & Hasbargen, 2004; Kohn, 2004; Lyon, 2007; Lyon & Mirivel, 2010, 2011; Tracy, 2004) have studied pharmaceutical companies in various contexts. Because of the degree to which pharmaceutical companies can directly affect our daily lives, communication scholars have a responsibility to study the ethicality of their communication with the public (Lyon, 2007; Lyon & Mirivel, 2011). Lyon (2007) studied how Merck publicly responded to evidence that one of their drugs, Vioxx, was linked to tens of thousands of deaths over a four-year period in the early 2000s and that the company intentionally withheld knowledge of the risks of the drug from the public and shareholders. Lyon suggests that Merck used systematically distorted communication tactics to deceive their shareholders, first by conducting research that was more consistently aligned with market-driven needs and shareholder interests rather than clinical. Lyon and Mirivel (2011) also analyzed the tactics used by Merck trained sales representatives to avoid conversations about the potential risks when engaging with doctors. The company, the authors concluded, behaved with a moral obligation to its stakeholders rather than to
patients or to the public. Capitalism-driven market pressures and practices routinely privilege profit over individual health and, in some cases, human life (Law, 2006; Scheibel, 1996).

Although the relationship between government regulation and corporate interests is socially narrated as tenuous, Nadesan (2008) suggests that the rise of the neoliberal enterprise and the move toward neoconservative governmentalities has given way to modern day economic-political sovereignty, a relationship that favors corporate expressions of sovereignty but does not erase the need for political sovereignty. Since the rise of the “corporation,” biopower over health has shifted from state authority to corporate authority (Nadesan, 2008). The relationship between the state and private industry is mutually serving and symbiotic, often referred to as the medical-industrial complex (Ehrenreich, 2016). Organizational communication scholars should consider ways their research might provide a public service, particularly in instances where research can illuminate the problematic ways in which institutional organizing affects public life and wellbeing (Lyon, 2007). Indeed, this can be seen in a recent study that found that all 210 pharmaceutical drugs approved by the FDA from 2010 to 2016 originated out of government-funded research (Cleary, Beierlein, Khanuja, McNamee, & Ledley, 2018). The authors suggest this represents a complementary relationship, insofar as the public-sector funds research and scientific evidence for the development of new drugs and then hands the research to the private sector to develop and market the drugs for use. However, this highlights a complicated relationship with how public health becomes (economically and axiologically) valued, distributed, and governed. Publicly-funded research is commodified and sold back to the very people who both already paid
for it and require it to live. Moreover, it is sold back reformulated with new biocapitalistic meanings, values, and medical-industrial forms of power.

Medical governance, distribution, and cost are all of considerable importance for critical communication research in many ways. First, they present a rationale by which to examine the role of pharmaceutical drugs through a lens of biopower. Second, they explain how and why non-normative groups like biohackers may be targeted, excluded, or silenced by the dominant Discourse. And third, they provide a framework by which to consider how politics of the body influence the rise of dynamic social issues. This study will attempt to consider the complex role biopower and biopolitics play in the EpiPen crisis’ unfolding. Specifically, this study will consider how the dominant Discourse around pharmaceuticals resulted in perceptions about viable medical alternatives like the EpiPencil as more dangerous to public health than the highly acknowledged unethical and leeching practices of pharmaceutical companies. Fundamentally, biohackers do not function to operate within corporatized pharmaceutical organizing. Their participation does not intend to profitize or compete along institutional logics. In their organizing, they do not intend to sustain traditional forms of organizing. Rather, they constitute a unique organizational position whose discursive and material outputs function as a way of (dis)organizing.

**Communicatively Constituted Organizing (CCO)**

Organizational communication scholars turn to various theoretical frameworks for considering how communication creates, sustains, and ends organizing (Schoeneborn & Vasquez, 2017). Rather than treating organizations as places where organizational activity merely occurs, some scholars argue “the properties of language and interaction
produce actual organizing” (Fairhurst & Putnam, 2004, p. 13). In other words, organizing arises through an interplay of texts, conversations, and social practices (Taylor & Van Every, 2000) that produce various ritualized talk, behaviors, and resources that make up and sustain organizing. Communicative Constitution of Organizations (CCO) is the metatheoretical framework used by organizational communication scholars to conceptualize the processes and various aspects of organizing as communicatively constituted. Additionally, multiple perspectives about what constitutes organizing exist within the CCO framework. This study borrows from several schools of thought but most often engages the Montreal School perspective due to its more fluid definition of organizing as co-orientating and emergent (Cooren, Kuhn, Cornelissen, & Clark, 2011; Cornelissen & Kafouros, 2008).

Scholarship building upon CCO and its development has historically been theoretical with few studies contributing to its deployment and application in context (Koschmann, 2011). The field has additionally made calls to better understand core components of CCO (like agency) in-context through observable cases of analysis rather than as an a priori understanding. CCO has, to date, lacked clear distinctions between “organizations” and other forms of social collectives like networks, communities, or even social movements. Dobusch and Schoeneborn (2015) suggest that CCO should be expanded to assess a variety of other social groups, such as loose and fluid networks made up of organizations and groups, by focusing on their “organizationality.” Indeed, not only should other organizing forms like social movements be considered for their organizationality, but we can alsovaluably examine how various social actor groups—
organizations, social movements, and governmentalities— influence and interplay with each other in specific contexts.

Applied CCO research has typically contained instances of organizing, particularly how acts of organizing unfolds within specific organizations. These studies tend to focus on the processes within a specific organization and do less to examine larger social or institutional contexts. An analysis of the biohacker movement as a referent social and connected action has the potential to illuminate how certain actors behave in response to other referent contexts or other social actors, like organizations or social constructions. How biohackers frame and are framed by social constructs like bioethics and institutionalized talk influences how organizing occurs. This research will explore how CCO can explain the biohacker community attempts to legitimize in the context of a crisis, how the counter-narratives and materialities produced by individuals, social collectives, and connected groups can act as forms of resistance and contestation, and how institutionalized talk and text emerge in response to counter-logics. These biohacker goals are often pursued through material production.

**Matter and meaning as constitutive.** Much the same way maktivism can focus on the material production of social movements, CCO literature has also made the material turn toward the agentic nature of materiality as a constitutive function of organizing (Ashcraft, Kuhn, & Cooren, 2009). Scholars argue that social constructs like values, principles, or ideas are not necessarily less material than physical objects and that the social and material world are intrinsically intertwined in action (i.e., the possibility for action-in-use is inscribed in a particular object’s existence, but its properties for action only emerge through its use). As a result, a focus of materiality is concerned with how the
social and material world are entangled (Leonardi, 2011). The “materials of bodies, sweat, machines, factories, cubicles, wages, benefits, exhaust fumes, timber and effluent [can] help explain why and when workers constitute their own organizing, display resistance, or fail to do so” (Cheney & Cloud, 2006, p. 505). That is, objects like technology, texts, and bodies are entangled within communication processes and carry various forms of meaning. Materials, in this case, are not merely artifacts but shape meanings for organizational members that orient behavior, thought, and activity. As Montreal School scholar Francois Cooren explains, “artifacts have a big role to play in the communicative constitution of an organization. They matter a lot. They count. They display agency to the extent that they ‘make a difference’” (Schoeneborn & Blaschke, 2014, p. 298, emphasis in original). Indeed, the material turn is a shift toward exploring how matter makes itself known and is experienced, focusing on how materials come to represent and do more than what they are materially comprised of/from.

Research on materiality has primarily focused on the role, function, and use of communication technologies within organizations. Scholars argue that material and social action, taken together, create new possibilities for action, to fundamentally change organizational or social structure, enact new routines, and create new alternatives (Leonardi, 2011). To understand the ways materials are agentic and constitutive of various comportments, including objects that resist, protest, and participate politically, this study will examine the sociomateriality of both the EpiPen and DIY epinephrine auto-injector alternatives.

Reed (2010) suggests that, in general, CCO has fallen short of considering the material, discursive, and relational power in larger political contexts. There is a need for
research that focuses on specific material cases in the contexts of various constituting authorities beyond a single organization, including institutional authority, political authority, and competing corporate logics. Because social institutions are continually co-constructed not only through everyday communication but also through space, place, and time, material resources should be considered central to the research; therefore, there is a need for research that explores how meaning and matter become materialized in larger sociohistorical contexts. Critical perspectives using CCO as a framework attend to the function of power and order, including notions of expertise, hierarchy, access to information, and ability to author artifacts of control, in the process of organizing and consider how materials constitute forms of authority (Cooren, Fairhurst, & Huet, 2012; Taylor & Van Every, 2014), as well as how they provide opportunities or create barriers for contestation.

Issues of power are central to critical organizational communication research and can borrow from multiple perspectives in order to arrive at diverse and meaningful conclusions while also keeping critical perspectives at the forefront of CCO research. Notions of resistance are central to CCO research; however, rarely have concepts of un-structuring or alternative organizing been considered (Kuhn, 2010). By studying alternative forms of organizing and social actors, like biohackers, this current study may contribute to the advancement of this literature. Despite a great deal of generative theoretical research on CCO and the role of materiality in organizing, several questions about the constitutive nature of organizing remain unanswered. This research aims to understand how organizing happens in the context of the EpiPen crisis. By examining research in context, I intend to intersect multiple critical theoretical frameworks to
consider how notions of organizing, biopower, and sociomateriality function in this study.

**Summary**

This chapter contextualizes biohacking within multiple conceptual, theoretical, and socio-historical domains. Biohacking is a subculture that operates outside of the formal institutional boundaries of science and medicine. Biohackers participate in epistemological discourses of science and medicine yet simultaneously reject many of the dominant logics of corporate, political, and authoritative medicine. The movement is one of activism and making and engaging in sociomaterial forms of resistance. Organizational communication theory and scholarship have explored various aspects adjacent to biohacker culture, including notions of alternative organizing and resistance. Additionally, a critical post-structural lens provides an appropriate perspective for better elucidating biohackers as actors in the larger context of biopower and the economic-political governance in the United States. This chapter presented multiple research questions to consider how a study of biohackers can contribute to various organizational communication literatures. The next chapter overviews the methodological approaches and procedures used to collect and analyze data.
CHAPTER 3:
METHODS AND PROCEDURES

Organizational communication research has a rich metatheoretical tradition of collecting, categorizing, and analyzing data across multiple discursive and organizational levels. Drawn from structuration theory (Giddens, 1984), multilevel analysis attempts to highlight/demonstrate the tensions between agency and structure in human organizing (Ashcraft et al., 2009). Because identities and relationalities are, at once, constructed across the individual level, the organizational level, and the institutional level, multilevel data ordering is often used as a way to delineate how functions of micro, meso, and macro orders interplay across space and time (Barbour, 2017). However, multilevel data analysis often attempts to categorize data into groupings that are not neat or discrete (Barbour, 2017). Further, communication phenomena have long and tangled histories, and the relationship between agency and structure is continually fluid and recursive. Whether data are categorized across hierarchical levels of social order (i.e., micro, meso, macro) or parallel discursive levels depends on the need and goals of the study at hand. This dissertation attempts to categorize data across, through, and in-between institutional, organizational, and group level discursive contexts. Therefore, this study borrows from and combines multiple approaches to data collection, organization, and analysis found within organizational communication research.

Methodological Underpinnings

The following section provides an overview of the various methodologies used to systematically identify, historically situate, and meaningfully categorize the data used in this study.
Critical Case Study

Case study research provides a framework for looking at the specific ways organizational activities unfold. Critical cases are a nuanced approach for examining how social forces (e.g., power) influence individual behavior, aspects of organizing, and larger more enduring social constructs (Flyvbjerg, 2001). Critical cases also provide a context for solving and generalizing social issues that can lead to social transformation. Context-based research helps situate multiple (oft-competing) voices in a particular context by depicting them in ways that both provide rich description and equally represent multivocality rather than a single master voice of authority (Tracy, 2007). Thus, a situated critical case study presents the opportunity to “track the passage of certain d/Discourses and the closure of others” (Broadfoot, Deetz, & Anderson, 2004, p. 198).

Issues of access and health are important to examine in contexts and cases where notions of the body influence (and are influenced by) discourses of power, health, money, and science. Given the prevalence and influence pharmaceutical care has over how bodies are governed and disciplined, organizational communication scholarship can provide a practical lens for engaging critically with the complexities that influence the larger constitution of organizational and institutional knowledge within society. Crises can provide a specific context for examining how technologics subject new material interactions and collective meanings. Looking at the variety of potential biopolitical, bioethical, and critical organizational implications of the EpiPen crisis provides a unique context for contributing to health communication research, organizational communication research, and critical inquiry.
Discourse Tracing

Discourse tracing is a useful method for organizing and analyzing data relative to a particular issue, case, or historical event. Discourse tracing attempts to map discursive changes across time in order to illuminate how various discursive practices interact, influence, and contest throughout time (LeGreco & Tracy, 2009). Certain discourses produce authoritative texts and routinized practices, reify social logics, and create new meanings, but they also silence, dismiss, or delegitimize other possibilities. Discourse, therefore, is how knowledge becomes structured, collectively accepted through the logics of that knowledge (i.e., the rules and facts that are seen as naturalized, the taken-for-granted assumptions that underlie structures of knowledge), and given power within a social order through its (re)production in talk and text (Foucault, 1972).

Tracing the “formation, interpretation, and appropriation” of certain discourses can elucidate how certain social and institutional systems come to be and persist in-context (LeGreco & Tracy, 2009, p. 1519). Critical-interpretive scholarship emphasizes the role of discursive power, including how discursive constructions create meanings that lead to preferred ways of knowing (Lyon & Chesebro, 2011). Discourse tracing has been used as a methodological approach for investigating how rhetorical acts circulate various contexts and systems and how power becomes historically situated through such moves. Further, discourse tracing allows for data collection and analysis of multivocality (LeGreco & Tracy, 2009) by preserving the “little stories” in a particular case that may have become silenced, hidden, or historically forgotten (Boje, 2001; Deetz & McClellan, 2009). Because discourses are historically situated, continually (re)constructed, and circulate across various contexts, I used purposeful sampling (Tracy, in press) to “choose
data that fit the parameters of the project’s research questions, goals, and purposes” (Tracy, in press, n.p.). Selection criteria included setting parameters of sociohistorical context, identifying a precise timeframe for the case, and limiting the case to certain discourses and actors. The following sections outline the methodological decisions and data management strategies I utilized to identify, gather, categorize, and code the data included in the parameters of this study.

**Rupture point.** Discourses circulate across various contexts and permeate various contiguities without clear start or end points. Therefore, my goal was to identify a meaningful starting point from which to scope the “case” at hand. Drawing from discourse tracing, I first attempted to identify a rupture point (i.e., an event of significance that changes or signals a shift in the discursive organizing of a group or society, such as a sudden rise in costs or a natural disaster that results in a disruption in daily routines) (LeGreco & Tracy, 2009). Born out of Foucault’s (1972) notion of discursive formations, rupture points help a researcher scope their research project by identifying a moment of significance from which observable discursive changes or new discursive constitutions can be mapped and analyzed. For example, the terrorist attacks on September 11, 2001, “signaled a clearly defined shift in discourses about airport security and the eventual development of the Transportation Security Administration” for Malvini Redden’s (2017, p. 3) research on the constitution of new body politics through airport security pat-downs. However, rupture points do not necessarily need to be the main focus of the study. For example, Malvini Redden (2013) did not specifically study the events of 9/11 but instead used the event as a “jumping off point [from which] to focus on subsequent discursive practices” (Malvini Redden, 2017, p. 3).
Although this case study primarily centers around the discursive practices following EpiPen pricing in 2016, it is also a case of alternative discursive practices of resistance to historically dominant discourses of accessibility, ownership, and cost of medicine. The discursive and social conditions that EpiPen pricing grew out of predate and extend beyond the primary scene of the case. Thus, this case is situated within the realm of various discursive formations without neat time and space boundaries, which have been historically situated through enduring discourses. Although this is a study of a singular issue, the use of a rupture point should be thought of less as a singular event and more as the result of various logics that culminated in new divergences.

What is the rupture of this particular case? In 2015, issues of pharmaceutical price-gouging received international attention when Martin Shkreli, then-founder and CEO of Turing Pharmaceuticals, unapologetically raised the price of Daraprim (a drug that was also effective at combating toxoplasmosis related to the AIDS virus) from $13.50 per pill to $750 per pill (a 5,000% increase) a month after he purchased the exclusive rights to sell the drug (Daraprim Price Hike, 2018). The price hike drew immediate and overwhelming attention from politicians, journalists, health advocacy groups, and shocked citizens (Calderwood & Adimora, 2015). Almost overnight, pharmaceutical pricing became a public issue. However, when called in front of a senate committee hearing, Shkreli refused to answer questions and publicly mocked the members of congress who had questioned him on social media. Shkreli also unabashedly acknowledged that the price hikes were solely to make the company’s shareholders money. While profit has always been the cornerstone of United States capitalism, never before had a company been so unapologetic about price exploitation. Shkreli was dubbed
“the most hated man in America” by the national media, which further fueled a growing populist narrative around greedy Big Pharma executives who load their bank accounts while everyday Americans struggle to afford medications that keep them alive.

This immediately preceding event provides an important context for why EpiPen pricing became amplified throughout 2016 and 2017. Heightened political interest in, and media attention toward, pharmaceutical pricing, combined with a strong public memory of corporate pharmaceutical greed, directly contributed to the ways in which EpiPen pricing gained attention and drew such derision. Martin Shkreli is not the focus of my study; however, the series of public events surrounding him represent a historical turning point from which the specific case in this study (the EpiPen pricing crisis) chronologically and situationally emerged. The course of events leading up to the scope of this case represent a rupture (or divergence) from the traditional dominant and authoritative discursive practices. Further, the preceding events represent a type of divergence that more closely mirrors a boiling point. Said another way, Shkreli was the fuse that lit the stove burner, mass media attention and public opinion turned the heat up, and soon Mylan found itself in the proverbial pot of hot water for its similar pricing tactics. For this study, the EpiPen price hike serves as a point of departure (forward and back) from which to analyze the specific conditions of the case at hand.

To validate an accurate rupture point, I mapped the height of online public interest around “EpiPen,” “epinephrine,” and “anaphylaxis” using Google Trends (n.d.), which illustrates the historical frequency of searched terms and phrases on Google.com dating back to 2012. In all instances, online interest and coverage around the EpiPen price crisis
peaked in August 2016 (see Figure 1)—immediately following the rupture point described above.

![Figure 1](image-url)


**Biohacker material-discursive practices.** One of the reasons this case is ripe for analysis is that it marks the emergence of new discursive moves and modes of resistance *in situ*. Although the EpiPen is the central context of this case, this is not merely a case study of pharmaceutical bad behavior. Rather, it is a study of the ways alternative discourses emerge in times of crisis, how resistance is enacted and materialized, and how social change can constitute new meanings and challenge preferred ways of being and knowing (Lyon & Chesebro, 2011). Although the biohacker community has received some academic attention (e.g., Delfanti, 2012; Dunbar-Hester, 2014), few studies have attempted to observe and analyze the enacted discursive practices of the biohacker community implanted in action. Indeed, this case is one of the few (and certainly early) examples of the biohacker community moving from fringe conversations (on the internet and in small social circles) to the dominant narrative, in response to a social crisis. Thus, the discursive practices of biohackers in response to a social crisis provides a case ripe
for analysis. And the rupture point functions primarily as a point of departure from which to map the “formation, interpretation, and appropriation” of various discourses over time (LeGreco & Tracy, 2009, p. 1519) and consider how certain discursive fields become situated, hidden, contested, or transformational in context—something I turn to next.

**Discursive fields.** Discourse tracing typically attempts to categorize data into three discrete levels of analysis: micro-level data tends to focus on localized talk and individual practices (Fairclough, 1995); meso-level discursive practices include analysis of data focused on group-level (e.g., team, organizational) practices, interactions, and processes that have become routinized and formally codified (say, through organizational policy); and macro-level data functions to reveal enduring systems of thought and normative social practices spanning across institutional contexts (for example, in laws or ideological norms) (LeGreco & Tracy, 2009). This type of categorization is useful for studies that attempt to examine instances of discursive activity within a single scene. As mentioned previously, Malvini Redden (2013) employed discourse tracing as a method of mapping the ways the creation of the Transportation Safety Administration (TSA) led to body screening procedures and policies that changed the treatment of bodies in public spaces (specifically airports and security screening lines). Malvini Redden mapped the ways post-9/11 macro-level discourses of fear and safety became enacted agency (meso-level) pat-down policies and constituted new authorities over travelers’ bodies and identities (micro-level). Similarly, LeGreco (2007) studied the effects of food politics on adolescent attitudes and behaviors toward food. Her study traced the ways federal and state laws (macro) became interpreted and applied in school cafeterias and lunchrooms (meso) to further define students’ attitudes and behaviors toward food (micro). In both of
these studies, the foci were on micro-level interactions in relationship to the interpreted enactment of meso- and macro-level moves.

Although this study looks across multiple levels of discourse, the micro/meso/macro distinction can also be problematic for several reasons. First, discourse tracing is a categorically messy form of analysis. Way (2012) reminds that “in practice, levels of discourse do not operate in a vacuum or separate from one another, but are highly dependent upon one another and deeply intertwined” (p. 55). Discourse tracing can also result in data categorization issues. For example, macro-level data, which evidences enduring systems of thought and taken-for-granted assumptions, can be observed through macro-, meso-, and micro-level data sources. Given the “robust and sometimes unwieldy dataset” (Malvini Redden, 2017, p. 2) appropriate for discourse, data categorization specific to the unique demands of the case at hand should be developed. Further, my particular study diverges from traditional discourse tracing because the primary focus of this case is not localized micro-level behaviors and talk. While this study focuses on biohacker collectives, its focus is not on the interactions or local talk of biohackers. To resolve these differences, this study will diverge from the multilevel micro/meso/macro distinction typical to discourse tracing and instead categorize texts, talk, artifacts, and practices by types of discursive actor(s) and discursive fields.

To define and categorize by discursive fields (i.e., groupings) and data within each field, I used the following orienting questions: 1) what systems (actor groups) contributed to creating the kind of knowledge necessary to lead this case to its rupture point; 2) what institutional structures and materialities preserved certain historical
discourses over time; and conversely, 3) what voices/actors shaped the norms and practices that had become embedded into the social fabric of the case at hand; and finally 4) what materialities were deployed to dispute historically dominant discourses? These questions provide a frame of reference that deviates from the traditional discourse tracing by focusing on both discursive formations before the rupture point as well as the discursive moves following the rupture point. Doing so extends the scope of the case at hand and situates the case in a larger socio-material context.

From these questions, I identified the following primary actors responsible for, or involved in, the creation, proliferation, preservation, and disruption of prominent discourses within the rupture point:

- **Government actors:** e.g., senators, government agencies, and the enactment of government policy
- **Organization-level actors:** specifically, Mylan, its tactics, and influence over other meso-level actors to advance the development and dependency of the EpiPen in the allergy community
- **Industry actors:** including consumer advocacy groups, medical professionals, and legal experts (derived from data collected)
- **Broad public opinion and representations of public opinion in mass media:** and
- **Biohackers:** including the texts and artifacts produced and enacted as a way of resisting dominant discourses

These categorizations allow for a more precise extrapolation of how various actors’ interests, logics, and knowledge(s) become situated in various discursive formations
(Foucault, 1972) and how various discourses converge, diverge, and compete over discursive practices over time (Fairclough, 1995).

**Data Gathering**

As noted previously, discourse tracing can be a messy endeavor. To create an in-depth description and chronology of the case and to accurately capture the various discursive practices across various actors, I included a variety of data types, sources, and methods of collection (Denzin, 1978). Because the primary crisis in the EpiPen case was related to the cost of EpiPen devices and to establish an accurate chronology of events, I began by collecting historical data relevant to EpiPen pricing using internet searches, historical newspaper archives, news reporting, and data sources from Mylan. Then, I traced a chronology of news coverage of the EpiPen crisis from historical newspaper archives and internet searches, using key terms. From there, I reviewed various types of data across all actor groups, including texts (e.g., publicly available documents, laws), talk (e.g., online conversations and discussion boards, transcripts of interviews), and practices (e.g., data on buying habits, citizen petitions), and other artifacts (e.g., images, videos). Data were gathered from mass media and news reports, corporate press releases, publicly available congressional documents, state and federal laws, legal briefs, online discussion boards, YouTube videos, social media data, medical guidelines, data retrieved through Freedom of Information Act (FOIA) requests, and other publicly available online data sources. During my initial data discovery, I collected and reviewed 57 unique data sources, including 2,775 single-spaced pages of text, 24 hours of transcribed video, and 22 images.
I continued to collect and immerse myself in open data collection until I felt I had reached maximum variance sampling (Tracy, in press) to ensure that usually overlooked and marginalized data are considered for inclusion. I determined initial data collection complete when I was able to notice consistent patterns across the data. I approached initial data gathering with the goal of establishing requisite variety (Weick, 2007).

**Data Validity and Purposeful Reduction**

During my initial data collection, I cast a wide net with the goals of including a polyphony of voices, mapping the larger context for the case, and ensuring that the data adequately illuminated issues of power and conflict (Flyvbjerg, 2001). Doing so provided me with a large set of disparate data. However useful, casting such a wide net naturally resulted in some data that were hard to validate/substantiate, may not have had data validity, or may not have been useful for analysis.

For example, I looked for data specific to “public complaints about EpiPen pricing.” One of the sources from my initial data collection included an online citizen petition asking congress to “Stop the EpiPen price gouging” on the website Petition2Congress.com. Another was a list of all complaints submitted to the Federal Trade Commission (FTC) about Mylan and EpiPen pricing. Although the online citizen petition to congress was signed by over 145,000 individuals and was mentioned in multiple news reports as evidence of public discontent, my review of the data suggested that the source was not necessarily valid for analysis. For instance, I had no way to verify the actual number of unique individuals who signed the petition (e.g., individuals could sign the petition multiple times and as often as they wanted). Similarly, a review of each of the 95,000 public comments added to the petition revealed that the same people had
left comments multiple times, and some of the responses seemed be added for the purposes of internet trolling (i.e., comments that are meant to intentionally sow discord, distract from the primary purpose, or provoke others). And although the website the petition was hosted on appeared legitimate, there was no way to verify that the petition responses had ever been shared with any government agency or congresspersons. Thus, the petition was heuristically useful (and therefore remained as a part of the data set) but I deemed it was not valid enough to use for data coding. On the other hand, citizen complaints about Mylan and the EpiPen submitted to the FTC were obtained from a reporter who had retrieved them from a FOIA request. The latter data source provided the same level of insight but with more validity for coding.

For my entire data set, I applied the same rigor of assessing what ways the data were valuable and valid and then engaged in purposeful reduction (Tracy, in press) to only include data that provided the most benefit to further analyze by using specific discriminating criteria.

Primary Data

Primary data were categorized by “type” of data, with a consideration for both the producer of the data and the format of the data (See Appendix A). The following section provides descriptions for each of data types included in this study.

Institutional texts. As part of my primary data considerations, I used the definition of “text” to mean that which is written and codified with a consideration for what those texts do (i.e., what unfolds as a result of the enactment of a text) (Taylor & Van Every, 2000). Institutional texts refer to artifacts that create the structures of discourse fields, in this case medicine (and more specifically the medicalization of
anaphylaxis-related care). For the purposes of this study, primary texts were limited to those that were constitutive or contractual in nature (Cooren, 2004), signified agreement between two or more of the actor groups, or was produced by an actor group in direct response to another actor group present in this case. Institutional texts, as defined in this study, are those that are meant to be declaratory or agentic (created to be authoritative, constitute particular options, advance the interests of a particular group, and/or establish an official stance). I also chose to prioritize official and formal texts that were created by actor groups across the various discursive fields used in this study. These texts include official press releases, official statements by company spokespersons, transcriptions of official legal or congressional testimonies, state and federal laws, publicly available company policies, patents, legal documents, website content authored by the organization and more. Most of the data were available online through government and corporate websites or archival data searches.

**News reporting.** Mass media reports are useful data sources for analyzing enduring social and institutionalized ways of thinking. Cooren’s (2010, 2012) notion of ventriloquism (which treats communication as the constitution of many authors and voices through a speaker) provides insight into not only what an author is explicitly saying but also “all the things that might be speaking through” that person (Cooren & Sandler, 2014, p. 238). Thus, ventriloquism “problematizes the question as to who or even what is speaking, or more generally, saying or doing something in a given situation” (p. 230). Løvgaard & Strand (2014) suggest that news writers and reporters act as “puppet actors” who express enduring systems of thought and preferred ways of knowing through their reporting. They note that discourse is not what is said, but rather “discourse
is what ‘decides’ what is meaningful to say” (Løvgaard & Strand, 2014, p. 263). Media reporting serves as a function for gathering broad public opinion, as media are known to simultaneously shape public opinion while representing it. As such, I considered the key points and issues journalists and reporters were attempting to inform the public about through their writing and identified what institutionalized constructions (e.g., the news, medicine, etc.) were present. I also considered what discursive constructions and enduring frames of reference (e.g., deference to expertise, neoliberal ideologies, broad social apprehensions, etc.) led the author in determining what was included in each text and, conversely, what was left out or disregarded.

Therefore, news media were considered a primary data source for analysis and coding for both what is being said or written in the article and for what the article says and reveals about how problems are framed, what solutions are considered/available, and where authoritative voices may shape how decisions are made and whose interests are taken up. To delineate and prioritize mass media texts, including news articles, reports, and journalistic coverage, I chose to focus on texts that were primarily about the EpiPen crisis, biohacker responses to EpiPen pricing, or articles that specifically mentioned Mylan, EpiPens, or biohackers. Further, I prioritized news stories that included quotes or statements from experts or authoritative voices, including consumer advocacy groups, government agency spokespersons, medical professionals, university professors, and legal experts. These second-hand quotations are both a matter of convenience—gathering perspectives and voices of individuals across various groups—and reveal what voices are shared and what perspectives are validated through ventriloquizing.
While gathering media sources, I attempted to collect stories from a variety of outlets, including international, national, local, and industry-specific sources. Primary news media were gathered from internet resources like web searches, website archives, historical newspapers articles, and online news reports. Because media companies in the United States are often classified in terms of their political bias, I also attempted to include representation of sources across the political spectrum to get a broad sweep of perspectives and interpretations. In all, I gathered 66 primary news sources for analysis.

**Materialities.** This study primarily centers around discourse produced through medicalized devices, specifically epinephrine auto-injectors and the medical components that make them up. Thus, this study is concerned with the relationship between materialities and discursive constructions. Material storytelling considers materials not simply as objects but also as sites of enactment (Sørensen & Strand, 2014). For example, rather than focusing on a “chair,” material storytelling considers the way(s) a chair functions as a form of inter-activity. Sørensen and Strand (2014) suggest that objects (apparatuses) hold constitutive agency; therefore, this study includes various material apparatuses as primary data and considers them in terms of their material-discursive constitutions. That is, this study analyzed how materials function as sites of enactment (e.g., how materials become enacted and function to create various types of inter-activity). Primary material data included multiple epinephrine auto-injectors, do-it-yourself options, and on-the-market products. I also analyzed the sites where material and discursive inter-activity occurred, particularly the spaces and places where materialities like the EpiPen and EpiPencil were invited and, conversely, where they were not allowed. For example, the primary mechanism for demonstrating how to make a do-it-yourself
epinephrine auto-injector occurred on YouTube; therefore, this study analyzed the ways in which devices were represented, deconstructed, reconstructed, and used in YouTube videos. Using material-discursive modalities of analysis, this study will be able to consider what aspects of hegemonic and discursive power materialities hold in the case, particularly related to where contestable boundaries lie.

**Visual artifacts.** Cooren and Sandler (2014) suggest that individuals ventriloquize and are ventriloquized by more than just talk and conversation, including anything that might be deemed as “animating, moving, preoccupying, interesting, or enthusing” talk and conversations (p. 238). Therefore, this is a study of things that materialize through discursive and material productions. Photos/images are a central form of cultural studies that can illuminate the subjectivities and context-dependent meanings created by and through their production over time (Margolis & Pauwels, 2011). Because images are useful to consider the primary materialities created by relevant discourses, as well as the primary discourses created by the relevant materialities, visual materials for analysis include historical photos, instructional online videos, instruction manuals, technical diagrams, and analysis of the production of devices through images and videos. Although all videos were transcribed for textual/content analysis, I took screen captures—still images from moments within the video—for visual analysis. Additionally, as part of this study, I obtained the materials needed to make a do-it-yourself EpiPencil as well as an EpiPen, in part to analyze the material similarities and differences. I documented my material analysis through photos, which also served as primary data for this study.
**DIYBio interviews.** I originally became interested in the biohacker movement several years before beginning this particular case study. Approximately one year before data collection on this project began, I had been conducting research on a biohacker collective known as DIYBio, a governing consortium that provides resources to local self-organized chapters spread across the world. While studying the organizational structure of the DIYBio groups, I developed relationships with nine biohacker communities across the United States. From my communications and relationships with the communities, I negotiated six semi-structured explorative responsive interviews (Rubin & Rubin, 2005). Questions focused on how members identify as “biohackers,” how they make sense of their role as non-expert citizen scientists, and what hopes and fears they have for the future of biohacking. Interviews were approved by the Arizona State University Institutional Review Board (IRB). All interviews were audio recorded, transcribed, and thematically coded. In all, the interviews resulted in 44 single-spaced typed pages of transcripts. While none of the interviews or subsequent conversations I had with the DIYBio groups specifically attended to the EpiPen crisis, my relationship with DIYBio attenuated me to an awareness of the EpiPen case as it unfolded. Further, the interviews provide interesting context that is useful for interpreting the case at hand. As such, in the analysis that follows, I reference excerpts from these interviews to provide perspectives and voices of the biohacker community.

**Expert source: Four Thieves Vinegar.** To more clearly understand the motivations and enterprising logics that guided the actions of the primary biohacker collective—Four Thieves Vinegar—in this case, I contacted the collective’s spokesperson and conducted a private expert interview for analysis. The ASU IRB-approved interview
provided a first-hand perspective about multiple issues. These included why the collective chose to respond to EpiPen prices and make their own device as a display of resistance, what intentions they had for the public using the device as a viable alternative to the EpiPen, and how they made sense of their desired and realized role in the larger discourse around medical access and cost. The interview was conducted virtually via video conference software, recorded, and then transcribed, which resulted in 10 pages of single-spaced text for analysis. The data were then uploaded to Dedoose data analytics software for analysis.

**Data Analysis**

Data analysis followed an iterative-abductive approach (Tracy, in press) that moved back and forth between data collection, analysis, asking specific/guided questions of the data, gathering more data as needed, and reviewing additional literature in order to best explain the phenomena observed.

**Chronological Ordering**

Consistent with discourse tracing, I first organized the primary and non-primary data in a chronological order of events, using the August 2016 rupture point (described earlier in this chapter) as the point of departure, both forward and backward (see Appendix B). Data ordering motivated my initial mapping of the dominant discourses that moved throughout time and space, and illustrated ways various actors’ material-discursive moves and tactics were enacted. Chronologizing the data allowed me to examine whether the data I had collected was sufficient to map a rich history of events relevant to the case and create meaningful coherence of the data.
As a result of chronological ordering, I also collected additional data that broadened the historical timeframe and background of the case. Additional data included rhetorical moves and communication events (i.e., discursive enactments) that further illuminated various discourses and actors. For example, I chose to include data that dated back to the pre-marketplace origins of epinephrine auto-injectors. Doing so allowed me to consider the \textit{a priori} logics that moved throughout the discourses in the case at hand, particularly related to medicalized knowledge and the genealogy of allergies and anaphylaxis. This theoretical sampling (Tracy, in press) of additional data resulted in my identifying and analyzing 66 new data sources. In all, 134 primary data sources were coded and analyzed (Table X). Twenty-two data sources were not coded, but were retained for heuristic value, context, and insight.

Table 1

\textit{Summary of Primary Research Data}

<table>
<thead>
<tr>
<th>Type of Data</th>
<th>Number of Sources (Pages)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional Texts</td>
<td>11 government texts (234); 11 Mylan texts (37); 7 pharmaceutical industry texts (143); 5 consumer/patient advocacy organization texts (49); 5 medical professional maker texts (116); 4 medical industry texts (56); 5 biohacker texts (20)</td>
</tr>
<tr>
<td>News Reporting</td>
<td>38 news sources (178)</td>
</tr>
<tr>
<td>Materialities</td>
<td>3 epinephrine auto-injector devices; 1 EpiPencil</td>
</tr>
<tr>
<td>Visual Artifacts</td>
<td>32 images; 7 videos (28 transcribed)</td>
</tr>
<tr>
<td>Interviews</td>
<td>4 DIYBio Interviews (20); 1 Expert Source—Four Thieves Vinegar (15)</td>
</tr>
</tbody>
</table>
Data Synthesis

As described earlier, data were collected and then prioritized as primary and non-primary data as a means of practicing purposeful reduction. Non-primary data remained in the dataset for their heuristic value and for building a clear picture of the relevant events of the case but were not used for further coding or analysis. Primary data, in contrast, were synthesized for interesting, significant, and frequent codes (Saldaña, 2015). Data synthesizing is an important practice for developing a “working skeleton” for the data analysis (Tracy, in press). Preliminary data synthesis provided guidance for identifying sensitizing concepts and themes. For example, I created themes pertaining to the regulation of medical device development, including issues of safety, regulatory processes, and guidelines around quality and use; commonly expressed concerns and fears, like those regarding safety, access, price, lack of oversight, and deviance from established medical protocols; and overarching issues in need of fixing, such as free market enterprise, healthcare affordability, importance of access for emergency response, and deference toward authority.

Primary Cycle Coding

During initial thematic data synthesis, and in line with recommendations from discourse tracing (LeGreco & Tracy, 2009), themes emerged by my asking specific questions of the data or creating questions my data could answer. Questions were guided by my research goals of elucidating the ways discourses move between, across, and among actors; how power becomes embedded in dominant discourses; and how resistance and dissent are enacted during social crises. To consider aspects of power, I considered: 1) who was speaking, 2) how authority was represented, and 3) who was
authorized to speak. Additionally, I borrowed from Flyvbjerg’s (2001) suggestions for critical case study research by considering who would benefit and who would lose from the represented perspectives.

This case primarily centers around discourses of health, money, and science and, more specifically, how institutional organizing affects public life and personal wellbeing. Therefore, I was especially attuned to analyzing texts and artifacts addressing issues of health, cost of care, access, and quality of care across the data sets. Further, because this is also a case of counter-narratives and dissent, I also analyzed for the ways in which discursive and material dissent were enacted and considered what solutions are seen as legitimate, which are not, and why.

For each theme, I then created a codebook to further categorize data by codes. Within the codebook, I wrote a description of each code and listed poignant examples from the data. For example, I coded for “FearAnaph,” which refers to data that express fears and concerns about the risks associated with anaphylaxis; “Use-Admin,” which refers to talk and text about use of the EpiPen as a preferred “fool-proof” technology (i.e., ability to administer epinephrine quickly, consistently, and safely); and “MedEnterprise,” which refers to instances where medicine and medical technologies are talked about in terms of their free-market enterprising roles and values. As with my themes, I also looked for sub-codes within my codes that expressed multiple perspectives of voices relative to each code. For example, when coding for how issues of “access” were framed, I sub-coded for how institutional actor groups and agencies addressed access (e.g., “Mylan emphasized that it has expanded access to EpiPens by distributing them for free at schools”), as well as sub-coded for how counter-voices framed access (e.g.,
“Pharmaceutical technology, like software, should be open-source and accessible.”). These codes were useful in teasing out the nuanced ways the problems were framed, institutionalized, and constructed, as well as how actors talked about and attempted to address those problems. Primary cycle coding also elucidated contestations, including what discursive constructs could and could not be contested within the dominant discourses.

**Phronetic Iterative Analysis**

Consistent with a phronetic iterative approach to analysis, “which alternates between emic, or emergent, readings of the data and an etic use of existing models, explanations, and theories” (Tracy, in press, n.p.), I used primary cycle coding as a preliminary step toward further organizing and synthesizing my data into larger interpretive concepts. Specifically, I next engaged in a process known as analytic casing (Ragin, 1992), which allows for taking a topical focus (i.e., a case) and analyzing a complex dataset in a way that raises up the findings to larger abstractions, such as theoretical concerns, methodological contributions and expansions, broader social concerns, and more. Observations about the EpiPen crisis, for example, “cases up” to larger empirical and theoretical issues regarding medicalized knowledge, biopolitics, institutional resistance, and sociomateriality. Therefore, secondary data analysis included using broader conceptual frames and methodological approaches to data categorization and synthesis.

To help in casing up, particularly as it is related to how enduring institutionalizations of medical knowledge and governance of the body in the context of allergy, I next turned to Rose’s (2012) guide for discursively analyzing a “history of the
“present.” In applying Rose’s methodology, I looked for the following frames present in the data:

- **Problematizations**: This refers to the way “problems” are presented and framed, often in relation to various (moral, political, economic, military, etc.) concerns. Building from primary cycle coding, I looked for how the authority groups I previously identified problematized issues in the case (i.e., issues of access, cost, and safety). I further considered what tactics have historically been used to preserve or guard against those issues.

- **Explanations**: This refers to operative concepts, such as how certain domains of evidence are designated, how criteria of proof are offered, and how forms of visibility, preference, remarkability, and calculability are granted to certain explanations but not others. To analyze for these explanations, I identified data that suggested the ways medicalized preference was given to measuring and evidencing how things like “safety,” “quality,” “reliability,” and other preferred functions of medicalization have been qualified and used as evidence for preserving dominant discourses.

- **Technologies**: This refers to how certain technologies, protocols, or treatments are constructed or deployed as a means of judgment, including what techniques are offered or employed to intervene, “reform,” or “cure” the problem at hand. I identified the various technologies seen as modes of treatment (e.g., legislation reform, medical treatments, etc.) to fix the problem by analyzing what was being proposed as a “solution frame” for
the problem by each of the various actors and examining what tactics and technologies of control were employed to solve the problems.

- Authorities: These refer to the ways certain expertise function as modes of authority, the ways certain procedures are used to acquire and maintain authority, and whose interests are advanced as a result of expert authority opinion. Authorities were previously identified and categorized during data gathering and analysis; however, a second consideration for new observations was given.

- Subjectivities: These refer to the those who are subjected to/by the prevailing discourses or traditional governance models of behavior and thought. To analyze these, I looked for terminology that frames or attacks individuals as creators of new forms of being and knowledge, particularly in the ways the biohacker communities were framed. Subjectivities for this study were also analyzed with special consideration for the sociomaterial artifacts, particularly as they related to forms of testing, privileged treatments, and regimens of acceptability (i.e., what individuals must do to themselves, what practices or regimes they should follow, and how they should conduct themselves). Subjectivities provided a lens to consider how new discursive formations of do-it-yourself technology were shut down and how biohacker responses to traditional forms of allergy treatment were still subjected to allergy governance.

- Strategies: These refer to certain actor groups’ aspirations and goals for governance and treatment, including the connections and associations with
political, organizational, and systematic logics. To analyze strategies, I explored the ways bodies, allergy, and treatment have been historically and systematically governed and become governed, particularly through the policy, agreements, and an ethos of self-care.

These dimensions allowed me to conceptually 1) identify the problem-spaces carved out by authorities, 2) consider how certain solution frames were legitimized and enacted through various technologies and strategies, and 3) analyze the ways subjectivities have come to be governed. In total, this approach painted a history of the present that revealed the ways epinephrine auto-injectors function as a material-discursive formation to govern allergy and considered how various discourses circulated among the various actors in this case.

Summary

Chapter 3 provided an overview and outline for the methodological choices made to identify, gather, organize, and make sense of data as part of this case study. A combination of phronetic-iterative and critical-interpretive approaches, including discourse tracing and critical case study analysis, provided the framework for the analysis techniques used that ensured processes were appropriate, credible, and rigorous. In the next chapter, I will highlight the primary findings from data analysis.
CHAPTER 4:
EPIPEN AS A HISTORY OF THE PRESENT:
DISCURSIVE AND GENEALOGICAL TRACING

The previous chapter provided a detailed overview of the methodological approaches used to collect, organize, prioritize, and analyze data for this study. Discourse tracing (LeGreco & Tracy, 2009) first recommends identifying a critical rupture point from which to map the discursive moves of various competing discourses. The rupture point in this case served as a reference point from which to “case.” Discourse tracing first requires chronologizing the relevant events in the case. Chronology is useful because it can show how various texts and conversations move throughout discursive fields in context. Thus, the first part of this chapter provides a chronology of the case.

The primary section of this chapter answers RQ1 by considering what discursive formations and institutional logics shape the case. To answer this question, I borrow from Foucault’s (1977) notions of genealogy as “histories of the body” in order to trace what historical systems, structures, and logics have come to produce certain domains of preferred knowledge, relationships of power, and new forms of subjectivity on society. Logics are codified and embedded “rules” that produce objects of power, such as texts, knowledge, artifacts, principles, protocols, laws, and more. The next section then traces the logics of medicine, specifically allergy and allergy governance, and logics in government-developed medical technologies. This chapter then re-situates the EpiPen as the dominant logic for allergy governance by analyzing various medical, corporate, and political strategies, tactics, and biopolitical enactments.
Chronologizing the Case

According to an economic analysis of wholesale epinephrine auto-injector prices over time, the original average wholesale price of a single EpiPen auto-injector in 1986/87 was approximately $35.59, or about $82 USD today, calculating for inflation (Westermann-Clark, Fitzhugh, and Lockey, 2012). Shortly after the EpiPen’s original commercial market release, the Associated Press (Siegel, 1988) published articles appearing in newspapers around the country describing the three primary options available for patients needing a prescription for emergency epinephrine: 1) The newly-available EpiPen, described as a “pre-loaded, push button syringe that looks like a fountain pen” (p. 8A), would cost patients $20–$30; 2) Patients who preferred to use the market alternative Ana-Kit (i.e., a small red emergency kit that included a syringe pre-filled with a double dose of epinephrine, several diphenhydramine tablets, and a couple rubbing alcohol towelettes—see Figure 2), could expect to pay “between $17 and $22” (p. 8A); and lastly, 3) price-conscious customers could simply purchase glass ampules of epinephrine for around $5 per vial and draw their own epinephrine using syringes that cost $.20–.50 cents each.
Although the cost of the drug epinephrine has not changed in more than three decades—a single vial today still costs around $5—the price of epinephrine drug delivery devices, most notably the EpiPen, have skyrocketed. In fact, at the height of the EpiPen pricing crisis in mid-2016, EpiPen wholesale acquisition cost hovered between $600 and $700. From their release in 1987 until 2007, EpiPen prices had remained reasonably affordable. However, in 2007, when Mylan purchased marketing and distribution rights for the devices, EpiPen prices began to increase. According to a congressional report on the price of EpiPens, in 2017 an EpiPen cost about $100 wholesale. By 2012, the cost of a 2-pack—in 2009 Mylan stopped offering the option to purchase a single EpiPen—had risen to $218. By 2014, the cost was $350, and by 2015 the price increased to $460. And by the summer of 2016, at the peak of public outcry, the price averaged $608 (Reviewing the Rising Price of EpiPens, 2016). In the nine years Mylan oversaw EpiPen distribution,
prices increased more than 500%. For comparison, the annual inflation rate in the U.S. over the same period of time is 1.78%, and the total/cumulative inflation rate over that same nine-year period of time is 15.8%. To put it more clearly, the price of a single EpiPen prescription was 30 times more than the annual inflation over the same nine-year period of time. Moreover, Mylan had established a dominant hold on the market by supplying more than 90% of all U.S. epinephrine-based prescriptions. By 2016, epinephrine auto-injectors had become standard practice, and EpiPens had become the preferred brand.

Public concern for EpiPen pricing traces back to as early as 2012 when Westermann-Clark, Fitzhugh, and Lockey published a letter in the *Journal of Allergy and Clinical Immunology* that cited evidence that a growing number of their patients were no longer able to afford to EpiPens and other auto-injector devices. The authors suggested that the increase in cost was “resulting in a significant economic burden for some patients and families” (Westermann-Clark et al., p. 822). In the same letter they reminded doctors that “lower-cost alternatives exist” (p. 822), such as reverting back to pre-filled syringes (PFS), and noted that they can still be “safely provided to patients who cannot afford prescription auto-injectors” (p. 822). EpiPen pricing received very little media attention in the year and half that followed.

Then, in 2014, two non-mainstream articles reignited concerns about EpiPen prices. In the first article, appearing in *The Valley Advocate* (an alternative news outlet), the author shared her experience of traveling to Canada to buy an EpiPen (which can be purchased over-the-counter) for $94 without insurance as opposed to more than $300 she would have to pay out-of-pocket (even with insurance) in the United States (Allen, 2014).
The second article, written by a pediatric emergency physician in the Pacific Standard (an independent journal focusing on social justice issues), expressed sticker shock over the cost of her daughter’s EpiPen prescription. She noted that “increasingly, some have no choice but to go without, forced to gamble on their children’s safety” (Arnold, 2014, para. 14).

That same year, overall concern for a trend toward rising pharmaceutical costs led two U.S. congressmen – Democratic Representative Elijah Cummins (ranking member of the House Committee on Oversight and Government Reform) and Independent Senator Bernie Sanders (chairman of the subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions) – to launch investigations into “soaring generic drug prices” (Sanders, 2014, para. 1) for 14 generic drugs that had seen marked increases in price. Generic medications (i.e., drugs that are no longer protected by drug patents and can be manufactured and sold through names outside of the original brand name) are meant to lower medication prices due to the possibility of increased market competition. However, Cummins and Sanders concluded that while “generic drugs were meant to help make medications affordable,” (Sanders, 2014, para. 5), certain generic drugs were experiencing “huge upswings” that were “hurting patients” (para. 6). In fact, they found that all 14 drugs in their investigation had average price increases between 388% and 8,281% (Sanders, 2014). Pharmaceutical pricing had become a national issue and was receiving widespread media and political attention. Drug pricing had become one of the most important platform issues for candidates in the 2016 presidential election, following a growing public concern for growing drug prices (DiJulio, Firth, & Brodie, 2015; Kirzinger, Wu, & Brodie, 2016;
Rovner, 2016) and a growing public distrust in pharmaceutical companies (Snyder Bulik, 2018).

In July 2016, multiple mainstream media articles cited that “some allergy sufferers are going to extraordinary—and dangerous—lengths as an alternative to paying through the nose for EpiPens” (Tuttle, 2016, para. 6). According to the authors, some parents chose to have their children rely on expired devices, while others turned to “riskier DIY alternatives” such as purchasing manual syringes and having them “filled with the epinephrine at a doctor’s office” (Swetlitz, 2016, para. 7). As media attention on EpiPen pricing increased, so too did political attention. Twenty senators joined together in writing to Mylan CEO Heather Bresch to express their “concern with the repeated and significant price increases” (Sanders et al., 2016, para. 1) for EpiPens and noted that the device “has become so exorbitantly expensive” that the price is putting U.S. citizens “in jeopardy” (para. 3). Concern was consistent across democratic-republican party lines. Senator Amy Klobuchar (chair of the Senate Judiciary Antitrust Committee) requested that the Federal Trade Commission (FTC) investigate possible antitrust violations by Mylan (Klobuchar, 2016). Senators Chuck Grassley (of the Senate Judiciary Committee), Susan Collins, Claire McCaskill, and Richard Blumenthal also sent inquiries to Mylan about EpiPen pricing arrangements and anti-competitive pricing arrangements. Senators sent inquiries to the Federal Drug Administration (FDA) to question its process for approving other possible alternative epinephrine administration devices (Grassley, Leahy, Klobuchar, Blumenthal, & Johnson, 2016). Finally, in the summer of 2019, Bresch was set to appear before a congressional committee to explain her company’s pricing practices. The EpiPen quickly became the epicenter of drug-pricing practices in America.
Medical Professionals Response

With mounting frustration that the Mylan congressional hearing would follow an all-too-predictable pattern of finger-pointing, outrage, and CEOs enduring “a day of public villainy [to] explain that high drug prices are sometimes-unfortunate cost[s] of innovation” (Zaitchick, 2018, para. 2), as had happened with previous inquiries into pharmaceutical companies, and with media reports expressing concern about the lack of affordable options available to patients, a handful of medical professionals intervened. According to medical professionals, if price was the issue, historical protocols and logics were readily available and cost-effective alternatives. Medical professionals were trained to administer medicine through a syringe and then manually inject it into a patient’s thigh. Before epinephrine auto-injectors, the vial-and-syringe method was the preferred protocol. Therefore, a number of medical professionals returned to old methods of delivery as a cost-cutting alternative.

For example, in 2013, King County Washington emergency medical technicians (EMTs) switched from emergency response protocols using EpiPens to vial-and-syringe protocols due to rising EpiPen prices. EMTs were retrained to treat anaphylaxis using “Check & Inject Kits” (see Figure 3), which the department produced itself (Husain, Nolan, Latimer & Eisenberg, 2017). Further, King County began selling their kits to other local first-response departments across the country as a way to curb pricing. Check & Inject kits cost $15 each while EpiPens cost more than $300 per pen.
Eastern Kentucky University’s Emergency Medical Care program also responded to rising EpiPen prices by advising that all EMTs in the state would be required to administer epinephrine via syringe and encouraged other states and fire departments across the country (which often have small operating budgets for medical supplies and often rely on volunteer first-responders) to move toward syringe-delivered epinephrine training as well (Fifer, 2016).

In September 2016, a United States-based surgeon with a popular YouTube channel published a video introducing a modified protocol: a vial-and-syringe solution using an ampule of epinephrine, syringe, and needle incorporated into a “3D printed activation container” (McLellan, 2016). In the video description, the doctor states, “When the EpiPen skyrocketed to $600 we were shocked just like you. […] In only 6 days we dreamed, designed and 3D printed the new Epi Injector solution which costs less than 10 dollars for all components” (para. 1; see Figure 4). Despite claiming to share the open-source design file online, the specs were not released.
In response to issues of price, medical professionals turned to their training and knowledge to modify traditional logics and, in one example, extend old protocols into new materials. However, the majority of outspoken medical professionals suggested that patients could revert to using pre-filled syringes filled either by a doctor in a doctor office or at home. Yet as more news articles cited doctors recommending the syringe-and-vial method as an alternative, other medical experts returned to focusing on the potential risks to patient safety. Food Allergy Research & Education (FARE) organization’s chief medical officer suggested that “anyone using [the vial and syringe] approach would require extensive medical training to do it effectively and safely, without contamination or accidental intravenous injection” (FARE, 2016, para. 2). Other industry authorities expressed concerns that if “your child is suffering from an allergic reaction [...] you don’t want to read the instructions in that moment. You just have to know how to use it” (Keshavan, 2016, para. 15). Indeed, the medical community broadly agreed that patients needed affordable access to epinephrine; however, they disagreed on what protocols should be considered “safe” and “reliable.” Despite vial-and-syringe protocols being...
standards just decades before, patients had grown accustomed to auto-injectors and had come to rely on the speed and simplicity of a device that could quickly administer it at the click of a button. Manual medical administration had become reserved for medical authorities. Thus, logics of auto-injection and convenience had come to normalize and replace older medico-administrative logics. However, these logics would also be challenged, as price and access persisted as a dominant social issue.

**Biohackers Intervene**

In 2016, I was in the second year of my PhD program and had become interested in the DIY biology and biohacker movement. Independent of this study, I began interviewing members of local DIYBio communities across the country. In revisiting these interviews for synthesizing concepts, multivocality, and perspective, I found quotes that aptly foretold the change that was emerging in the biohacker space relative to EpiPen pricing. During one of my interviews, I asked Thom, a biohacker in Raleigh (who was also previously a chemist for a pharmaceutical laboratory), whether he believed the DIYBio community could ever truly change the ways large institutions like pharmaceutical companies operate. His response was telling: “DIY is probably never going to supplant or take over the role of Big Pharma.” Big Pharma, he suggested, “will hopefully be forced to reform by our ability to open up technologies and bring competition.” In another interview I conducted with Heather, the head of a DIYbio community in Denver, I asked what she thought it might take for the biohacker community to become more broadly known and understood. Her response was candid: the community has to make waves. “If it doesn’t make waves, it doesn’t become a movement,” she suggested. Although EpiPens and EpiPen pricing never came up in our
conversations, biohackers around the country were looking for an opportunity to make waves—to contribute to a problem that could disrupt the discourse of medicine and science, and lead to positive change. The EpiPen pricing crisis became that opportunity. While Mylan tried to explain the cost away, biohackers moved to disrupt cost away through maktivism.

In September 2016, a biohacker collective by the name of Four Thieves Vinegar Collective published a video on YouTube advertising a DIY epinephrine auto-injector for under $30. They called their device the “EpiPencil.” The video featured a man, who identified himself as “Dr. Michael Laufer, chief spokesman for the collective.” According to the collective’s website, Laufer was not a medical doctor but rather held a Ph.D. in mathematics. In the video, he wore thin wire-framed glasses and a leather motorcycle jacket. He appeared to be in his mid-30s, and was recording the video in what appeared to be a dorm room, the walls a neutral off-white color and barren. Against the wall behind him was a small, unmade bed, next to which was a mini-refrigerator. The video unfolds as follows:

After introducing himself, he holds up a plastic blue cylindrical device with a label affixed to it that closely resembles the label on an EpiPen (see Figure 5).
He then begins to overview the various off-the-shelf components used to make the EpiPencil auto-injector. The plastic cylinder, he notes is an auto-injector “designed for needle-phobic diabetics.” Once fully assembled, the video then cuts to a recording of him sitting in a chair at a dining room table, his pants draped down just above his ankles. He is wearing the same leather jacket atop. As he looks at the camera, with the EpiPencil pressed against his exposed thigh, he instructs to “Press it in, press the button.” He then pushes the release lever on the device. As his face grimaces, he lets out a loud groan. He then looks back toward the camera while slowly pulling the discharged device away from his leg, and affirms “yeah, it hurts.” In addition to the instructional video, Four Thieves Vinegar published online instructions, a parts/purchase list, and a public statement (written in the style of a political resolution). The statement proclaimed that “auto-injectors and epinephrine are technology which belongs to the world” (Four Thieves Vinegar, 2016).
Shortly after the release of this video, other biohacker groups and DIYers began offering epinephrine auto-injector alternatives online. ProgressTH (an international design lab) released a statement announcing the development of a 3D concept for an at-home EpiPen alternative auto-injector, which could be printed for as little as $3 in materials (see Figure 6).

![3D printed epinephrine auto-injector concept prototype.](image)


Their press release encouraged individuals to “roll up their sleeves and create with their own two hands the change they want to see in the world.” (ProgressTH, 2016). They declared that “if Mylan refuses to create an affordable EpiPen, and other companies refuse to provide other life-saving essentials at affordable costs, we must create them ourselves” (para. 12). Other auto-injector designs and design specifications (specs, hereafter) also quickly appeared on open-CAD websites, where individuals can share 3D computer-aided designs for 3D printing.
Unlike 3D-printed models that required users to have software and a 3D printer to print devices, or be able to interpret CAD specs, Four Thieves Vinegar’s solution only required one to purchase already-available products online. News quickly circulated about EpiPen “hacks,” and the response was alarmist: “Please do not hack your own EpiPen” (Weil, 2016). The EpiPencil quickly garnered industry responses from patient advocacy groups and medical experts about the dangers to patient safety (e.g., the potential risk of drawing up too much of the drug, injecting a contaminated dose due to improper storage, greater possibility for human error, lack of proper government and medical oversight). *Popular Science* and *NPR* published articles highlighting the ethical risks (d’Adesky, 2017; Hess, 2016). Medical professors and bioethics experts pointed to the importance of drug-device regulation. One suggested that the EpiPencil was “new version of old quackery” (Hess, 2016, par 6.) and claimed that the hack was ushering in the possibility for complete deregulation of drugs. One author suggested that a “DIY pharmaceutical revolution is coming—if it doesn’t kill us first” (Brown, 2017, para. 1).

Eventually, even the FDA weighed in. Although the FDA could not stop biohackers from publishing instructions on how to make an EpiPencil or prevent citizens from making their own, FDA spokesperson Theresa Eisenman warned against “using unapproved prescription drugs for personal use” because the public cannot “have any assurance that unapproved products effective, safe or produced under good manufacturing practices” (as cited in Leonard, 2016, para. 16). Despite the fact that millions of Americans potentially risked being unable to afford emergency epinephrine through FDA-approved devices, in many experts’ minds, the risk of a DIY alternative (even one that simply reverted back to a historically common protocol pre-auto-injector) was more dangerous.
Discursive and Capitalistic Outcomes

In the end, political economics prevailed: pressure from politicians, the public, and arguably biohackers led to some slight marketplace corrections. In December 2016, Mylan announced it the release of a generic version of its own device at about half the cost (about $340) of the brand name EpiPen (Mylan, 2016a). One month later, CVS (one of the nation’s largest retail pharmacy networks) announced that it had partnered with pharmaceutical manufacturer Impax to provide its customers with an alternative generic epinephrine auto-injector, Adrenaclick, for around $110 for a two-pack prescription (CVS, 2017). CVS also announced that the manufacturer would provide a $100 coupon for much of its financially insecure population to reduce the out-of-pocket cost to about $10 per prescription. Finally, in August 2018, the FDA approved a generic therapeutic equivalent (i.e., a drug that can be substituted for brand name prescriptions) (FDA, 2018).

In evaluating the role biohackers played in this case, it is worth considering the discursive effects of their participation. First, this case marks an important moment for biohacking as a movement given it received widespread national media attention and industry reaction for participating. Although the EpiPencil and other biohacker contributions were criticized over concerns for safety, their material and discursive enactments had staying power. Even into 2018, news articles and television shows continued to discuss the EpiPencil in the context of outrageous pharmaceutical prices and price-gouging practices. For example, in May 2018, the daytime television series The Doctors (which has been broadcast on local stations across the country since 2008) ran a feature highlighting the EpiPencil and its efforts to combat pharmaceutical prices. In the segment, the hosts condemn pharmaceutical companies as “gougers” out to “rip
off” and applaud Four Thieves Vinegar for “highlighting a broken system,” yet also warn
that “DIY and medication shouldn’t be in the same sentence.” *Motherboard*, a popular
web and print news platform covering the future of science and technology, also
published follow-up articles on the EpiPencil (Oberhaus, 2018).

However, not all engagement was conversational. In January 2018, Laufer took to
Twitter to announce that “YouTube took down our video, claiming it was dangerous,
after being up for a year and a half, and something like a million views” (Laufer, 2018).
Although the video was removed from YouTube, the group re-hosted the video
elsewhere. When I interviewed Laufer, he informed me that since 2016 the collective had
received hundreds of “thank you” messages mixed in with some hate mail and death
threats.

In the end, an online video, a set of simple instructions, a handful of pre-existing
medical-grade components, and a print-your-own label were able to enter the national
conversation and contribute to counter-logics of price and access to essential medications.
To better understand the forces motivating preferences toward EpiPens and away from
market alternatives, the next section maps the institutional and dominant Discourses
disciplining this case.

**Genealogical Perspectives of Allergy and Allergy Governance**

RQ1 considers what institutionalized logics and dominant Discourses led to the
case at hand. To answer this question, I turn to a Foucauldian concept of “history of the
present” (Foucault, 1977). *Presentism*, or the study of the present is “a kind of historical
writing that approaches the past using concepts and concerns of the present” (Garland,
2014, p. 367). A critical history of the present requires revealing how certain values,
assumptions, and dominant solution-frames came to be constituted into the present. Thus, this section maps a genealogical history of allergy and anaphylaxis, including dominant forms of medical and political governance. Genealogy is useful for tracing “how contemporary practices and institutions emerged out of specific struggles, conflicts, alliances, and exercises of power, many of which are nowadays forgotten” (Garland, 2014, p. 372)—and is compatible with discourse tracing (LeGreco & Tracy, 2009), as described in the methods section.

Allergies are broadly the result of an overreaction in immune system response to allergens found in food, animal venom, plant toxins, medicines, and other environmental substances (Centers for Disease Control and Prevention, 2019a). Physiological response to allergens can vary depending on the amount of exposure to a particular toxin and one’s level of immune system response. Severe allergic reaction can trigger anaphylaxis, which causes swelling in the submucosal tissues (e.g., tongue, mouth, and throat), rapid loss of blood pressure (due to circulatory constriction of blood vessels), and tightening of the airways in the lungs (Tupper & Visser, 2010). Thus, the effects of some allergic reactions can be life-threatening. Despite the risk, however, anaphylaxis is a relatively rare autoimmune response. In fact, in the United States, anaphylaxis only results in the death of around 250 people in the U.S. per year (or .86 deaths per million people) (American Academy of Allergy, Asthma & Immunology, 2014). Of death-related fatal allergic reactions, most are caused by pharmaceutical drugs like antibiotics, followed by venom (as a result of stings from wasps, bees, or other insects), and then food-related allergies (American Academy of Allergy, Asthma & Immunology, 2014).
Yet, within the public psyche, the perception of prevalence of allergy and anaphylactic risk, particularly by/from food, is significant. Fear of allergy from food and food-byproducts containing nuts, lactose, eggs, soy, wheat, and fish have indeed increased over the past century. This can be seen in the removal of certain foods from shared public spaces including the removal of in-flight peanut snacks on airplanes and school lunchroom policies substituting peanut butter for other types of nut butter. Even the rise of allergy-focused consumer advocacy and patient advocacy groups indicates the prominence of food related allergy awareness.

Although allergy has been present throughout human history (Ring, 2014), allergy has developed into a unique modern-day malady (Jackson, 2006). The development of epidemiological medicine (i.e., the study of how pathogens and disease spread and disseminate across a population or geographic area), public health policies related to environmental politics and disease control, and changing cultural perceptions about medicine, health, and environmental pollution have all contributed to today’s dominant discourse of allergy treatment and governance.

**Medicalization of Allergy**

The greatest contributor to the rise of allergy science emerged from the development of epidemiologic studies at the turn of the 19th century (Jackson, 2006). Epidemiology is the modern-day medical approach to studying the ways pathogens (e.g., viruses, bacteria, etc.) are spread and dispersed across populations. The development of epidemiologic knowledge shifted attention from the localization of diseases in the body to the spread of diseases across populations. This epistemological shift created new technologies and logics of the collective body, such as new public health protocols,
medical therapies, and political acts to control the spread of diseases and viruses both within the body and within the larger population. For example, 19th and 20th century development of epidemiologic-based medicines such as vaccinations (Lahariya, 2016) and broad antibiotic use became prominent protocols for infectious disease prevention and treatment (Aminov, 2010). Epidemiologic knowledge also brought new broad public health initiatives aimed at monitoring and preventing the spread of communicable disease, and the U.S. federal government began allocating more federal resources to public health initiatives. Soon new government programs sprang up that were aimed to preserve the health, safety, and security of the entire population. For example, in 1946, the Communicable Disease Center was created with a mission of reducing the spread of transmittable diseases like malaria (Centers for Disease Control and Prevention, 2019b).

As medical, scientific, and political groups dedicated more resources to pathogenesis, new technologies and methods in the early 20th century allowed scientists to begin monitoring the movement of pathogens and focus on environmental conditions that facilitated infectious processes. As a result, the science of allergy and immunology emerged. Allergy pathogenesis focused on the various originations of allergy, including physiological responses to chemicals and the environment (Jackson, 2006). Epidemiological knowledge and the development of new technologies and information used to better track seasonal illness—combined with advancements in atmospheric physics in the early 20th century—led to goals of tracking and measuring the paths and quantity of airborne pathogens around the world, including more scientific approaches to measuring regional pollen counts (Jackson, 2006).
As public health expanded from localized sites to more geographic and environmental sites, scientists and politicians alike also expanded their interest in how environmental factors contribute to the spread of diseases. Water quality, air quality, food safety, and sanitation all became scientific areas of study. Decades of unregulated factory emissions led to dramatic decreases in air quality across the U.S. for much of the 19th and early 20th century. Further, decades of poor air quality contributed to a rise in respiratory-related illnesses over the same time period. Combined with a focus on the environmental and financial impacts of population health, scientists and government actors became increasingly interested and concerned with the link between air quality, pollution, and health (Environmental Protection Agency, 2019). In response, in 1970, President Richard Nixon established the Environmental Protection Agency (EPA), and Congress passed the landmark Clean Air Act Amendments to establish air quality standards and regulate factory pollution production.

With more attention dedicated to tracking and monitoring environmental changes in pollution, scientists began to notice rises in annual global pollen levels around the world. With greater attention came growing concern that motivated international scientific communities to issue stringent warnings that if modern air trends remained unchecked half the world would be suffering from an allergy in the 21st century (Jackson, 2006). The increase in allergy-related diagnoses led some to label allergy a global epidemic (Platts-Mills, 2016; UCB Institute, 2005). The scientific community agreed that “the potential impact of this explosion of allergies on health, happiness and longevity was clear: allergic reactions could severely compromise the quality of life and,
in some instances, kill” (Jackson, 2006, p. 216). Allergies had become both an individual medical problem as well as a population health concern.

With a greater focus on environmental factors on public health, environmental science in the 1960s and 1970s also began to take up the call for addressing public health concerns. Armed with new knowledge about the effects of industrial production and a growing awareness of the presence of the invisible toxins and health-related allergens in water, air, and food, “allergy” became a household word. As allergy became more ubiquitous, so too did social anxieties about its symptoms (Jackson, 2006).

**Ubiquity and Debate of Allergy in the Modern Lexicon**

In the late 20th century, a new faction of medical interpretation known as clinical ecology attempted to challenge the narrow definition of allergy held by the medical community. Clinical ecologists took up “anti-modern sentiments” to both medicine and commercial-industrial production of the 20th century and espoused modern medicine as a public health threat itself (Jackson, 2006). Environmental medical professionals preferred broader definitions of allergy that focused on myriad symptoms that could result from exposure to various environmental factors, including foods and toxins (Jackson, 2006). While traditional medical science defined allergy in terms of its metabolic calculability (i.e., a measurable increase in immunoglobulins in response to an environmental agent), clinical ecologists debated for broader definitions. Allergies, they suggested, are both biologically symptomatic and psycho-symptomatic. As a result, “allergy” became a diagnosis for a variety of acute and longer-term social and medical ailments. Indeed, one might be inflicted by food and chemical “sensitivities,” contributing to a new focus of food allergy for both traditionalists and clinical ecologists. Toxins,
Epidemiological and environmental concerns for sanitation and cleanliness also strengthened associations of allergy with dirt, poverty, and deprivation. Combined with broadening associations of allergy-as-sensitivity, allergy emerged as a “culturally constituted mark of social distinction” and social status (Jackson, 2006, p. 208). Ultimately “allergists were unable to resist popular appropriation of the term. In the closing decades of the twentieth century, allergy was increasingly employed to signify a bizarre assortment of physical idiosyncrasies, personal antipathies, psychological aversions, marital disagreements, personal conflicts, and international tensions” (p. 213). Thus, its diagnosis and meaning circulated across medical and social contexts.

Cultural attitudes and anxieties shaped by medicalization of allergy, fears about environmental contributors to health, and new social connotations and appropriation of allergy into non-medicalized contexts has led to a diffusion of allergy as serious and metaphoric, as individual and social, and as mild and life-threatening. Further, the history of allergy has led to the 21st century treatments and governance of allergy.

**Allergy Treatment and Governance**

Health and medicine are governed both through political and medical activities. In the 21st century, Western medicine follows four primary treatment traditions: 1) preventive care, 2) curative care, 3) palliative care, and 4) managed care. Each of the following overarching approaches situates unique tactics and discourses of practice. Preventive care includes medicine and science that attempts to prevent illness from occurring, including preventative medicine (e.g., vaccines) and disease eradication (e.g., smallpox, malaria). Curative treatments are those that can cure a disease or illness with the use of medicines, such as antibiotics, treatments such as chemotherapies, and medical
procedures such as surgeries. Palliative care involves treatments that attempt to improve quality of life (primarily through means to reduce suffering) for individuals with diagnoses for which there is no curative treatment and will ultimately lead to death.

Unlike preventive, curative, and palliative care (which all involve the conclusion of a therapy or treatment), managed care is sometimes used as a catchall to describe the practice of medicine that attempts to control or manage onset symptoms and side effects of various types of illness, diseases, and chronic or ambiguous pathologies. Therapy protocols for allergy typically rely on management tactics, including maintenance and suppression tactics that rely on medications to counteract, relieve, or prevent the effects of allergy reaction. These management tactics rely on logics of immunity (i.e., medications that pharmacodynamically influence immune system response). Immuno-logics can enhance (e.g., adrenal steroids), suppress (e.g., antihistamines), or desensitize (e.g., immunotherapy) immune response.

In the modern era, allergy emerged as a threat to both public and private life. Although allergies are treated through all three immunity management tactics, severe allergy has come to be primarily governed by epinephrine, a drug that both enhances and suppresses immune response to severe allergy, which is discussed in more detail in the next section.

**EpiPen: The Emergence of a Powerful Combination Device**

Epinephrine is a synthetic version of adrenaline. For over 100 years, epinephrine has been used as a first line against the effects of anaphylaxis by relaxing muscles in the airways and restricting blood vessels in the body to raise the blood pressure during an allergic reaction or asthma attack (Ram, Hoare, Arroll, and Hoare, 2012). Since its
discovery at the turn of the 19th century, epinephrine has a long and storied past as a pharmaceutical drug. Epinephrine was first found to be stable in its concentrated chemical form outside of the body by a Japanese biochemist named Jokichi Takamine (Arthur, 2015). In 1903, Takamine (1903) was granted a U.S. patent for his isolation techniques and would eventually license the patent to Parke-Davis, one of the largest pharmaceutical firms in the U.S. at the turn of the century, to synthesize and manufacture epinephrine. To be effective, epinephrine needs to quickly enter the bloodstream, so it must to be administered via intramuscular injection. Historically, epinephrine has been kept in small dark glass vials (epinephrine is light-sensitive) and can be withdrawn and administered using a needle and syringe.

This primary method of medical delivery stayed consistent until 1971, when Hollister-Stier Laboratories released the Ana-kit, an anaphylaxis emergency treatment kit that included a pre-filled syringe (PFS) (Hollister Stier, 2019; previously pictured in Figure 2). The product was originally marketed as an emergency insect (bee) sting kit. The Ana-kit was small and portable, which made it more convenient and compact for medical professionals (doctors, nurses, and EMTs).

**Auto-injectors: A Military-Industrial Venture**

At the height of the Vietnam War, the U.S. Government wanted more effective defenses against biochemical nerve agents for soldiers in battle. Previous antidote delivery devices were made of stainless steel, which would affect the chemical stability of some anti-nerve agents. Officials at the Pentagon desired a device that was made out of glass, could be more easily transported, and was an expedient method of medication delivery (Department of Defense, 2000). In 1973, the Pentagon contracted with Survival
Technology, Inc. to come up with a “quick injection” device. From 1973–1977, engineers at a medical equipment company Survival Technology (notably Sheldon Kaplan, George Calkins, Stanley Sarnoff, and Lawrence Dalling) patented technologies for a series “hypodermic injection devices”—technologies that would eventually become name the Pralidoxime ComboPen and AtroPen auto-injector (Kaplan, Calkins, Sarnoff, & Dalling, 1977; Sarnoff & Calkins, 1975; see Figure 7).

![In the public domain.](https://en.wikipedia.org/wiki/Mark_I_NAAK#/media/File:Auto-injector.png)


In 1983, Meridian Medical Technologies, the pharmaceutical manufacturer, saw an opportunity to use the “quick injection” technology used in the ComboPen and apply it to the consumer market. This is notable as the EpiPen served as *the first drug-device*
combination on the market and became fundamental in shaping an entire marketplace of drug-device combinations. In fact, today the FDA has multiple categories for combination devices in the marketplace today. Meridian patented the combination drug-device (epinephrine-auto-injector) and called it the EpiPen (Meridian Medical Technologies, Inc., 1987). Four years later, in 1987, the FDA approved the EpiPen for commercial use (Chowdhury, 2011).

Over the next 20 years, ownership of the EpiPen and its intellectual property was sold and licensed many times. Manufacturer Meridian Medical was eventually acquired by King Pharmaceuticals in 2003. King Pharmaceuticals was then acquired by pharmaceutical manufacturer Pfizer in 2011. While Meridian was the manufacturer of EpiPens through most of the 1990s, the EpiPen was eventually marketed and distributed by Dey LP, a subsidiary of international pharmaceutical giant Merck KGaA (Merck’s generic operations arm).

In 2007, Mylan purchased Merck KGaA for more than $6 billion. With the purchase, Mylan acquired marketing and distribution of the EpiPen, as well as exclusive rights to the EpiPen. EpiPen is not the only epinephrine auto-injector. Over the past three decades a number of pharmaceutical companies have attempted to develop epinephrine auto-injectors; however, the EpiPen has been the most successful and has cornered more than 90% of the auto-injector market since and accounted for 40% of Mylan’s profits since 2015 (Koons & Langreth, 2015).

What Do We Learn from a Historical Tracing?

The origins of epinephrine and auto-injectors is causally important to understanding how EpiPens came to dominate the logics and politics of allergy
governance. These findings can extend our understanding of the politics of immunity as a function of biopower. This section then analyzes two prominent logics emerging from genealogical tracing: immunity logics and military-medical logics.

**Immunity Logics**

Cohen (2009) suggests that immunity as a (Roman) political discursive construct (i.e., to be freed or immunized from punishment) has come to infect biological and medical discourses and knowledge. The study of allergy, for example, is firmly situated within a science of immunology, with immunity logics presupposing notions of a biologic “self-defense” (Jamieson, 2015). In explaining how politics become biologic, Jamieson (2015) suggests that “immunity is perceived as moving across different discursive domains, and, as such, it transforms our biology insofar as it transforms medical discourses and practices” (p. 15). Both the scientific development of epidemiology as epistemological study of the body and the environment, as well as the modern biopolitical immuno-logics of public health and disease spread, emerge from modern biopolitical immunologics. Thus, they emerge from historical political discourses of immunity. Biopower, for example, can explain how immunity logics have become naturalized as both biological in nature and as a taken-for-granted “regime of truth” (Foucault, 1963). Immunity politics are typically framed in terms of prevention and eradication, with goals of curtailing the spread of a (social, medical, biologic) disease. However, the primary and preferred method of treatment for allergy is based on management therapy rather than inoculation or vaccination. To survive an allergic pathogen, the prevailing response is to suppress anaphylactic response through synthetic medical materials (like epinephrine).
Immunity logics are at the center of the EpiPen. Although epinephrine is not an inoculation, genealogically examining the history of allergy alongside a politico-medical history of epinephrine auto-injectors reveals interesting embedded logics of immunity. Applying concepts of immunity logics and biopower (e.g., Martin, 1990; Cohen, 2009; Jamieson, 2015) helps illuminate how the EpiPen came to dominate cultural and political logics and discourse. Indeed, allergy is firmly rooted in the scientific knowledges of immunologics. As the discourse of allergy spread, so too did its localization. No longer was allergy something that was only found in dangerous substances like venom and poison; allergy was all around, potentially infecting us through our food, water, and air. Sensitivities to allergy, both in terms of our noticing/awareness and our lack of ability to self-defend against such, contributed to the development of new safety protocols in the form of antidotes, specifically giving the body a boost of adrenaline to be able to self-defend against anaphylaxis.

Military-Medical Logics

The notion of a “defended self” is also attributable to political power, particularly in historical aspects of Roman law and military logics. Auto-injectors emerged from the military-industrial complex and resulted in both the production of new material forms and discursive forms. Auto-injectors developed as a wartime need, to protect troops on the battlefield from unsuspecting biologic or chemical agents. Growing out of the same biologic-political discourse that weaponized the atomized world (through nuclear war), wartime logics also discursively weaponized biology. To provide wartime defense against new forms of bio-warfare (through biologic nerve agents), the scientific and military community looked to develop new biologic technologies of antidote self-
defense. Antidotes provided a last line of self-defense on the battlefield. However, these discursive logics transferred into medical logics as auto-injectors moved from the battlefield of war to the battlefield of everyday life.

Indeed, we see the logics of military-medical materially, discursively, and metaphorically injected into the logics of anaphylaxis governance through auto-injectors. Material meanings are markedly embedded into the design and administration of auto-injectors (see Figures 8 and 9 below). Consumer versions of auto-injectors initially looked very similar to wartime devices. However, this similarity is not artificial. With the commercialization of auto-injectors, military discursive logics also followed. Allergies quickly shifted from seasonal irritations to life-threatening pathogens. The rise of clinical ecology propelled the ubiquity of allergy and anaphylaxis. Allergies inherited both cultural and medical bio-logics and became both culturally ambiguous and epidemiological (medically substantiated). Allergy was truly environmental and posed danger to one’s health and safety in all aspects of life. Thus, allergy needed treatments that were equally potent at resisting the onset of attack and relied on military protocols and wartime metaphors. Auto-injectors borrowed from immunity logics by offering a “last line” of self-defense should one’s immunity become compromised.

We can see the ways “allergy” has been shaped by dominant historical discourses of environmentalism, epidemiology, and clinical ecology, particularly how advocacy groups like FARE and the Allergy & Asthma Network talked about recommended methods of treating allergy at the time of this case. For example, by 2016 consumer advocacy groups promoted epinephrine as a “first line of treatment – always” for any allergic reaction (Allergy & Asthma Network, 2016, p. 33). FARE also advocated for
using an EpiPen, even if a person is uncertain whether they are actually having an allergic reaction or simply having sensitivities such as “itching” or “feeling something bad is about to happen, anxiety, or confusion” (cited in Fugh-Berman & Batt, 2016). According to Fugh-Berman and Blatt (2016), “FARE’s treatment plan [even] includes an option to administer epinephrine to a highly food-allergic person who is having no symptoms and who is unsure whether or not they ate something they were allergic to” (para. 6). The Asthma & Allergy Network encouraged patients to use epinephrine over other allergy medications (e.g., antihistamines like Benadryl, which is readily available without a prescription and at a fraction of the cost), even for mild allergies and allergic reactions (Allergy & Asthma Network, 2016). Although antihistamines risk carrying side effects like dizziness, upset stomach, and constipation, they are relatively mild compared to the far more serious side effects that can be induced by epinephrine, including irregular heartbeat, fainting, stroke, trouble breathing, chest pain, and possible overdose resulting in death (Mayo Clinic, n.d.). Yet consumer advocacy groups continued to encourage over-prescribing and over-use of EpiPens.

The EpiPen is a discursive paradigm of allergy and anaphylaxis governance within a prevailing modern medical problem-frame of allergy as a biologic, deadly, and hiding in every corner of our mundane lives, infiltrating our basic needs (food and air). To combat this threat, the EpiPen is the fail-safe tactic. Therefore, it must be available for deployment at a moment’s notice and carried on one’s person. The EpiPen has risks, yet those risks get represented in a calculus of lives saved, so they tend to be de-prioritized in public health and legislation that encourages the use of EpiPen by making public spaces like schools have them available. While this might not be objectionable on some levels, it
illustrates the logic of governing out-of-control allergies (obscures some fundamental risks, particularly if people use them more than once), documented by more aggressive standards of use by consumer-advocacy groups. Thus, allergists, patients, politicians and international healthcare agencies struggling to loosen the grip of allergy on modern societies have adopted conflicting strategies (Figures 8 and 9).


Indeed, consumer products even pass along the instructions and protocols, particularly in terms of instructions for use. For example, the administration steps are nearly identical for administration. EpiPen users and nerve agent auto-injector users are first told to pull off the grey safety cap, push the injector “firmly” or “hard” against the thigh, and then hold device in place for 10 seconds (see Figure 10 for comparison). In future EpiPen product enhancements, the grey cap was eventually replaced with a blue cap, and the injection end was outfitted with an orange cap (to denote which end houses the needle). The speed of epinephrine delivery also increased from 10 seconds to three seconds.

![How to Use the Antidote Treatment Nerve Agent Auto-injector](image)


Tracing the EpiPen from government-funded injection device to commercial product is historically important because it reveals significant material-discursive constructs and logics that shaped attitudes, ideas, talk and materialities around allergies
and their treatment. Since its development, epinephrine has become the primary solution-frame to manage against the threat of anaphylaxis. The epinephrine-as-solution frame comes from historically tracing discourse around allergy as a modern-day malady and medicalized fears of anaphylaxis emerging and continuing military intentionalities and logics. We also see how consumerism and the biopolitics of medicine extends to consumers through various discursive forms, the socialized meanings that are built into auto-injectors.

Mapping the medical treatment of allergy across historical contexts is useful to situate the discursive formation of allergy. Logics of epidemiology, the governance and treatment of allergy, and biopolitical contexts reveal how allergy and anaphylaxis has become (re)constituted through medical and technological deployments. This context provides insight into how allergy has become normalized, commercialized, economized, weaponized, and further regulated through industry and governmental enactments and how anaphylaxis and epinephrine have become sociomaterially constituted into discourses of medicine, health, and governance.

Under neoliberal logics, medicine has become an economic endeavor. Thus, the EpiPen has also emerged through dominant corporate discursive enactments and strategies. The following section overviews an analysis of the specific corporate strategies and tactics used to further extend the EpiPen’s role in preserving economic-political sovereignty (Nadesan, 2008). Epinephrine is an effective intervention for severe allergic reaction, and auto-injectors are an effective method of administration. While these are not inherently problematic solutions, the EpiPen has become an instrumentality of power situated within biopolitical contexts that give it authority over other equally
 plausible logics and alternatives. Thus, the EpiPen disciplines toward safety. The problem in this case instead emerges out of a concern for access. If EpiPens are indispensable in the fight against allergy, what happens when people cannot afford them? To better understand how EpiPens became instrumentalities of power, this study next turns to an analysis of the EpiPen as a corporate politic.

EpiPen Entrenchment into Private and Public Spaces

Since 2011, Mylan has used a variety of medico-political tactics to place EpiPens in public and private spaces across the U.S. During her prepared congressional testimony in 2016, Mylan CEO Heather Bresch implored committee members to understand the EpiPen’s numerous positive impacts to health. She explained that the product saves countless lives and reduces overall healthcare costs by serving as an “insurance policy” against anaphylaxis shock for millions of Americans. She expressed that too much focus had been placed on EpiPen pricing and not enough attention on her company’s efforts to increase access to the device. Her concern centered on the fact that the company had helped stock more than 700,000 EpiPens across 66,000 schools in the United States, “no strings attached” (Reviewing the Rising Price of EpiPens, 2016, p. 2). However, during the hearing, Senator Tammy Duckworth illuminated that Mylan also reached out to those 66,000 schools with a contract that allowed them to buy additional EpiPens at a heavily discounted rate ($112 as opposed to $600) so long as the schools do not “in the next 12 months, purchase any products that are competitive to EpiPen auto-injectors” (Reviewing the Rising Price of EpiPens, 2016, p. 18).

In 2012, Mylan also launched the EpiPens4Schools program, a tactic that developed partnerships with individuals and groups at the national and state level. One of
the most prominent supporters and promoters of the program was the recently appointed chair of the National Association of State Boards of Education (NASBE), Gayle Manchin, who also happened to be Bresch’s mother (O’Donnell, 2016). Manchin, in her new role with the NASBE, began a nationwide campaign known as the “epinephrine policy initiative,” which aimed “to help state boards of education as they develop student health policies” and “set the stage for [national] policy development (National Association of State Boards of Education, 2012, para. 2). Mylan also fostered its relationships with consumer advocacy organizations like FARE to promote the need for new state and federal legislation requiring public places like schools to keep stock of epinephrine auto-injectors. In exchange for their advocacy, Mylan sponsored educational events and developed educational materials for NASBE (O’Donnell, 2016). The epinephrine policy initiative focused on education about the risks and dangers of anaphylaxis and the universal acceptance of epinephrine as a fail-safe drug for anaphylactic treatment.

Their efforts contributed to enacted laws in 12 states across the country that required schools to keep epinephrine auto-injectors on premises. It also resulted in the passing of the federal “EpiPen Law” in 2013 (Access to Emergency Epinephrine Act, 2013). The law authorized:

the Department of Health and Human Services to give funding preferences to states for asthma-treatment grants if they: maintained an emergency supply of epinephrine (EpiPens), permitted trained personnel of the school to administer epinephrine, and developed a plan for ensuring trained personnel are available to administer epinephrine during all hours of the school day. (Jarrett, 2013, para. 2)
EpiPens had become so ubiquitous with epinephrine administration that they discursively became the only solution. Even in cases where schools had to train personnel to administer the drug, those individuals were most likely trained in how to administer EpiPens. The “EpiPen Law” used economic-political incentives to encourage public spaces to stock EpiPens in exchange for federal grant money.

As part of its efforts to promote public health, access, and awareness, Mylan also paid consumer advocacy groups through sponsorships and donations. Patient and health advocacy groups (i.e., groups that “claim to represent the interests of patients with a particular condition”) often receiving funding from industry corporate sponsors like pharmaceutical companies because these groups are “very effective in spreading industry messages that appear free from the taint of industry bias” (Fugh-Berman & Batt, 2016, para. 10). And Mylan used its relationship with several in the early-to-mid 2010s to help encourage and promote the use of epinephrine in allergy care.

Mylan’s self-promoted billion-dollar investment to make EpiPens more “available” to the public also included efforts to include epinephrine on the “federal preventive drug list.” Under the Affordable Care Act of 2010, the federal preventive drug list ensures that individuals who are prescribed a drug on the list are free from copayment, co-insurance, or out-of-pocket deductible. If successful, Mylan could, in effect, continue to charge high prices for EpiPens while hiding the cost at the counter for patients and “mute the protests” (Lipton & Abrams, 2016, para. 1).

Mylan again partnered with consumer advocacy groups like the Asthma & Allergy Network and medical professionals to advance lobbying efforts and shift industry perception in Mylan’s favor. One of Mylan’s paid consultants, Dr. Leonard Fromer (an
assistant clinical professor of family medicine at the University of California, Los Angeles), published a letter in the *American Journal of Medicine* that suggests “the cost of auto-injectors compared with the costs of emergency department visits and hospitalizations associated with failure to treat anaphylaxis appropriately” (Fromer, 2016, p. 1250). Given his status as a paid consultant, it is not surprising that Fromer urged support for epinephrine auto-injectors by saying that they should be added to the preventive drug list “due to at-risk individuals remaining at chronic high risk of recurrence” and suggesting that anaphylaxis is “routinely underrecognized and undertreated” (p. 1244). Although the preventive drug list ostensibly could be interpreted as eliminating financial barriers for patients, Dr. Fromer’s paid consulting work served to further embed epinephrine as the primary course of care for the treatment of allergy and anaphylaxis. Despite deploying political tactics to make epinephrine auto-injectors (broadly) indispensable, the EpiPen had become nearly interchangeable with auto-injectors, and Mylan intends to keep it that way.

Despite epinephrine being a generic drug, in 2012 Teva Pharmaceuticals was prepared to bring a new generic epinephrine delivery system to market. Teva’s product would be in direct competition with the EpiPen. However, according to congressional testimony, Mylan and Teva reached an agreement “preventing [Teva] from putting a generic on the market until 2015 or earlier under certain circumstances” (Reviewing the Rising Price of EpiPens, 2016, p. 34). Committee members pondered aloud about a possible anti-competitive “pay for delay” scheme. Then, months before Teva’s settlement agreement with Mylan was set to expire in January, 2015, Mylan filed a “505(q) citizens petition” on drug safety to the FDA citing safety concerns.
Within the petition, Mylan claimed to have commissioned a study that found Teva devices had a 93% failure rate. According to Carrier and Minniti (2016), citizen petitions are meant to give everyday citizens an opportunity voice concerns for a product related to its safety or effectiveness. However, industry reporters have found that “citizen petitions represent a hidden tool in brands’ toolkit of entry-delaying activity, and when used inappropriately force consumers to pay high drug prices while providing no offsetting safety benefit” (p. 306). In fact, Carrier and Minniti (2016) found that 92% of citizen petitions are actually filed by corporations. They may as well be called “corporate petitions.” When asked about the decision to file a citizen’s petition, Mylan responded that “we submitted a petition, which is a public process that gives anyone with a view the opportunity to voice an opinion by submitting comments, and puts the decision in FDA’s hands, where it belongs” (cited in Zhang, 2017, para. 13). And although the FDA ultimately denied Mylan’s petition, Teva’s FDA application for market entry was denied in 2015 under uncertain circumstances. That same year, the FDA rejected another possible alternative device by Adamas.

In each of these examples, Mylan attempted to advance the interests of their organization through political-medical tactics and used medico-administrative logics to advance corporatized goals in the name of health, safety, and access. Taken together, the instrumentality of these political acts reflects an economic-political model that preserves discourses originating within its walls and deploys historical military and public health logics that have been embedded into 21st century neoliberal economic-political partnership. Although these tactics circulate across multiple institutions, they use common policies and support common solution-frames. The medicalization of allergy,
the extension of military technologies and logics to defend against allergy, and corporate-political maneuvers to commodify allergy have resulted in EpiPens as a powerful discursive form that has become entrenched into all aspects of life.

**Summary**

Within neoliberalism, discipline and techniques of preferred order converge through policies, laws, authorities, and common knowledge and rely on, borrow, and co-opt institutional expertise. Under neoliberalism, we see that instead of having a contentious relationship between the state and corporations, each deploy similar authorities and rely on similar knowledge that moves across contexts (in this case of health, wellbeing, and medicine). EpiPen has become a prominent object of discipline. The medical and military logics that codify the EpiPen have established it as the prominent form of allergy governance. Further, the EpiPen has become an object of biopolitical significance that extends its reach in the public and private sphere and (re)produces logics that have resulted in making it unthinkable to do anything other than use it. The next chapter shifts focus back to the case at hand by focusing on the role and function of maktivism in responding to the EpiPen crisis that this chapter foregrounds and contextualized.
CHAPTER 5:
MAKTIVISM THROUGH PARTICIPATION, BOUNDARIES OF CONTESTATION,
AND DECONSTRUCTED LOGICS

The previous chapter provided a detailed history of the EpiPen case that focused on analyzing the historical discursive formations and institutional logics that created the conditions for the case to unfold. This chapter turns toward an analysis of critical making and maktivism in the context of biohacker engagement and presents interesting findings about how resistance moves through dominant domains of medicine and technology. This chapter begins with an analysis of how maktivism can be participatory and resistant. Next, I present findings for how participation through maktivism de-constructs certain dominant logics and re-constructs others—in particular, how maktivism becomes subjected to certain dominant Discourses. Finally, I overview where the primary boundaries of contestation existed in this case and which dominant logics were ultimately contestable.

**How Can Participation Function as Resistance?**

RQ3 asks how material activism (maktivism) is performed in this case, with a particularly interest in the role of material resistance. As previously discussed, resistance is often conceptualized as rejecting dominant preferences. Maktivism, however, provides a conceptualization for considering the role of critical making (in this case biohacking) as a form of social justice action and intervention. Activism primarily emerges through acts of protest. Although maktivism can also function as a form of protest, in this study, we see protest and counter-narrative through participatory enactment and problem-solving.
Rather than breaking down (as in the case of hacktivism), biohackers produce and participate by offering alternative solutions, and with them alternative logics.

Four Thieves Vinegar is the catalyst for maktivism by biohackers in this case. Interestingly, their “hack” does not reject conventional medicine. In fact, Four Thieves Vinegar sources the parts to make the EpiPen from already-existing, readily available medical-grade parts. In my interview with Laufer, I asked how it was that he came to choose the EpiPencil design, and his answer was illuminating. He noted:

The best counterfeits are not counterfeit. You just use the real thing and everything that is used in that is, those are all off-the-shelf parts that are medical devices. You know, it wasn’t like “Oh make a needle out of something” or “make a syringe.” It was like “Go buy a syringe.”

Laufer continued.

There’s sort of an urge in the hacker world to do things in a hacker way, to do a work-around just because you can, not because it’s necessarily necessary or even the best approach. There’s something that riles up the heart of the hacker when you say “I can build it myself. I don’t need infrastructure.”

Writ large, biohacking commonly deploys tactics of using materials that are already available or can be easily “hacked” to construct new technologies. For example, biohackers who published examples of hacked PFS approaches turned to everyday household materials to lower the cost of their hacks, which evoked the ethos of DIY (see Figures 11, 12, 13).
Figure 11. Screenshot of a PFS hack using a toothbrush container for a case. Adapted from How to Make Your Own EpiPen, in YouTube, n.d. Retrieved September 28, 2018, from https://www.youtube.com/watch?v=E9kgX1qtfo. In the public domain.


Laufer commended that sometimes hacker communities use hacks as a way to gain credibility within the biohacker community or choose to use alternative materials because they evidence or give “cred” (credibility) to the hacker community. While the ultimate goal for biohacking is to produce alternative solutions, Four Thieves Vinegar focused on making “something that was going to work, something that was simple, something that was cheap, something that was accessible, and something that was safe.” I make the case that it is interesting and telling that Four Thieves Vinegar’s chose to co-opt and appropriate medical devices both to resist traditional convention and to preserve much of the medical integrity of the materials and of the counter-narrative.
Unlike other “hacks,” Four Thieves Vinegar’s choice not to use alternative materials, such as 3D printed parts, or repurpose non-medicalized components for their device was in part a matter of convenience—auto-injector technology, medical syringes, and vials are generally available for purchase. However, the group also rejected certain logics of hacker culture and, thereby, also resisted the desire to demarcate the functionality of the device as having been hacked. Thus, they simultaneously participated in biohacktivism and medical problem-solving. Where their maktivism was most visible, however, was through their instructional video and the product label (see Figure 14).

Four Thieves Vinegar presented an alternative to the EpiPen by repurposing the EpiPen label and, in doing so, repurposed the EpiPen. By re-presenting the EpiPen label as the EpiPencil label, Four Thieves Vinegar co-opted the utility, familiarity, and otherwise hidden medical protocologics embedded within it.

Regarding the label, Laufer stated, “Making the label was specific because part of the argument for auto-injectors being good technology or important technology is that they can be picked up by somebody who has never seen one before, and they can read the label, and [inject].” As if disclosing a secret, Laufer continued, “[the label] is almost the same. It’s not really different. // I changed a little bit of the verbiage, and I put our logo on it. And that was it.”

Four Thieves Vinegar still resisted dominant logics and discursive formations by creating a device that utilized off-the-shelf medical parts, included the same preferred medication for anaphylaxis treatment, relied on the same medico-administrative logics and protocols, and repurposed the logo of the most common and familiar product. Through their production and participation, the collective was able to reveal certain flaws in the dominant narrative around EpiPen prices and access. Through their participation, the collective produced something that is both antithetical to the dominant narrative and uses the dominant narrative. By redeploying old materials in new ways, biohackers reconstituted new meanings into various materialities. Four Thieves Vinegar took this one step further by co-opting medical technologies and medical protocols to constitute new meanings and, in the process, reveal hidden absurdities embedded within those materialities. These findings have important implications for how we think about micropolitical resistance and participation, particularly across and within dominant discursive forms.

This section lays out a case for biohacking as a mode of resistance. The next section analyzes the way biohackers’ discursive-material production served to contest
dominant discursive assumptions. In doing, the next section provides findings relevant to RQ2, which considered what discourses and discursive logics were contested in this case, and conversely which were not.

**Biohacking Resistance to the EpiPen Crisis**

To answer the question of what discursive logics were contestable in this case, the following section summarizes the key discursive-material contestations presented by biohackers. This section also includes an overview of what logics biohackers attempted to contest, as well as an analysis of which were contestable. Non-contestable discursive logics refer both to those that tried to be contested by biohackers and instances where biohackers were ultimately subjected to dominant logics despite their resistance.

**Contesting Price**

Cost and affordability are unequivocally at the center of this case. Neoliberal logics of price emerged as the central problem-frame and proposed solution-frame across all actor groups focused on fixing cost. Across dominant institutions, price functions in the neoliberal context of free market enterprise. Government actors, for example, were primarily concerned with intervention for the sole purposes of encouraging fair marketplace competition and preserving political-economic biopolitical power. Public dissent circulated around issues of affordability and the high cost of medical care. Finally, critical makers (both medical professionals and biohackers) created alternative devices to protest price logics and provide cheaper alternatives. Four Thieves Vinegar expressed disdain that “the pharmaceutical industry continues to put profits above human life” (Four Thieves Vinegar, 2016).
Despite contesting price, it is important to note the conceptual difference between price logics of biohackers and capitalistic price logics. The difference is most noticeable in the way various actor groups talk about price. For example, at the congressional hearing with Mylan, politicians expressed their disinterest in hindering Mylan’s ability to turn a profit. In contrast, DIY alternatives function as micropolitical expressions of resistance and contest neoliberal logics of price by demonstrating how easy it is to remove barriers to price. Syringe-and-vial alternatives, for example, attempt to disentangle the price of epinephrine from the price of EpiPens. Auto-injector alternatives take it another step in their attempts to disentangle the price of the self-injection technology. In doing so, both alternatives challenge core assumptions about price.

In my interview with Laufer, the Four Thieves Vinegar founder, he explained that the collective had explored the possibility of manufacturing epinephrine and realized “it was a huge pain.” However, he resituated the problem:

Getting epinephrine is not hard. It’s everywhere, and it’s fucking cheap. And if you have a fear of anaphylaxis, you can ask your doctor to just give you a prescription for a vial of it, and you can load it.

Across the board, epinephrine rarely emerged as the problem. Rather, the problem was the need for a dramatically cheaper medical delivery system. In the end, biohackers were successful at contributing to counter-logics of price, as they were able to “shame Mylan by showing how much it really costs to make an EpiPen” (Sorrel, 2016).
Contesting the Pharmaceutical-Industrial Logics

Mylan primarily framed the problem of price as one of medical-industrial constraints rather than that of corporate greed and deployed a number of traditional tactics to excuse away their prices.

The pharmaceutical-industrial ecosystem. Mylan also largely blamed “the system” for EpiPen prices. In her congressional testimony, Bresch claimed that “the system has been around for decades,” “the system rewards higher prices,” and that “Mylan didn’t make the system” (Reviewing the Rising Price of EpiPens, 2016, pp. 48–49). To illustrate, Mylan issued a press release, in the name of “price transparency,” with the hopes of helping to “meaningfully address the U.S. healthcare crisis” (Mylan, 2016b, para. 2). Bresch suggested that Mylan only realized $274 per EpiPen prescription, of which just $50 could be considered profit (Reviewing the Rising Price of EpiPens, 2016). Of the remaining money Mylan saw, $69 went toward paying for the cost of goods (i.e., raw materials and manufacturing costs for each pen), and $105 paid for other “EpiPen related costs” (likely referring to various miscellaneous expenses related to marketing, distribution, licensing, business operations, legal fees, training, lobbying, and sales activity). The significant reason for the additional $334 per prescription, she argued, was the result of the full supply chain (i.e., pharmacy benefit managers, wholesalers, pharmacy retailers, and insurers) driving up the price so they could make their own profits.

The “system is broken” became a dominant discursive boogeyman in this case. It most notably showed up in the various instances where the problem-frame was the institutional structure itself. While Mylan blamed the downstream supply chain, most
blamed corporate greed. Others blamed the FDA for the slowness with which it had approved alternative products (Newman, 2016) and for a regulatory environment that lets “drug companies push prices as high as possible until there’s public outrage” (Emanuel, 2016, para. 4). Still others blamed pricing structures and incentives (Ho, 2016). Taken together, “the system” came to be a discursive form all its own. The system, in this case, is both visible and hidden. That is, it circulates across discursive boundaries of medicine, politics, and economic logics. Rather than a coordinated partnership, “the system” was portrayed as tenuous rather than a dominant force. Thus, “system-is-broken” emerged as both a dominant problem-frame and a scapegoat dominant solution-frame for politicians and pharmaceutical companies. Biohackers also agreed the system was broken. However, “the system” was not broken because it was dysfunctional like the dominant system portrayed. Rather it was broken because it was working just as intended—to profit off sick lives and hoard medical care for those who could afford it.

In our interview together, Laufer suggested that dominant actors propose that when infrastructure is not working “we should fix the infrastructure.” On the other hand, he sees the biohacker community as proposing a “work-around” in the meantime rather than a complete overhaul without any intermediating steps. He states:

Yes, we have infrastructure, and yes we should work to make it so that it works as we want it to; // “however, if it’s not [working], we don’t have time to sit around and wait for laws to be passed, or policy to change, or approval and regulations to shift if your life is on the line. You need a stopgap. You need something to fill in.

Biohackers acknowledge their (lack of) role in “the system” and, in doing so, acknowledge that they must offer temporary solutions in extra-infrastructural ways on
their way toward creating systematic change. Earlier in our interview, Laufer said that Four Thieves Vinegar’s goal is ultimately to not exist as an entity. Biohacker interventions, he suggested, indicate/evidence gaps that need filling. The system will only ever be fixed when it goes away (i.e., once a critical mass of distributed and emancipated health solutions and knowledge exist), and there is no longer need for “hacking” as a form of deviance.

While this notion is utopian, it explains the motivations of biohackers and the role of temporality in their participation in social issues. For biohackers, the system-as-broken serves as a call that necessitates meaningful response, whereas the system-as-broken for others is a convenient inconvenience that sometimes results in corporate price gouging. In sum, the system-as-broken has become a powerful discursive apparatus such that even moderate responses like biohacking seem radical and that people taking care of their own health in non-preferred-systematic ways is a social risk.

Despite claiming the system is broken, Mylan also relied on a variety of systematic tactics to defend its prices.

**Pharmaceutical research and development.** Pharmaceutical companies have long maintained that the profit they realize from drugs helps to offset the expensive costs associated with bringing those drugs to market. Research and development (R&D) costs (e.g., biochemical research, clinical trials, market research, FDA approval process, etc.), thus, are a common justification for prices, particularly when drugs are still under patent. In her written congressional testimony, CEO Heather Bresch claimed that Mylan “must invest heavily in research and development and manufacturing in order to produce billions of doses and bring hundreds of new products to market every year” (Reviewing
the Rising Price of EpiPens, 2016, p. 19). She noted that the “overwhelming majority of what we’ve spent [on EpiPens] has been on access and awareness programs” (p. 20).

However, as previously outlined in this chapter, very little has changed about the EpiPen other than its price since Mylan purchased the rights to sell it in 2007. In fact, it is worth noting that in 2009 Mylan voluntarily decreased the expiration period of EpiPens, which caused customers to purchase them more frequently.

However, biohackers successfully contested narratives of R&D through their making. By developing alternatives quickly and, in the case of Four Thieves Vinegar, doing so by offering a solution that followed similar administrative protocols, critical makers emancipated research and development. Further, by bringing previous technologies forward as alternatives, they attempted to juxtapose previous administrative techniques with the cost justifications of new, more automated administrative logics. These contestations contributed to a growing shift in the public discourse about whether pharmaceutical companies can attribute iterative R&D costs to medical pricing. Although biohackers discursively and symbolically contested notions of R&D, the larger narrative turned to a focus on the cost of safety and convenience. Journalists expressed concern that alternatives introduced too much risk. Political contiguities also focused on the role of balance between price and public safety. Mylan emphasized the importance of ensuring that their devices work every time. Thus, an emphasis on safety and reliability superseded the value of offsetting logics of R&D.

**Pharmaceutical patents.** Patents are also powerful deterrents in American economic-politics that are meant to conceal knowledge (intellectual property). Although the federal government is responsible for issuing patents, they brand themselves merely
as bookkeepers in such legal matters. A large part of the broad biohacker narrative focused on an ethos of “copyleft” and open-technology logics. Biohackers aimed to emancipate knowledge by freely publishing instructions, sharing computer-aided designs (CAD), and encouraging other DIY makers to create their own alternative devices and solutions. Thus, biohackers challenged intellectual property logics through their participation.

When I asked whether Four Thieves Vinegar had concerns about patent violations, Laufer suggested that that the EpiPencil uses medical grade parts and that their instructions encourage the product be used in the way it is originally intended (i.e., to draw up a prescribed medication and inject it intra-muscularly). Further, unlike the dominant narrative, which focused on market competition, biohackers were not encouraging a product. Rather, they are merely providing information (that should already be readily available) to people who might benefit from it. Taken this way, the EpiPencil has already inherited certain forms of knowledge and medico-administrative meanings that give it credence as both a tool for medical use and for emancipating knowledge.

Four Thieves Vinegar attempted to appropriate old meanings to make new ones and reveal taken-for-granted inconveniences about dominant notions of medical access and price. By reframing traditional medical-grade parts as a “hack” in response to EpiPen prices, the DIY community essentially co-opts materials and their embedded meanings in order to reveal cracks in their discursive logics.

In this section, I discussed how biohackers and critical makers objected to and contested economic/capitalist/political logics through their participation in this case. The
next section focuses on non-contestable boundaries of biopolitics and medico-administrative logics.

**Uncontested Boundaries and Medical Subjectivities**

Critical makers, in this case, are primarily concerned with addressing institutional/economic barriers affecting individual access to affordable medicine by creating intermediary alternatives. However, economic-political logics are only one part of the dominant discourses that circulate throughout this case. Next, I overview the dominant medico-administrative logics and discursive formations that remain unchallenged or become reproduced through biohacker engagement.

**Medical Authority**

DIY makers do not challenge the dominant medical solution-frames of epinephrine as the preferred allergy governance chemical, injection as the dominant delivery method, or pharmaceutical companies and doctors as medical gatekeepers. This is particularly interesting because Four Thieves Vinegar is a self-proclaimed anarchist group with a long-term goal of emancipating the production of medicine through DIY solutions. In fact, Four Thieves Vinegar’s mission is to promote and enhance the development of an “open-source automated lab reactor, which can be built with off-the-shelf parts, and can be set to synthesize different medications” (Four Thieves Vinegar, 2016, para. 1). In response to the EpiPen crisis, biohackers could have presented tactics focused on alternative medical production and governance, including its development and dispensing.

In an attempt to meaningfully contribute to and democratize medical knowledge, biohackers oscillate between participator and activist by situating themselves within
certain medical discourses and aligning their solutions to the dominant solution-frame. Thus, we see biohackers performing activism through cooperation. This oscillation reveals an interesting aspect of biopolitics, one that influences the challenges confronting fringe groups desiring to promote the diffusion of institutional knowledge and, in doing so, preserve the institutional logics that give it power. Therefore, biohackers simultaneously attempt to cooperate and resist, and distance themselves through efforts to create practices that are more inclusionary. Consider the following example of discursive conflict for the collective.

**Deviance ↔ Inclusion Paradox**

The Four Thieves Vinegar collective borrows its name from an allegorical tale born out of the European plague outbreak in the late 1500s to early 1600s. As the legend goes, four brothers created a potion that prevented them from succumbing to the plague. Rather than use their potion to save others, they chose instead to steal from the sick and the dead. Eventually the brothers were caught; however, to avoid prosecution they offered their potion in exchange for immunity from prosecution.

In this modern-day context, the biohacker group function as the four thieves, their alternative products as the potion, and corporate pharmaceuticals as a modern-day plague. The collective’s potion is also two-fold: a cure for medical ailments and a cure for the illness that is for-profit medicine. In our interview, Laufer reflected that “those four brothers were caught,” but “instead of being executed, they were let free by sharing information they had. And in exchange, others got the information that let them live.” Emancipating medical knowledge, from Laufer’s viewpoint, “is enough to save lives.” Four Thieves Vinegar acknowledges their identity as medical deviants and reenacts
immunity logics that have historically framed hackers as epidemiological-like risks to society. Despite their emancipatory and democratizing goals, because the collective is participating with medicine outside of traditional institutional boundaries, their contributions are largely only seen in antagonistic ways (Jamieson, 2015).

Interestingly, the allegorical tale of the four brothers emerges from pre-epidemiological Discourse. In fact, community plague doctors believed that infections spread through air and infected those who breathed the “bad air” in, a theory known at the time as *miasmatic theory*. Miasmatic theory materialized through certain medical protocols, most notably the use of plague doctor uniforms. The plague doctor mask, for example, was long and beak-like. To avoid bad air, doctors filled the mask with herbs and other aromatic items. The prevailing theory was that the aromatics could trap the disease and keep it away from the face (see Figures 15, 16, 17).


Although miasmatic theory eventually fell out of favor (in place of germ theory and then again by epidemiological science), the Four Thieves Vinegar collective borrows from and co-opts a historical tale that illustrates a historical contestation of medicine and access that has formed and re-formed over centuries. Through this example, and this case, we can see the historical biopolitics of power over time and see historical logics portraying biohackers as a possible modern-day version of an ancient battleground over health, access, and politics of immunity.

To further illustrate how the organization oscillates between cooperation and activism, consider the collective’s logo. The logo is ominous and draws from historical visual representations of both medicine and hacking. Like other computer hacker groups, the logo deploys a masked character, one that is wearing the mask of historical medical experts (meant to protect the medical doctors from illness) while simultaneously evoking a kind of masking consistent with shadowed/hidden organizations like computer hacker groups, such as Anonymous.

Four Thieves Vinegar also operates in similar ways to hacker groups by primarily contesting medical logics in non-medical spaces. For example, members participate in secret—Laufer notes that in some cases members do not know the identities of other members—and communicate through encrypted online chat channels. To fund their work, they accept donations through cryptocurrency and display a “warranty canary” on their site. Essentially a digital canary in the coal mine, a warranty canary functions as a transparency tactic among open-source and hacker communities to disclose whether the group has received any formal written order(s) from a government agency or is part of a legal process that would prohibit them from being able to say publicly that they had
received such an order. Because some subpoenas include secret gag orders as part of a federal or state investigation, warranty canaries let biohacker groups discretely defy the gag orders. For example, not updating the warranty beyond the specified timestamp, removing the warranty from the website altogether is a discrete indicator to the public that the group has, in fact, been approached with a formal written order, or that the government has sought or obtained access to its information or records.

Thus, the discursive enactments that shape the Four Thieves Vinegar allegory exemplify how historical discursive formations reemerge in modern socio-historical contexts. This also reveals how multiple dominant discourses continue to vie for power, circulate throughout time and across various contexts, and reconstitute themselves in new ways. Politics of immunity can help explain how their deployment of common medical protocols and logics in this case represent both cooperation and resistance. Next, I highlight another boundary of contestation for biohackers.

**Performing Medicine: Democratization through Demonstration**

Biohacking has historically been enacted through production and performance in ways that often blur the line between deviance and participation. Several DIY makers in this case enacted participation through demonstration (i.e., creating videos that demonstrate an alternative solution). Four Thieves Vinegar does this by deploying a form of resistance common in the biohacker community: participating through self-experimentation. This kind of performative engagement is important to biohackers and challenges the boundaries between often cautionary and prohibitive medical logics. For example, in 2015, a California biohacker group named Science for the Masses documented an experiment that attempted to identify whether injecting certain protons
into a person’s eye could produce effects similar to having night vision. They published images of their experiment along with an open-source scientific paper via their website (see Figure 18).


This type of “show and tell” functions to destigmatize scientific experimentation by pulling back the proverbial curtain on medico-logics and, thereby, challenging the embedded authority of scientific participation. Unlike other examples in this case, Four Thieves Vinegar takes biohacking from informative to performative and extends the spaces where contestation occurs. Laufer extends the doing of biotechnology into private spaces, such as in bedrooms and at dining room tables.

Although EpiPens had successfully moved into private spaces like the home, Laufer extended the development, production, and administration of medical procedures into the bedroom and kitchen. By bringing such devices into private spaces, Four Thieves Vinegar performed activism by proscribing medicine and techniques and, thereby, attempting to normalize injection protocols through alternative materialities, which
further contributed to the demystification of medical technologies (Dunbar-Hester, 2014). However, the medical expertise and the pharmaceutical industry owned the preferred medico-administrative logics, and ultimately YouTube removed the EpiPencil instructional video for violating community guidelines. The removal of their video also reveals another interesting biopolitical logic relevant to this case—legal disclaimers as an object of institutional power.

**Legal disclaimers as biopolitical texts.** Wright (2008) notes that legal disclaimers “presume an underlying tension of some sort” and that “generally, a disclaimer tells some audience that some other text or circumstance does not mean or imply what one might otherwise think (p. 88). In January 2018, a year and a half after initially releasing the EpiPencil instructional video, Laufer shared on Twitter that YouTube had removed the video from its site. According to the email he shared (Figure 19), YouTube claimed that Four Thieves Vinegar had violated the community guidelines for acceptable content by encouraging or promoting “violent or dangerous acts that have inherent risk of serious physical harm or death” (see Figure 19).
Hi Michael Laufer,

As you may know, our Community Guidelines describe which content we allow — and don’t allow — on YouTube. Your video ‘EpiPencil’ was flagged for review. Upon review, we’ve determined that it violates our guidelines. We’ve removed it from YouTube and assigned a Community Guidelines strike, or temporary penalty, to your account.

Video content restrictions

YouTube doesn’t allow content that encourages or promotes violent or dangerous acts that have an inherent risk of serious physical harm or death. For example, it’s not okay to post videos showing drug abuse, underage drinking and smoking, or bomb making.

The only depictions of such activities that we may allow need to be educational or documentary in nature and shouldn't be designed to help or encourage others to imitate them. When uploading a video, make sure to post as much information as possible in the title and description to help us and your viewers understand the primary purpose of the video. Learn more here.

The impact of strikes

This is the first strike applied to your account. We understand that users seldom intend to violate our policies. That’s why strikes don’t last forever – this strike will expire in three months. However, it’s important to remember that additional strikes could prevent you from posting content to YouTube or even lead to your account being terminated.

How you can respond

If you believe this was a mistake, we’d like to hear from you. Please follow both of these steps as simply deleting the video won’t resolve the strike on your account.

- The next time you sign in you will be asked to acknowledge this strike on your account.
- If you would like to appeal this strike, please submit this form. Our team will thoroughly review your appeal and will contact you again very soon.

We value your opinions and feedback. Please take a few minutes to fill out our

Figure 19. YouTube message to Four Thieves Vinegar regarding the removal of their EpiPencil video. Image courtesy of Michael Laufer.

Other DIY epinephrine alternative videos remained on YouTube, so I asked Laufer why YouTube removed his. He suggested that it was because he refused to add a legal disclaimer or statements noting that a video “is for information purposes only, don’t ever do this.” “Fuck that,” he exclaimed. “I’m sorry, [but we are] encouraging people to take control of their own health and encouraging people to, you know, technically practice medicine […] on themselves.” He noted that individuals providing legal advice to the collective suggested adding a disclaimer to the video because it “offers you some protection”; however, he lamented that it is antithetical to their goal of telling people they
can make an EpiPencil for themselves. Indeed, all other DIY maker alternative videos on YouTube included legal disclaimers.

While sites like YouTube mediate the promulgation and propagation of counter-narratives, in this case we see an example of how certain mechanisms of control create boundaries around forms of contestation, including self-experimentation and producing knowledge that encourages action. Legal disclaimers function in this case to preserve certain dominant discursive logics about how knowledge is privileged, including who can contribute, how individuals can participate, and what participation looks like. In other words, legal disclaimers allow for the production of “alternative” information within the dominant domain as long as there are clearly marked signposts delineating it from authoritative knowledge and participation. Thus, legal disclaimers reduce participation to aspects of voyeurism and entertainment rather than meaningful co-production of new and contestable knowledge. By refusing to play the “post a disclaimer game,” Four Thieves Vinegar intentionally resisted certain dominant biopolitical norms. But in doing so, it also made it more likely that they would be censured for their critical making.

In this section, I presented findings about how biohackers contested institutional-pharmaceutical and corporate logics and medico-authoritative logics. Next, I will discuss biohacker resistance in the context of drug-device combination techno-logics.

**Deconstructing/Reconstructing Materialities and Techno-logics**

Although medicine is important to this case, the “drug-delivery system” was the central problem-frame. As auto-injectors moved from military projects to commercial use, the device itself became the prominent historical innovation around which economic discursive texts (e.g., patents, administrative logics, and profit) emerged. Thus, these
embedded logics continue to circulate through the dominant narrative of corporatized epinephrine auto-injectors and alternative DIY productions.

EpiPens are both “medical” and “devices.” Therefore, they (re)produce both medical and technological authority and order. For example, Mylan claims that,

although it may look simple, [the EpiPen] is actually quite complex. In the event of a severe allergic reaction, the more than 15 critical component parts in this device must work EVERY TIME ... IN SECONDS ... to deliver medicine to treat life threatening symptoms quickly and without fail. (Reviewing the Rising Price of EpiPens, 2016, p. 20)

Indeed, the technology administers the medicine and provides a sense of safety. Although the device consists of a syringe and vial, it conceals these components and rejects alternatives that are merely syringe-and-vial based. The EpiPen conceals both its operations and its medical parts and, in doing so, appears both medical and non-medical.

Further, instructions on the label are administrative and emphasize the technical components of the device. In that way, the EpiPen disciplines users toward its technologic protocols.

One of the most prominent ways Mylan maintains its role as a disciplining authority is through the deployment of training/practice devices. Prescriptions for EpiPens also include a training device, which merely consists of the external material components (see figure 20). Each training pen allows a person to practice using the device and become familiar with its technologic behavior. Through familiarity with the device as a technology and by borrowing from its embedded medical meaning but removed from its medical application, trainer pens orient users toward their use.
Training pens have come to constitute and normalize EpiPen use by not only shaping behavior but also reducing the need for medical expertise and medical involvement. Therefore, EpiPens become the medical expertise through their techno-logics. What is interesting about this is that EpiPens are, in fact, a do-it-yourself (at-home) device.

Biohackers attempted to deconstruct EpiPens by focusing not on the medico-administrative logics but on the material components, which contested the material meaning of the device. To demonstrate, I procured the parts needed to produce an EpiPencil (Table 1), and then assembled them following the instructions on Four Thieves Vinegar’s website (Figure 21).
Table 2

*Parts and Materials for Personal EpiPencil Build*

<table>
<thead>
<tr>
<th>Item / Quantity</th>
<th>Price</th>
<th>From</th>
<th>Single Use Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 (five) 1ml 1cc sterile (individually wrapped) disposable medical-grade syringes with luer slip tips</td>
<td>$5.99</td>
<td>Amazon.com</td>
<td>~$1.20</td>
</tr>
<tr>
<td>10 (ten) 22G 1-inch sterile (individually wrapped) single-use hypodermic needles</td>
<td>$8.85</td>
<td>Amazon.com</td>
<td>~$.89</td>
</tr>
<tr>
<td>Auto-ject 2 non-fixed needle injection aid device</td>
<td>$31.94 with shipping</td>
<td>ADW Diabetes (online)</td>
<td>$31.94</td>
</tr>
<tr>
<td>Epinephrine prescription from licensed prescriber (5ml vial)</td>
<td>~$5.00</td>
<td>Healthcare provider</td>
<td>~$1.00</td>
</tr>
</tbody>
</table>

**Total single-use cost** $35.03

*Figure 21. EpiPencil components purchased from the parts list in Table 1. Image courtesy of Matt Donovan*
In my experience as an individual with no medical expertise, I was able to easily purchase the necessary medical parts, follow the instructions, and assemble a full-working EpiPencil in approximately 15 minutes. My experience validated that Four Thieves Vinegar was able to demystify medical technology by empowering individuals to make their own devices (Dunbar-Hester, 2014). By demystifying technology, DIY making is most successful at problematizing material logics.

Device de-construction became a central aspect of the national conversation. In October 2016, a California newspaper published an online news article about two mechanical engineers who had disassembled an EpiPen in order to calculate the cost of its raw material parts. Based on their engineering backgrounds, the two people involved estimated that raw materials cost about $8, to which one of the engineers exclaimed, “Now I’m even more outraged at how badly we’re being gouged by the pharmaceutical industry” (Seipel, 2016, para. 30). In this case, we can see another dominant discursive formation circulate across the DIY maker movement. Privileged notions of technological deconstruction and reconstruction emerge from a discursive shift occurring since the late 20th century away from “traditional public sector values” and toward “entrepreneurial” and “enterprising” organizational values (du Gay, 1996, p. 156).

**Entrepreneurialism and the Entrepreneurial Imperative**

Born out of a growing discourse around greater global market competition and the rapid growth of information technologies, the entrepreneurial imperative embraced attitudes and values of “increased economic efficiency” and “improved services at reduced cost” over more bureaucratic ethos. Entrepreneurialism offers a strong critique of “bureaucratic culture” and positions itself as the solution that focuses on principles like
rapid change and the premise that only those organizations that are “ever more enterprising will survive and prosper” (du Gay, 1996, p. 154). In the deployment of this new contemporary discourse, bureaucracy became synonymous with a lack of progress, predictability, “waste, inertia, and unnecessary regulation” (p. 153) and likely became the “first casualty of such an uncertain environment” (p. 154).

The move toward privileging an entrepreneurial discourse presupposed that all organizational industries, including hospitals, nonprofits, banks, and even government agencies, would all have to develop and embrace enterprising norms and entrepreneurial tactics to preserve economic prosperity. Supply-side sovereignty, enterprising logics presupposed, was the only way to ensure national sovereignty in a globally interconnected and accelerated world (Nadesan, 2008). As such, the role of government agencies moved from providing goods and services to allocating them through commercial enterprises. Entrepreneurial logics also caused shifts in perception and attitude about the government’s role in society. The entrepreneurial imperative reconstituted the relationship between government and business by moving government agencies out of the “business” of operationalized institutions (e.g., prisons, schools, healthcare) and into more contract-based relationships with institutions (Freedland, 1994). Additionally, government agencies came to adopt many of the economic principles that undergird the enterprising ethos. As a result, economic logics became the principle method for “programming the totality of governmental action” (Gordon, 1991, p. 43). The entrepreneurial imperative is convenient because it is often used to present a dualism between bureaucratic government and public sector enterprise (du Gay, 2004), and often functions as a rhetorical move to scapegoat institutional violations of public
trust (such as drug price gouging). However, enterprising logics also frame non-institutional engagement, particularly when the solution is framed in terms of its technological affordances (Delfanti, 2012).

By contributing to, and participating in, activities that emphasize technological alternatives and de-emphasize medico-administrative logics, DIY makers in this case chose dominant entrepreneurial forms. This is particularly noticeable in the use of 3D printing. Indeed, 3D printing has become synonymous with critical making in recent years. 3D printing represents the possibility for emancipating manufacturing as well as adoption of technologies that are not currently institutionalized. By deconstructing and reconstructing technological materialities, certain DIY makers in this case adopted strategies that closely mirror enterprising logics and, as a result, emancipated technologics that demystify technology but rarely produce meaningful social change or widespread adoption of alternative techno-logics.

**Summary**

This chapter presented some of the key dominant Discourses in this case across various discursive fields. Across each Discourse, biohackers and DIY makers attempted to resist and contest certain logics. Biohackers also deployed various discursive and material moves to create both counter and participatory narratives. In the end, this study presents a nuanced perspective on how critical making functions on the fringe of multiple Discourses competing for power. Biohackers are constantly oscillating between issues of resistance and participation, deviance and inclusion, and breaking down discursive-material meanings and building up new meanings. The next chapter provides a discussion of these findings including their theoretical and practical implications.
CHAPTER 6:
DISCUSSION, IMPLICATIONS, AND FUTURE DIRECTIONS

Summary of Dissertation

This study set out to better understand the function of maktivism as a fringe practice—one that delicately oscillates between the boundaries of inclusionary participation and exclusionary resistance within institutions and institutionalized realms of knowledge. Turning to critical case study analysis and borrowing from various discursive and historical tracing methods (Foucault, 1977; LeGreco & Tracy, 2009), this study examined DIY making in the context of epinephrine auto-injectors. The case analysis provides a rich illustration of critical intervention in a prominent social issue (pharmaceutical pricing and access) while also operating at the intersections of technology and medicine.

First, I identified a modern case where biohackers engaged in critical making as a way to intervene in a complex social issue (Ratto, 2014). The 2016 EpiPen pricing crisis was ripe for analysis because it marked one of the first times biohackers received such widespread response. Further, the crisis provided a “rupture point” from which to analyze the discursive and material practices and strategies employed by various actor groups over time and map their interactions over time. Borrowing from discourse tracing, I first presented a chronology of events relevant to the case, particularly the discursive and material enactments across three primary discursive fields: organizational, governmental, and maktivist. Then I traced the strategies, discursive productions, and tactics deployed by various actors across each field and made particular note of where certain dominant logics intersected and diverged. Next, I situated the case within a “history of the present”
(Foucault, 1977) by examining the discursive formations of allergy and allergy governance. Then, using phronetic-iterative analysis techniques, I analyzed how certain discursive forms shaped whether resistance and contestation were possible for DIY makers in this case.

Throughout, the analysis focused on discursive-material production as a form of resistance, which provided interesting perspectives about how participation can both contribute to and contest dominant logics. These findings, which are discussed throughout the rest of this chapter, have particularly important implications for this study and for future research.

Theoretical Considerations

Although there could be many answers to the overarching question “what is this a case of?” this study primarily focused on counter-dominant narratives and competing historical tensions/logics. I focused largely on notions of resistance and social action, evidenced through modes of discursive and material production and participation. To further implicate each of these case aspects, the following section will case up (Ragin, 1992) by drawing enumerating conclusions to better explain and refine theoretical concepts (Eisenhardt, 1989).

Critical Making and Maktivism

First, this case demonstrates the role and function of critical making and maktivism in action. Maktivism—do-it-yourself activities deployed as a form of sociopolitical engagement and critical activism through critical material making (Ratto, 2014)—is useful for describing biohacker responses to EpiPen pricing and access in 2016. Social activism is a coordinating and propagating activity. Thus, social issues are
often a mobilizing force for activism. Notions of hacking and activism (i.e., hacktivism) have previously been described and associated with subversive resistance tactics and protesting logics: virtual sit-ins, creating protest websites, and virtually vandalizing websites (often referred to as e-graffiti) (Auty, 2004). Critical making, on the other hand, has focused on activities that are more largely situated under a hacker ethic of activism through positive deviance (e.g., concern for democratizing technology, participatory technology, civil society activism, positive political change, social empowerment, and the spread of awareness of issues) (Ratto, 2014). This study conceptualizes the DIY makers in this case to have participated in activities that are more appropriately described in terms of their adherence to critical making. What can this study contribute to the study of maktivism?

**Maktivism as a “Pop-up” form of Organizing and Material Action**

Social activism is an inherently participatory activity. As such, social issues and crises are often a mobilizing force for engagement. Indeed, this study presents a case of biohackers taking up the call to “intervene in social life” (Ratto, 2014, p. 228). In this case we see their responses as co-arising and dispersed, emerging in a similar but diffused way. Rather than resist for the sake of resisting, DIY makers in this case chose to participate as a way of offering solutions to a single emerging problem. Said another way, DIY makers were interrelated and coordinated in their response not through organizing logics but through problem-solving logics.

**Pop-up as heeding the call.** Weick (2001) notes that problem-solving activities often develop from *heed concepts*, which invite individuals to take up, attend to, or try something new. Whereas habitual action in organizing replicates preceding behaviors and
logics, “in heedful performance, each action is modified by its predecessor” (p. 264). Heedful performance has been previously conceptualized as group interrelated activities, where group interrelating is both the *product* and *condition* of actions of individuals (Asch, 1952). Yet, heedful interrelating can also help explain the disconnected yet interrelated activities of DIY makers in this case. We can think of DIY makers in this case as interrelated by their activities rather than their coordinated engagement (Weick, 2001). Taken together, maktivism was a heed concept that was taken up as a social call to action and interrelated through the production of collective information. Further, I suggest that modification, co-optation and appropriation in this case were important for our understanding of heedful interrelating. Rather than thinking about resistance as a unified force, heedful interrelated allows for critical making to be performed in meaningful micropolitical and fluid ways. Like little bubbles under the water, critical makers can materialize and reveal surface-level tensions.

Previous literature has extended heedful interrelating within organization-specific contexts (Weick, 2001); however, this study applies heedful interrelating to activities that span beyond organizational or institutional boundaries. In fact, we see heedful interrelating from medical professionals and biohackers in this case. We also see heedful interrelating across materialities through the use and deployment of both medical and nonmedical materials. DIY makers heed techno-logics and medico-logics to produce concepts that attempt to solve problems of price and access by resisting dominant logics of medical production.

Thus, this study can extend conceptualization of maktivism as both ongoing and momentary and emerging as needed, over time, through modes of “material showing.” In
other words, maktivism allows for an emphasis on storytelling and solution-frames through artifacts of resistance rather than structuration—instantiation rather than institutionalization. Taken this way, maktivism “pops up” through counter-production. Rather than competing against dominant capitalist logics of new production and manufacturing, DIY makers in this case simply redeployed old techno-logics, in new and meaningful ways. Said another way, DIY makers made visible the discursive debate that was circulating within the crisis. Rather than relying on the diffusion of historical knowledge about alternative methods of epinephrine administration, they reconstituted old logics through new productions and, in doing so, further problematized the dominant discourse. Unlike traditional capitalist logics, DIY makers in this case re-presented old knowledge in new ways, thereby demystifying both technology and medico-administrative logics. Taken this way, DIY makers harken back and point forward through their making. Maktivism “pops up,” contributes through material showing, then dissolves to leave behind revealed truths and micropolitical artifacts of resistance.

**Pop-up maktivism as bricolage.** To better understand pop-up maktivism as a process, I turn to the concept of *bricolage*. In organizational communication literature, bricolage is a process of sensemaking (Weick, 2001). Quite fittingly, a bricoleur is a tinkerer, and bricolage is colloquially defined as a do-it-yourself cognitive process. More precisely, however, bricoleur emerges from the Levi-Strauss conceptualization of “a means to use whatever resources and repertoire one has to perform whatever task one faces” (Weick, 2001, p. 62). Bricolage, thus, allows the bricoleur to create/produce something new from whatever materials and resources are available, a kind of improvisation that sensitizes others to the “possibility that there are many more potential
resources” (p. 62) than currently seem available. Taken in this context, DIY makers in this case were bricoleurs of old medical logics who repurposed materialities to solve new social problems.

Bricolage can help explain how “crucial uncertainties” came to be addressed, particularly in terms of how DIY makers challenged the relationship between dominant domains of knowledge, normalized protocols, and economic market subjectivities. While they did not produce meaningful socio-behavioral change through their material productions, they engaged in micropolitically demystifying the dominant techno- and medico-logics of epinephrine administration, which contributed to the larger public discourse of price and access. These material redeployments make the unseen seen again or, said another way, allow them to pop up in the collective social mind. Pop-up maktivism is a conceptual-theoretical interpretation meant to consider the larger implications of resistance across and within dominant domains. The following section attempts to interpretively consider the meaningful role pop-up maktivism can play in social action.

**Boundaries of Contestation: Toward a Conceptual Model**

The biopolitical boundaries outlined in this case (i.e., who can and cannot participate in medicine, where expertise lies, how hygienic protocols become embedded in everyday life, etc.) were established over time through various discursive and material (re)enactments. Discourses are social systems that produce domains of knowledge and meaning. As discourses become more widely adopted and circulated, they become embedded, normalized, and produce forms of subjectivity (power relations). Discursive logic, too, becomes seen as rational, factual, and true. Dominant discourses also circulate
within and along various contiguities/boundaries that often overlap with and cross various other systems of power. For example, in this case, discursive domains of capitalism, governmentality, and medical knowledge are prevalent. Discursive spheres also produce institutions of power and authority that attempt to preserve power and, in many cases, extend into new territories. Discursive logics are the hidden and embedded rules that make knowledge seem value-neutral and preferred. However, logics are political, and they become enacted in formal and informal policies and protocols.

Deleuze and Guattari (1988) suggest that power is akin to the travel of water—moving toward available spaces, trickling downwards and into new spaces, carving new territories by seeping into fissures and gaps, and slowly eroding that which might stand in its way. Metaphorizing power as water is a useful illustration for explaining how power moves to claim new territories or boundaries. As previously discussed, the power of power is in its invisibility, its seeming objectivity and value neutrality, and its movement into the governance of everyday thoughts and behaviors. Thus, dominant discourses continually attempt to extend their reach into other systems. These borders exert power throughout discursive and material spaces. (See Figure 21.) Deleuze and Guattari (1988) suggest that capitalism, for example, has gained power by shifting the flow of wealth in society, and state sovereignty has increased in power by extending its boundaries through military technologies of air and naval power. Biopower, too, functions as an example for expanding hidden boundaries of power for economic-political sovereignty by governing health through biopolitical and anatamo-political means (Lemke, 2011; Nadesan, 2008). We can see examples of all three types of power in this case. Simply put, power
structures are not confined to traditional spaces or modes of power and discipline. I created Figure 22 to visually illustrate.

![Figure 22. Illustration of dominant discursive formations present in this case.](image)

Organizational communication scholars have a rich history of investigating resistance to dominant modes within organizations (Alvesson & Willmott, 1992; Bain & Taylor, 2000; Ball & Wilson, 2000; Contu, 2008; Fleming & Spicer, 2003; Knights & MaCabe, 2000). However, organizational or institutional contexts are built within discursive realms. Therefore, this study illustrates broader territories of resistance (Munro, 2016).

DIY making is arguably, at best, a form of micropolitical resistance in this study. It emerges within dominant discourses and deploys/repurposes the discursive logics of the dominant while simultaneously existing on the fringe/periphery. The kind of
resistance enacted by biohackers in this case requires a nuanced perspective about whether dominant discursive power can truly be contested or whether contestation is always situated within dominant logics. If we conclude the latter, then scholarship on resistance might seem by some to be futile. Deleuze and Guattari’s (1988) conception of power, in part, insinuates such a futility. They suggest that power emerges through nodes that reject chronology and traditional conceptions of organizing. Nodes of power (i.e., where power makes itself seen and felt) can be “deterritorialized” (or broken off) through contestation and resistance; however, they argue that power continues to exist under the surface and eventually appears again through other nodes. That is, power is rhizomatic (Deleuze & Guattari, 1988), sprouting up in new and seemingly disconnected spaces but always connected under the surface, and making that which interacts with it part of its “reproductive apparatus” (p. 9). This proverbial power whack-a-mole presents a challenge for scholarship on resistance and social action.

If nodes of power reject chronology and organizing in predictable ways, perhaps we might consider that pop-up maktivism is just another example of predictable but somewhat futile resistance. However, I believe that, instead, there is another lesson available about power.

**What can we learn from a study on contested logics and boundaries?** This case utilizes the notion of “rupture point” as a methodological concept (LeGreco & Tracy, 2009). However, we might also think of rupture more discursively. Rather than relying on notions of resistance as supplanting or subverting dominant discursive logics, I propose we might reconsider the goal and function of contestation and resistance.
As documented in the chapters 4 and 5, maktivists in this case are subjected to both neoliberal entrepreneurial imperatives and medical logics. Thus, maktivism is inherently situated in dominant discourses. Perhaps, however, it is worth considering that maktivism is as much a subjectivity as a kind of peripheral activity that borrows from and repurposes dominant logics to draw new edges, carve out, or cut notches into the boundaries of various discursive formations. If and when dominant logics become noticeable, as was the case with pharmaceutical pricing, and creates a “rupture”—a crisis or a noticing—resistance has the ability to “hold the line” so to speak, even if temporarily, of those discursive logics. Additionally, because maktivism is always peripheral in nature, discursive and material enactments and productions function as deviance, even when borrowing from dominant logics. Taken this way, maktivism can point to problems in the dominant logic but also reveal inconsistencies and resist taken-for-granted assumptions.

Resistance through participation can reveal certain boundaries of power. Maktivism can attempt to carve small ruts in the edges where institutional discipline circulates. Further, micropolitical contestations like this might provide researchers and makers with a new perspective about how contestation and resistance become successful. Just as dominant discourses of power circulate and (re)emerge over time, so too do opportunities for micropolitical resistance and making. These spaces of contestation function to dot the landscape and more visibly trace and reveal the cracks in the hidden
surface of power, something I visually depict in Figure 23.

Figure 23. Illustration of points of peripheral contestation and resistance to dominant discourses. This visual should be considered in tandem with that above (as a close-up of one section of the bottom left part of Figure 1.

In this case, maktivists and DIY makers were able to deconstruct and reconstruct certain techno- and medico-administrative logics into new forms. That is, through their production, DIY makers materialized logics.

**Reconceptualizing Successful Maktivism**

Some critical organizational communication scholars (see Deetz, 2008) argue that orientations toward studies of power bifurcate the relationship between oppressor and oppressed. Others suggest that scholarship routinely masculinizes notions of power and success (see Nadesan & Trethewey, 2000; Jamieson, 2015; Martin, 1990). Indeed, after a close reading of this study, one might conclude that Four Thieves Vinegar, in creating an
EpiPencil, just reconstituted the neoliberal capitalistic logics of the EpiPen. Similarly, one might argue that a failure to dismantle power structures limits the effectiveness of biohackers in this case. Further, one might wonder whether anyone even used the EpiPencil. Indeed, I had that question myself.

When I asked Laufer whether he knew of anyone making the EpiPencil or advertising that they had used one, he responded that none of the feedback nor kind notes he had received clearly indicated that anyone actually replaced their EpiPen with an EpiPencil. He noted that the goal was not to replace EpiPens but to give people options.

I would argue that actions that result in people “having options” is an important aspect of successful resistance. Certainly, dominant neoliberal logics present success as growth-type measures (e.g., yield, production, volume, consuming, and adoption). However, a study that similarly conceptualizes success in these same terms may well be contributing to privileged and masculinized notions of success. Instead, this study asks us to consider an alternative conceptualization of success, one that is antithetical to dominant interpretations. This mode rests in alternative notions of participation as a function of resistance and contestation. Thus, this study asks us to consider what we can learn by reconceptualizing participation and mirroring dominant logics as micropolitical forms of resistance.

Ratto and Boler (2014) note that activism and hacktivism have largely moved from the virtual and digital world to the material world. Maktivism is both the literal and physical enactment of taking matters into one’s own hands to address political, civil, and social issues (Jacka, 2003). Sociomateriality provides a lens by which to consider the “constitutive entanglement of the social and the material” (Orlikowski, 2007, p. 1438) by
focusing on how human bodies, physical objects, and technologies come to be entangled with language, interaction, and human activity (Jarzabkowski & Pinch, 2013). This dissertation is, in part, a study of the (re)production of materialities that challenge various embedded scripts and meanings in material things, most notably medicalized technologies.

This study analyzed the role of “alternative possibilities” through the rearrangement and assembly of medical materials and, thereby, produced new technical affordances and made visible historically embedded meanings. This study contributes to research on sociomateriality by considering how DIY maker devices constituted new (and old) material meanings, by intentionally and unintentionally deconstructing and reconstructing material scripts through reproduction. This study takes a new perspective toward sociomaterial production by considering how material meanings are simultaneously resisted and recodified through the repurposing of materials and open-source instructions. I argue that this kind of resistance is successful because it uses dominant logics to evidence power, and it constitutes the rational possibility for more meaningful social action. The next section more fully explicates these ideas.

**Introducing Mirrored Materiality**

At first glance, one might consider the Four Thieves Vinegar EpiPencil “hack” to lack sophistication or nuance. The EpiPencil was merely a parts list consisting of already-available medical-grade components. Their instructions told users to use the components as they were intended (e.g., syringes and needles are meant to store drugs and inject them into the body). Even the label design was borrowed from Mylan—the company Four
Thieves Vinegar was claiming to contest. However, the EpiPencil became a symbol of resistance, an artifact of fear. How can we explain this?

I argue that through their participation in (re)constructing a medical device, Four Thieves Vinegar was able to co-opt the social meanings and institutional logics embedded within the medical material components. And in doing so, they were able to reframe the material axiological values and epistemological logics of the device. Said more specifically, by merely repurposing medical materials for use in new ways, fringe participation revealed otherwise hidden aspects of power within those materialities.

Broadly, DIY makers in this case also similarly participated in solving issues of price and access by repurposing materials to produce meaningful alternatives, including the use of both medical and non-medical components (e.g., 3D printed dispensers, repurposed toothbrush holders). Other biohacking groups, too, chose to modify medico-administrative logics (i.e., injection protocols that modified the order of steps and physical forms of auto-injectors). These approaches are also effective at revealing issues of power (in this case, by contesting logics of price by revealing cheaper manufacturing solutions). That said, the difference between Four Thieves Vinegar’s approach and other do-it-yourself “hacks” is important: Four Thieves Vinegar participated in resistance that closely mirrored dominant logics through their redeployment of normalized injection protocols. Four Thieves Vinegar was able to effectively “deterritorialize” certain aspects of power—like manufacturing and cost of goods—by deterritorializing medical knowledge and contesting boundaries of production and participation.

Issues of price and access circulated throughout the dominant narrative, as did demand for intervention and market alternatives. By offering a fringe alternative, the
EpiPencil problematizes certain dominant logics and, in doing so, both participates and contests.

Table 3

*Aspects of Mirrored Materiality Present in This Study*

<table>
<thead>
<tr>
<th>Logics of the EpiPen</th>
<th>Discursive Politics of (the Mirrored Materiality of) the EpiPen Alternatives</th>
<th>Revealed Incongruity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price of EpiPen ($600)</td>
<td>Alternative can be produced for $35</td>
<td>Incongruity of value</td>
</tr>
<tr>
<td>EpiPens are made of patented technology and materials; EpiPens are patented and protected technology and materials</td>
<td>Materials that comprise EpiPens are easily purchasable, readily available online, and simple to construct at home (open-technology)</td>
<td>Incongruity of techno-logics (demystifying technology); Incongruity of ownership</td>
</tr>
<tr>
<td>Justification by Mylan that the cost is associated with specialized manufacturing</td>
<td>Can be assembled (co-opted) using just five off-the-shelf parts currently used in other healthcare contexts</td>
<td>Incongruity of complexity (deconstruction)</td>
</tr>
<tr>
<td>Alternative devices pose a risk to safety; EpiPens have been approved by the FDA</td>
<td>EpiPencil uses medical-grade parts, already available and approved for medical use; Still requires a doctor prescription; Administration and application are similar/same</td>
<td>Incongruity of access (public good); Incongruity of medical authority</td>
</tr>
</tbody>
</table>

To more fully flesh out this concept, I borrow from the notion of *perspective by incongruity* (Burke, 1959). Perspective by incongruity traditionally explains how the juxtaposition of unfamiliar or opposed terms, metaphors, or images serve to sense-break familiar patterns and shift power through a kind of “intellectual vertigo.” However,
perspective by incongruity functions to resist power by jarring that which is expected but is somehow different.

Much the same way one finds new wrinkles when looking in the mirror and expecting the same face as we had years ago, incongruities can reveal otherwise taken-for-granted wrinkles in material power. Thus, the power of the mirrored materiality lies in its material (re)form. Materialities gain power through their (re)construction and (re)production over time. Mirrored materiality, then, occurs within dominant structures regularly. We even see this within the logics (e.g., administration, design, protocols) of the EpiPen. However, I argue that mirrored materiality can also contest dominant logics when it gives perspective by incongruity. By borrowing from or (re)producing parts of dominant logics while resisting others, mirrored materiality can also be used to reveal or problematize materials of power, and their modes of discipline.
Incongruities (e.g., value, manufacturing, access, medical ownership)

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**Figure 26 (right).** EpiPencil. Image courtesy of Matt Donovan.
The EpiPen, in this case, is embedded with (material, political, medical, etc.)
logics and values, which have been historically constructed. Biohackers, although
operating within the dominant problem-solution frame, (re)created alternative DIY at-
home epinephrine auto-injectors as a form of contestation. Biohackers attempted to resist
certain dominant discourses (e.g., affordability, medical gatekeeping, etc.); however, they
also situated their (re)creating within other dominant logics and values. Biohackers’
social activity and discursive logics of contestation were imbued within a new material
production that embedded some new social meanings while reflecting other more
dominant meanings. Taken together, the final product was a mirrored materiality that
evidenced/illuminated flaws in the techno-logics of the dominant discourse. By mirroring
through co-opting, appropriation, and even subjectivity, the absurdity and difference in
the politic of EpiPens and EpiPencil is actually amplified and brought to light.

In organizational communication research and critical post-structural
perspectives, notions of resistance often center on qualities of “opposition” and
“difference.” Literature on resistance tends to focus on “fixed identities and normalized
conflict that preclude meaningful ways forward” (Deetz, 2008, p. 389). Scholars have
historically argued that forms or acts of reproduction usually contribute to, reify, and
further substantiate power. In fact, critical organizational communication scholars
exploring the often complex and usually contradictory ways employee identities become
implicated in tensions of power have often suggested that power and identity are
mutually defining (Putnam, 2015) and that efforts to articulate resistance often result in
the reproduction of existing power relations and forms of control (Ashcraft, 2005;
Fleming & Spicer, 2003; Trethewey, 2001). Rather than resolve the tension between
participation and resistance as dialectic, this study highlights how one side of a seemingly opposing activity (in this case, participation) can be enacted as a means to achieve the other (e.g., resistance) (Tracy, 2004). Biohackers constantly oscillate between discursive acts that are both participatory and resistant, revealing how participation can function as a form of resistance, while also reifying other dominant power structures. This case illuminates how power and forms of resistance to it are in constant tension. By highlighting these tensions, we can begin to see the recursive nature and structure of these tensions in context.

Whereas previous studies have focused on the ways the (re)production or mirroring of dominant logics reifies hegemonic power structures, this study suggests that (re)production can also reveal power tensions in certain contexts. This mirroring or re-presentation of that which is being resisted or opposed reveals embedded sociomaterial meanings within new material productions and original (mimicked) materialities. Mirrored materiality as resistance provides a lens by which sociomaterial engagement can problematize and (re)politicize various discourses through their production. Critical theory asks how things come to exist, (co)exist, and interrelate in the (re)production of organizing. This study helps us consider how matter comes to absorb certain aspects of preferred knowledge, how protocols and behaviors come to be seen/felt as naturalized, and how discursive power suppresses other possibilities (possibilities for alternatives).

Epinephrine auto-injectors, in this case, function as sociomaterial artifacts and archetypes of power and resistance. In resisting, biohackers created an artifact (“objects to share with”) that, through its production, attempted to bring change at the local level, contribute to new knowledge and logics, and provide value to the populace through
material function (a viable, usable medical alternative and an artifact that constituted new meanings and creating alternative discursive logics about dominant techno-logics).

Therefore, do-it-yourself alternative devices functioned simultaneously as resistance in physical form (i.e., an artifact to make a public statement) and participation through tangible contributions (i.e., objects that solve a problem).

Critical making as both participation and resistance reveals the sociomaterial potentiality of technologies. In other words, material artifacts challenge both what is possible and where possibilities for change might exist, not only by creating new objects but also by mobilizing and evidencing new domains of knowledge and establishing new archetypes (social constructs). Thus, biohacker alternative devices in this case also serve as sociomaterial archetypes (i.e., as representations, models, and prototypes that are repeated and reconstructed as a visage of the original). Mirrored materialities illuminate how material meanings are inherited by the sociomaterial constructs that produce them. Epinephrine auto-injectors function, in this case, as the archetype from which new copies can be made and shows how newer models and meanings can disrupt taken-for-granted patterns of behavior situated within historical objects.

**Limitations and Future Directions**

Organizational communication scholarship concerns itself with communication processes and social dynamics that influence perceptions, attitudes, and beliefs about various technologies. These attitudes, in turn, affect how technologies are used and adopted. As such, one goal of organizational communication scholarship is to give attention to matters that come to matter, particularly in contexts that demand social
action. This particular case suggests that maktivism can more capability and meaningfully produce technologies that solve real-world problems.

One limitation of this study is that it was focused on discursive constructs and sociomateriality, broadly. However, this study could very easily include more micro-level discursive analysis. I made a number of assumptions about individuals who use EpiPens that relied on second-hand data. However, to more fully substantiate maktivism as an activity for greater citizenry, this study should consider incorporating more representative and individual data to create more multivocality. By understanding the concerns and needs of individuals who would benefit from medical alternatives, future studies on this topic could further elucidate how alternative medico-logics are (or are not) embedded into the public psyche.

Second, this research limited its scope by placing parameters on the case. Therefore, it excluded a variety of discursive moves, particularly related to political and capitalistic engagement and policy. Following studies could usefully begin to fill these gaps by focusing more closely on the relationship between economic-political sovereignty. For example, tracing the historic interactions and political maneuvers enacted between biohackers and government agencies can help provide greater context of the governmentality of biohackers through various apparatuses of security.

Third, this case included instances of both institutional and non-institutional actors as DIY makers. Although this study did not set out to compare the tactics of critical making across institutional “experts” and “non-experts,” this case provides interesting possibilities for considering the role of medical professionals as within-
institution maktivists. Further research should consider how institutional experts and medical gatekeepers influence issues of contestation, participation, and resistance.

Fourth, this research topic deals with issues of risk—medical, social, political, and more. However, risk was not a primary focus of this study. Future studies should consider an analysis of this topic through the lens of risk analysis and risk literature. Similarly, there are natural research extensions to health policy and health communication research. Health communication policy research can benefit from this topic by focusing on how knowledge is constructed across multiple systems and structures (Canary & McPhee, 2009).

Finally, this study did not include an analysis of the organizing of biohacker actor groups. Biohackers and biohacker groups organize in similar ways to other alternative organizations but different in others. Heedful interrelating describes how DIY makers function more as a sort of connective cooperation or co-arising activity rather than a traditionally collective action. Future studies should valuably consider contributions to notions of alternative organizing in the context of biohacker groups as social connective activity.

**Resonance and Significance**

As with much applied research, this case study uses various theoretical frameworks as a lens by which to potentially explain a particular phenomenon in context. Further, the findings are valuable to providing rich and detailed context to an important social issue beyond traditional surface-level explanations. This study aims to create resonance (Tracy, in press) by offering new and meaningful connections or transferability to issues of public health policy, medical consumerism, or the discursive formation of
medicalized topics. Although this study examined pharmaceutical pricing in the specific historical and rhetorical context of EpiPens and epinephrine, the problem of pharmaceutical pricing continues. Insulin, for example, has emerged as the next pharmaceutical crisis, leading new biohacker coalitions find ways to produce insulin outside of traditional laboratory or manufacturing sites (Open Insulin Project, n.d.). Therefore, the historically and culturally situated knowledge within this study can provide transferability to future problems in similar contexts.

Conclusion

This study aims to continue to add to a growing body of research and literature attempting to shift institutional logics that stand in the way of providing affordable access to healthcare in the United States. By focusing on research that demonstrates key areas of contestation and exposes the strategies long-employed by pharmaceutical companies, research on pharmaceutical pricing is important. Studies like this are also relevant as pharmaceutical pricing continues to be an issue in other contexts.

Recently, rising prices have led to difficulties in access within the United States. Further, groups like Four Thieves Vinegar have larger missions of contributing to do-it-yourself medicine and moving from device technology to the at-home manufacturing of pharmacological drugs. As more institutional logics continue to be contested in the future, more research should examine the implications of biohacker communities. Organizational communication scholars stand to provide substantial utility to these important efforts.
REFERENCES


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Laufer, M. [MichaelSLaufer]. (2018, January 1). “Yesterday, YouTube took down our EpiPencil video, claiming it was dangerous, after being up for a year and a half, and something like a million views. I’m not sure who is targeting us, but the nice folks at the internet archive are hosting it now” [Twitter Post]. Retrieved from https://t.co/UsNvvUdSNT


*Reviewing the rising price of EpiPens: Hearing before the Committee on Oversight and Government Reform, House of Representatives, 114th Cong. (2016).*


APPENDIX A

TYPOLOGY OF PRIMARY DATA SOURCES
<table>
<thead>
<tr>
<th>Actor</th>
<th>Data Type</th>
<th>Example Data Sources</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Survival Technologies Auto-injector Patent US3,882,863</td>
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<tr>
<td></td>
<td></td>
<td>Survival Technologies Patent US4,031,893</td>
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<td></td>
<td></td>
<td>EpiPen Patent US7,449,012</td>
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<tr>
<td></td>
<td></td>
<td>Meridian Medical Technologies Patent US7,449,023</td>
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<tr>
<td>Device Safety Texts</td>
<td></td>
<td>Pralidoxime Nerve Agent Auto-Injector Label and Safety Instructions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FDA Guidance for Staff: Technology Considerations for Pens, Jets, Injectors</td>
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<tr>
<td>Agency Policy Documents</td>
<td></td>
<td>NASBE Press Release: NASBE Launches Epinephrine Policy Initiative</td>
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<tr>
<td></td>
<td></td>
<td>2013 Emergency Access to Epinephrine Law (EpiPen Law)</td>
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<td></td>
<td></td>
<td>FDA Policies for Drug-Device Combinations</td>
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<tr>
<td></td>
<td></td>
<td>Press Release: President Obama Signs new EpiPen Law to Protect Children with Asthma</td>
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<tr>
<td>Congressional Oversight</td>
<td></td>
<td>Reviewing the Rising Price of EpiPens – Congressional Hearing with FDA and Mylan</td>
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<tr>
<td>Texts</td>
<td></td>
<td>Congressional Letter to Robert M. Califf, FDA</td>
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<td></td>
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<td>Congressional Letter to Heather Bresch/Mylan</td>
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<td></td>
<td></td>
<td>Cummins &amp; Sanders Investigation into Staggering Generic Drug Price Increases</td>
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</table>
| **Pharmaceutical Industry** | **Mylan Texts** | EpiPen Administration Instructions (2000s)  
Archival EpiPen Labels (1990s, 2000s, 2010s)  
Company Mission  
Citizen Petition against Teva Pharmaceuticals  
Press Release: Mylan Launches First Generic for EpiPen  
Press Release: Mylan Taking Immediate Action to Further Enhance Access to EpiPen  
Understanding the Pharmaceutical Supply Chain |
|---|---|---|
| **Other Pharmaceutical Manufacturer Texts** | Antidote Treatment (AtroPen & Pralidoxime ComboPen) Guide – Meridian Technologies  
Intelliject NDA Submission to FDA (2011)  
| **Consumer Watchdog Texts** | Fact Checking Mylan Claims they Raised the EpiPen Price because of Improvements (American Council on Science and Health)  
The EpiPen Problem: Analyzing Unethical Drug Price Increases and the Need for Greater Government Regulation  
Mylan Pricing Summary: A Case Study in Increases (PolicyMed)  
The Lack of EpiPen Competitors is the FDA’s Fault (Mises Institute)  
EpiPens and the Sale of Fear (Hastings Center) |
<p>| <strong>Patient/Consumer Advocacy Group Texts</strong> | Understanding Anaphylaxis (Asthma &amp; Allergy Network) |</p>
<table>
<thead>
<tr>
<th>Medical Industry</th>
<th>Medical Professional Maker Texts</th>
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<tr>
<td>Personal Communication: Emails from Food Allergy Research and Education (FARE)</td>
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<td>Epinephrine: Answers to Key Questions on Alternatives, Expiration, and Needs (FARE)</td>
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<td>Epinephrine Assistance Resources (FARE)</td>
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<td>ACAAI Statement on EpiPen Pricing</td>
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<tr>
<td>Pre-filled Syringe using Straws to Prevent Inadvertent Plunging Instructions – Altman MD</td>
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<td>DIY*EpiPen [video]</td>
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<td>3D Printed Epi Injector – Dr. Thomas McClellan [video]</td>
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<th>EMT/EMS Texts</th>
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<td>KS Board of EMS Emergency Epinephrine Administration Training Materials</td>
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<tr>
<td>Treating Anaphylactic Sticker Shock (EKU School of Emergency Medical Care)</td>
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<tr>
<td>Check and Inject Kit Design and Instructions</td>
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<tr>
<td>King County (Wash.) EMS Saves $334,000 Annually by Switching to IM Delivery of epi by EMTs</td>
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<th>Medical Group Texts</th>
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<tr>
<td>Mythbuster: Why Homemade Epinephrine Kits should not be used (Children’s Mercy)</td>
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<td>Infectious Disease Society Letter to Turing Pharmaceuticals</td>
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<th>News Reporting Media Texts</th>
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<tr>
<td>An Anarchist is Teaching Patients to Make their own Medicine (Scientific American)</td>
</tr>
<tr>
<td>A DIY Pharmaceutical Revolution is Coming – If it Doesn’t Kill us First (Gizmodo)</td>
</tr>
<tr>
<td>Don’t Only Blame Mylan for $600 EpiPens (Fortune)</td>
</tr>
<tr>
<td>Mylan CEO on EpiPens: The System Rewards Higher Prices (CNBC)</td>
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</table>

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US FDA Warns Against $30 DIY Alternative to Mylan’s EpiPen

EpiPens Have Become so Expensive People are Using Riskier DIY Alternatives (Scientific American)

Please Do Not Hack Your Own EpiPen

Absurdly Expensive EpiPens are Driving Families to Dangerous Lengths (CNN)

**Biohacker**

**Formal Interviews**

DIYBio Interviews (4)

Expert Interview – Michael Laufer (Four Thieves Vinegar)

**DIY epinephrine autoinjector materials**

EpiPencil Instructions, FAQ, Parts List, Label

Introducing the EpiPencil [video]

EpiPencil Update/FAQ [video]

Michael Laufer Twitter Posts (1,500)

Four Thieves Vinegar Twitter Posts (1,500)

Drug Delivery Device (3D CAD) specs from GrabCAD

Stratasys Drug Delivery Device (3D CAD) specs from Shapeways

3D Prototype from ProgressTH

EpiPen Alternative Housing Design for 3D Printing [3D CAD] – TinkerCAD

How to Make your Own EpiPen – Treat Outside the Box [video]
APPENDIX B

CHRONOLOGICAL ORDERING OF EPIPEN PRICING & DIY BIOHACKER ACTIVITY AND ADDITIONAL CONTEXT ABOUT DRUG-PRICING IN AMERICA
Additional Context about U.S. Drug-Pricing

All prices listed in the table below are variable. Data on EpiPen wholesale pricing (i.e., the price the distributor sells a drug to another entity) and out-of-pocket cost (i.e., the cost a patient must pay out of their own pocket after formulary price, insurance rates, rebates, and coupons are applied) were gathered from various sources and cross-referenced for accuracy. If a cited source used an estimated cost, I report the estimate. In some cases, prices listed in this study were based off of first-hand accounts. In those instances, I report those prices. At the time of this writing, prescription prices in the US are highly variable and depend on a number of factors. Because this is not an in-depth study of pharmaceutical pricing, the following is a simplified explanation for some of the reasons related to price variability. This explanation is meant to illuminate the highly complex ways pharmaceutical drugs are priced in America.

In America, the price of pharmaceutical medication is not regulated by the federal government. Nearly all other developed nations have specific policies that limit pharmaceutical companies’ abilities to price-gouge the government or citizens through drug sales. Many countries have price controls, regulations, and health-based outcome pricing models that ensure a fair price is being charged for medications. In those countries, the government is also the primary or sole buyer of medications for the country, and therefore the State negotiates the prices of all medications sold within the country. Because pharmaceutical companies operating in those countries only negotiate with a single government entity, they have less negotiating power. In the United States, however, various for-profit and nonprofit entities buy pharmaceutical drugs specifically for their consumers. Insurance groups and hospitals, pharmacies, health plans, and
retailers might individually negotiate prices for the drugs they buy, resulting in sometimes different and unregulated pricing. Antitrust laws in American prevent negotiated prices from being shared, limiting the negotiating power of buyers to buy at a fair or competitive price. In cases where medications are protected by patent, and thus no generic alternative(s) on the market, pharmaceutical manufacturers have the ability to freely set the price point for their drugs. However, in recent years concern of the rise of high-cost generics has become central to this debate.

To further complicate the issue, most health insurance plans and pharmacy benefit plans include out-of-pocket costs such as co-pays (i.e., a fixed amount of money a patient must pay in exchange for their medication). In some cases, individuals on the same health insurance plan may pay different prices for the same drug depending on variables such as what pharmacy they choose to fill their prescription with. Pharmaceutical manufacturers have recently started offering coupons and rebates to lower the out-of-pocket costs for consumers; however, the amounts of rebates are often kept hidden from consumers, and rebates are not always passed onto consumers. In some cases, the amount an individual has to pay for a prescription drug can be higher when using their insurance than when buying the medication without using insurance. This may be due to the fact that the pharmacy has negotiated a better retail price for the medication than the individual’s health insurance plan, or the result of the pharmacy using a manufacturer rebate to be reimbursed a portion of the prescription cost. Coupons and rebates ultimately do little to offset or lower the actual cost of drugs in America; they do however help lower the impact felt at the counter when a patient goes to pick up their medication from a pharmacy. In the US, drug prescribing and dispensing are highly regulated, sometimes
leaving customers with few options for medication selection, alternatives, and price. In cases where there are multiple products for the same drug, (e.g., generics or therapeutic equivalents), there are times when a pharmacy cannot substitute a cheaper alternative for a more expensive one. One factor is whether the prescribing doctor writes a prescription allowing a generic alternative (e.g., today a doctor who writes a prescription for an “EpiPen” (brand name), as opposed to an “Epinephrine auto-injector” (generic alternative) will result in a patient receiving the brand name product. Another factor is whether a patient’s pharmacy coverage (or lack thereof) includes particular drugs on their formulary (a list of drugs, their prices, and conditions related to whether certain drugs can or cannot be substituted for others). In some cases, another drug may be available on the market, but an individual’s insurance does not cover it. Ultimately the ability to know the true cost of a medication is systematically unavailable and necessarily complicated. Because Americans have little-to-no price transparency, thus limited options to shop by price, drug prices in the US remain disproportionately higher than anywhere else in the world. In fact, Americans on average pay 2-6 times more for prescription drugs than the rest of the world (International Federation of Health Plans).
<table>
<thead>
<tr>
<th>Date</th>
<th>List of Historically Relevant Events</th>
<th>Price of EpiPen*</th>
</tr>
</thead>
</table>
| 1903  | • Japanese biochemist Jokichi Takamine is granted US patent for the development of synthetic epinephrine  
      • Takamine licenses his patent to Parke-Davis (a pharmaceutical firm) for epinephrine manufacturing. Epinephrine is only available for emergency medical use in hospitals and by medical professionals |                 |
<p>| 1971  | • Hollister-Stier Laboratories releases Ana-kit as a bee-sting kit for consumer use. Ana-kit includes a single dose of epinephrine in a pre-filled syringe                                                                                       |                 |
| 1973-1977 | • Pentagon contracts Survival Technologies to develop a “hypodermic injection device” for soldiers to quickly self-administer nerve agent antidotes in battle                                                                               |                 |
| 1983  | • Scientists at Meridian Medical extend injection device technology to applications in the consumer market, patent epinephrine auto-injector device                                                                                       |                 |</p>
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<tr>
<th>Year</th>
<th>Event</th>
<th>Price Notes</th>
</tr>
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</table>
| 1987 | • FDA approves Meridian Medical epinephrine auto-injector device for commercial use  
• EpiPen first released to the market | $35 ($99 today, adjusted for inflation) |
| 2007 | • Mylan purchases rights to EpiPen marketing and distribution through acquisition of Merck Generics (MGKB) for $6.6B | $100 (wholesale) |
| 2009 | • Mylan applies for EpiPen patent protection extension by modifying/adding a bright orange cap (added as a “safety feature”) to EpiPen design, and updating the instructions on the label. | |
| 2011 | • Mylan began selling EpiPens exclusively in two-packs. Mylan also reduced the expiration period for its EpiPens from two years to one year, requiring customers to purchase them twice as frequently | $163 |
| 2012 | • Mylan launches EpiPens4Schools initiative. Partners with the National Association of State Boards of Education (NASBE) to promote adoption of state and federal laws encouraging or requiring schools nationwide to keep a stock of EpiPen devices nationwide  
• Teva Pharmaceuticals and Mylan report reaching “confidential agreement” which includes a decision for Teva to delay the release of its epinephrine auto-injector alternative device until 2015 | $219 (July) |
| 2013 | • Mylan successfully lobbies 10 states to pass legislation requiring EpiPens be stocked in hotels, restaurants, and other public locations  
• (November) H.R. 2094 – School Access to Emergency Epinephrine Act – passed as federal law | $265 (July) |
<table>
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<tr>
<th>Year</th>
<th>Events</th>
</tr>
</thead>
</table>
| 2014 | • First media report(s) about rising cost of EpiPens appear in online, fringe media outlets  
  • The rising price of EpiPens led several local fire departments in Washington and Kentucky to re-train EMTs to administer epinephrine via syringe. Some departments created kits that mirrored Ana-kits |
|      | $350 (May)  
  $380 (Sept) |
| 2015 | • Mylan introduces lawsuit to prevent generic (Teva) from being approved by the FDA  
  • Mylan uses FDA review process to file a “citizen petition” citing safety concerns, discourages FDA approval of Teva device  
  • FDA rejects Mylan’s citizen petition, but ultimately rejects Teva application for commercial use  
  • (August) American doctor (sponsored by Mylan) publishes article in the American Journal of Medicine advocating for the EpiPen to be added to the federal preventative drug list  
  • (October) Mylan claims it performed post-market tests on EpiPens to ensure “quality standards.” The company suggests these Research and Development (R&D) efforts contribute to rising device costs  
  • Minor market epinephrine auto-injector competitor (Avi-Q) institutes complete recall of all products, reducing market competition  
  • (November) Consumer advocacy groups and doctors (compensated by Mylan) advocate for EpiPen to be added to Affordable Care Act federal preventative drug list |
|      | $461 (May) |
2016

- *Business Insider* published one of the first mainstream articles on EpiPen pricing titled “EpiPens have become so expensive some people are using riskier DIY alternatives”
- Medical professionals (allergists and EMTs) begin returning to lower-cost alternatives including the use of syringe and vial delivery. Some create their own do-it-yourself alternatives

----- RUPTURE POINT -----

- (August) VT Senator Bernie Sanders posts “There’s no reason an EpiPen, which costs Mylan just a few dollars to make should cost families more than $600” on social media
- MT Senator Amy Klobuchar calls for Federal Trade Commission and Senate Judiciary Committee to investigate EpiPen prices
- Mylan Specialty spokesperson resigns, pens open letter criticizing Mylan for EpiPen prices
- US House Committee on Energy and Commerce send FDA Commissioner official letter of inquiry related to the lack of epinephrine auto-injector generic alternatives on the market
- Dr. Ryan Neuhofel (licensed allergist) releases instructions on how to build a DIY epinephrine auto-injector
- (September) FARE (Food Allergy & Research Education) consumer advocacy group responds to risks of “DIY” EpiPen alternatives
- Four Thieves Vinegar biohacker collective releases DIY “Epipencil” (including open-source instructions, how-to video on YouTube, and manifesto) for $35
- MIT Technology Review is the first to report on Epipencil
- Philippines-based biohacker group ProgressTH respond to Epipencil release, announces plans to release instructions and specs for 3D printing Epipencil parts to lower cost of device to $3 USD
- Other DIY “hacks” appear online with various at-home epinephrine auto-injector solutions
<table>
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<th>Year</th>
<th>Event</th>
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<tr>
<td>2017</td>
<td><em>Silicon Valley engineers deconstruct EpiPen, suggest cost to manufacture is less than $10</em>&lt;br&gt;<em>FDA and Mylan testify to US House Committee on Oversight &amp; Government Reform for questions related to EpiPen pricing</em>&lt;br&gt;<em>FDA warns public against using Epipencil</em>&lt;br&gt;<em>(October) Four Thieves Vinegar releases Epipencil “Update and FAQ” video on YouTube</em>&lt;br&gt;<em>DIY hacker “Treat Outside the Box” releases instructions for DIY epinephrine auto-injector on YouTube</em>&lt;br&gt;<em>(December) Mylan releases its own generic EpiPen alternative</em>&lt;br&gt;<em>Mylan offers manufacturers coupon to lower out-of-pocket costs</em></td>
</tr>
<tr>
<td></td>
<td><strong>$340 EpiPen Generic, $650 otherwise</strong></td>
</tr>
<tr>
<td>2018</td>
<td><em>(January) CVS, largest retail pharmacy network in US, announces it is offering authorized generic of alternative epinephrine auto-injector Adrenaclick to patients ($110)</em>&lt;br&gt;<em>(December) Four Thieves Vinegar Epipencil video removed from YouTube for violating community guidelines (“content that encourages or promotes violent or dangerous acts that have inherent risk of serious physical harm or death”)</em></td>
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<tr>
<td>2025</td>
<td><em>Mylan patent protection for EpiPen expires</em></td>
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2017:
- Silicon Valley engineers deconstruct EpiPen, suggest cost to manufacture is less than $10
- FDA and Mylan testify to US House Committee on Oversight & Government Reform for questions related to EpiPen pricing
- FDA warns public against using Epipencil
- (October) Four Thieves Vinegar releases Epipencil “Update and FAQ” video on YouTube
- DIY hacker “Treat Outside the Box” releases instructions for DIY epinephrine auto-injector on YouTube
- (December) Mylan releases its own generic EpiPen alternative
- Mylan offers manufacturers coupon to lower out-of-pocket costs

2018:
- (January) CVS, largest retail pharmacy network in US, announces it is offering authorized generic of alternative epinephrine auto-injector Adrenaclick to patients ($110)
- (December) Four Thieves Vinegar Epipencil video removed from YouTube for violating community guidelines (“content that encourages or promotes violent or dangerous acts that have inherent risk of serious physical harm or death”)

2025:
- Mylan patent protection for EpiPen expires