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ABSTRACT

The emergence of new product categories within stigmatized industries poses a theoretical puzzle. Unlike in the case of mainstream industries where new product categories draw on schemas of existing products to gain acceptance and legitimacy from social groups, drawing on the schemas of existing stigmatized products can lead to stigma transfer and compound legitimacy problems. This observation forms the motivation behind my research question: *How do new product categories emerge within stigmatized industries?* To address this question, I studied the emergence of electronic cigarettes (e-cigarettes) as a new product category in the stigmatized US tobacco cigarette industry. Using a microhistory case study design, and guided by a technology entrepreneurship inquiry frame, I examined the actions of various social groups over critical events that have shaped the category’s emergence. I also considered the role of materiality by examining the material-discursive possibilities that emerged as social groups interacted with one another and with the product’s materiality.

My findings show that emergence of new product categories in stigmatized industries is a contested process implicating the participation of multiple social groups who constituted different possibilities for the category based on their own frames of reference. By qualifying the category using their own evaluative considerations, social groups engaged in categorical work, which led to either sanitization or stigmatization of the emerging product category. More provocatively, I found that entrepreneurial initiatives to sanitize the product in turn activated forces that re-stigmatized. Overall the new product category emerged through a dialectical tension between *forces of sanitization* and *forces of stigmatization*. The findings from this study contributes to the existing literature on categories, stigmatized industries and technology entrepreneurship. Speaking to the categories literature, this study surfaces a dialectical model of
new category emergence in a stigmatized industry setting. To the literature on stigmatized industries, this study offers a material-discursive perspective to reveal the contested nature of destigmatization initiatives. The study also contributes to the technology entrepreneurship literature by highlighting not only the distributed nature of entrepreneurship, but also surfacing temporal issues, such as the dynamic shifts that can occur in the meaning and scope of opportunities over time.
# TABLE OF CONTENTS

List of Tables .................................................................................................................. vi  
List of Figures ................................................................................................................... vii  
Acknowledgements ........................................................................................................ viii  

Chapter 1. INTRODUCTION .......................................................................................... 1  
Contributions ................................................................................................................ 4  

Chapter 2. LITERATURE REVIEW .............................................................................. 7  
Categories ....................................................................................................................... 7  
Stigmatized Industries .................................................................................................... 12  
Research Question ......................................................................................................... 16  
Inquiry Frame ................................................................................................................ 17  

Chapter 3. RESEARCH SETTING, DESIGN, AND METHODS .................................. 24  
Research Setting ............................................................................................................. 24  
E-cigarette Market in the US ........................................................................................... 26  
Research Design ............................................................................................................ 29  
Research Methods ........................................................................................................ 30  
Data collection ................................................................................................................ 30  
Data analysis .................................................................................................................. 32  

Chapter 4. FINDINGS ................................................................................................. 35  
First Order Findings: Material-Discursive Possibilities .................................................. 35  
First Order Findings: Descriptive Case Narrative ............................................................ 39  
Second Order Findings: Categorical Work ..................................................................... 65  
Categorical work of sanitization ..................................................................................... 66  
Categorical work of stigmatization ............................................................................... 71  
Second Order Findings: Analytical Summary of Emergence Process ............................ 78  

Chapter 5. DISCUSSION .............................................................................................. 82  
Process Model of New Product Category Emergence in Stigmatized Industries ............ 85  
Contributions ................................................................................................................ 88  
Contribution to the literature on categories ................................................................... 88  
Contribution to the literature on stigmatized industries ............................................... 90  
Contribution to the literature on technology entrepreneurship ..................................... 92  
Conclusion ..................................................................................................................... 94  
Limitations ................................................................................................................... 95  
Future research .............................................................................................................. 96  

References ..................................................................................................................... 98  
Appendix A: TABLES .................................................................................................. 114  
Appendix B: FIGURES .................................................................................................. 123
LIST OF TABLES

Table 1: Data Sources ............................................................................................................. 114
Table 2: Social Group’s Category Labels and Discursive Possibilities ................................. 115
Table 3: Discursive Possibilities Provided by Constituent Material Elements ....................... 116
Table 4: Data Structure: Categorical Work of Sanitization .................................................... 117
Table 5: Data Structure: Categorical Work of Stigmatization ............................................... 119
Table 6: Chronology of Events and Critical Events ............................................................... 121
LIST OF FIGURES

Figure 1: Technology Entrepreneurship Inquiry Frame .................................................................123
Figure 2: “Smokeless non-tobacco cigarette” Invented by Herbert A. Gilbert ..........................124
Figure 3: “Electronic atomization cigarette” Invented by Hon Lik .............................................124
Figure 4: ‘Cig-a-like’ E-cigarette Sold by NJOY ........................................................................125
Figure 5: Open System E-cigarettes ............................................................................................125
Figure 6: E-cigarette Product Category Sales (in million USD) .....................................................126
Figure 7: Adult Per Capita Cigarette Consumption and Smoking Prevalence in the US ..........127
Figure 8: Relative Risk Profile of E-cigarettes ..............................................................................128
Figure 9: Texts and Images from Smoking Everywhere’s Promotions ........................................129
Figure 10: Texts and Images from Sottera Inc.’s Promotions ......................................................129
Figure 11: Advertising Themes from Lorillard’s Promotions of BLU E-cigarettes ....................130
Figure 12: General Model of New Product Category Emergence in Stigmatized Industries ......131
Figure 13: Dynamics of New Product Category Emergence in the Case Study .........................132
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CHAPTER 1

INTRODUCTION

How do new product categories emerge within stigmatized industries? This is a question of great significance which has relevance going beyond the context of traditionally stigmatized industries such as tobacco, arms and ammunition, gambling, and nuclear energy (e.g., Durand & Vergne, 2015; Galvin, Ventresca, & Hudson, 2004; Garud, Gehman, & Karnøe, 2010; Hudson, 2008; Vergne, 2012). Indeed, many industries such as the beverage industry, the genetically modified food industry, and the fossil fuel industry among others, are also facing stigmatization on account of the potential negative consequences of their products on human health (e.g., Brownell & Frieden, 2009; Landrigan & Benbrook, 2015; Malik et al., 2010) and the environment (e.g., Davis, Caldeira, & Matthews, 2010; IPCC, 2014). Such stigmatization of an industry, while being problematic at one level, presents opportunities for the creation of new products that address the stigma attached to the focal product, at another level. For example, the beverage industry has introduced products using ‘low-calorie’ sweeteners, and the fossil fuel industry has made forays into ‘natural gas’ extraction. Seen in this context, the tobacco cigarette industry—the research site for this study—has also witnessed the emergence of electronic cigarettes (e-cigarettes) as a less harmful alternative to traditional combustible cigarettes (e.g., Cahn & Siegel, 2011; Farsalinos & Polosa, 2014; McNeill et al., 2015). These developments call for investigations into the emergence of new product categories in stigmatized industries, a relatively underexplored topic in the management discipline.

Taking up this study on how new product categories emerge within stigmatized industries has enabled me to build upon the existing literature on categories and stigma. While the existing categories literature offered a wealth of insights into category properties, and the effects of
categorization (please see Vergne & Wry, 2014 for a review), research on stigmatized industries shed light on how organizations in these industries deal with stigmatization (e.g., Durand & Vergne, 2015; Hampel & Tracey, 2016; Helms & Patterson, 2014; Hudson & Okhuysen, 2009; Vergne, 2012). What was missing, however, was an account of how new product categories emerged in response to the stigma attached to an industry’s focal product, which is the focus of this study. Departing from mainstream conceptualization of categories, the findings from this study on the emergence of e-cigarettes in the US tobacco cigarette industry, showed that new product categories did not necessarily converge and stabilize around a dominant meaning (Grodal, Gotsopoulos, & Suarez, 2015). Category meanings instead, are always characterized by equivocality and contestation. The study also revealed that while stigmatization of an industry provided social groups with opportunities to materialize a sanitized substitute product, such initiatives also invited a backlash from opposing social groups who engaged in initiatives to stigmatize the new product. These findings both build upon and depart from prior conceptualizations of categories, and also shed light on the entrepreneurial dynamics within stigmatized industries.

Product categories have been conceptualized as schemas that define and classify goods that are exchanged as “experientially similar products” (Lounsbury & Rao, 2004: 970) They are socially constructed (Berger & Luckmann, 1966) through interactions between producers, consumers, regulators, and other social groups (e.g., Bijker, Hughes, & Pinch, 1987; Garud & Rappa, 1994; Kennedy, 2008; Rosa, Porac, Runser-Spanjol, & Saxon, 1999), with scholars highlighting the closure or settlement of product category meanings in these interactions (e.g., Grodal et al., 2015; Kaplan & Tripsas, 2008; Suarez, Grodal, & Gotsopoulos, 2015). Once product category meanings are stabilized, they confer legitimacy to offerings that conform to
existing conceptual systems, while sanctioning others that do not (please see Hsu, 2006; Zuckerman, 1999 for arguments on categorical discount). As a consequence, new products that do not fit neatly into existing product categories must form new category spaces that define and create value for their offerings (Santos & Eisenhardt, 2009), which they do by drawing on schemas and the understanding of existing products in order to secure both cognitive and sociopolitical legitimacy (e.g., Aldrich & Fiol, 1994; Hargadon & Douglas, 2001; Suchman, 1995). Thus, extant notions of category emergence emphasize that new product categories must not only convey their distinctiveness, but must also establish their relationship to pre-existing categories (e.g., Grodal et al., 2015; Jones, Maoret, Massa, & Svejenova, 2012; Khaire & Wadhwani, 2010; Navis & Glynn, 2010; Rosa et al., 1999).

However, such conceptualization of category emergence when extended to new product categories in stigmatized industries poses a theoretical puzzle. While new products in such industries must build on the schemas of existing stigmatized products to be recognized and appeal to existing users, such associations can also become problematic, as audiences may continue associating prior delegitimized symbols with the new product offering, thereby transferring stigma (Hudson & Okhuysen, 2009). Thus, new product categories in stigmatized industries will also need to dissociate from the existing stigmatized products to scrub away the stigma transferred. These observations provide the theoretical basis for my research question: *How do new product categories emerge within stigmatized industries?*

To answer this question, I conducted a historical case study analysis using microhistory methods (e.g., Bijker et al., 1987; Garud & Rappa, 1994; Hargadon, 2016; Hargadon & Douglas, 2001) to examine the emergence of e-cigarettes as a new product category in the stigmatized US tobacco cigarette industry. I gathered longitudinal timestamped archival data from multiple
sources, and supplemented this with additional data gathered from participant observations at conferences and semi-structured interviews. To analyze the data, I employed both grounded theory (Glaser & Straus, 1967) and qualitative process methodology (Langley, 1999). As previewed earlier, my analysis of the data showed that new product category emergence in stigmatized industries is a contested process, whereby social groups attribute different meanings to the category based on their own frames of reference (Bijker et al., 1987). Such category meanings were not just descriptive, but also took on evaluative connotations leading to the categorical work (Bowker & Star, 1999) of sanitization and stigmatization. Overall, efforts to sanitize the new product category generated countervailing initiatives to stigmatize, and it was through such a dialectical process (Van de Ven & Poole, 1995) involving forces of sanitization and forces of stigmatization that the new product category emerged.

**Contributions**

The study’s findings make the following contributions: First, the findings show that new product category emergence within stigmatized industries is a contested process characterized by temporary settlements laying the ground for renewed contestations. Hence, the study’s findings problematize the existing accounts of category emergence in which category meanings converge and stabilize around a dominant meaning (e.g., Grodal et al., 2015; Kaplan & Tripsas, 2008; Suarez et al., 2015). In the case of e-cigarettes, there was no convergence towards one meaning, as “interpretive asymmetry” (Garud & Karnøe, 2003: 280) around the product category’s meaning continued to prevail amongst the interacting social groups. Second, the findings from this study suggest a departure from an essentialist conception of matter to a material-discursive perspective (Barad, 2003). It is not only what matters, but how it matters and to whom. Thus, the same product category was neither completely stigmatized nor sanitized, as social groups
engaged in categorical work of sanitization and stigmatization to qualify the category with
evaluative properties (Bowker & Star, 1999) based on their own frames of reference (Bijker et
al., 1987). It was in this dialectical tension (Van de Ven & Poole, 1995) between opposing social
groups engaged in sanitization and stigmatization activities that the category emerged. Third, this
study offers a symmetrical treatment of both the material and social (Callon, 1986; Latour, 1987,
2005), as materiality providing the discursive possibilities for different social groups was critical
to the product category’s emergence.

These findings also contribute to the ongoing conversations in the management literature
on categories, stigmatized industries and technology entrepreneurship. This study contributes to
the developing stream of research on category emergence (e.g., Granqvist & Ritvala, 2016; Jones
et al., 2012; Navis & Glynn, 2010) by revealing a dialectical process model of new product
category emergence. By highlighting the contested nature of sanitization initiatives in core-
stigmatized settings and the role of materiality in such initiatives, the findings from this study
contribute to the literature on stigmatized industries examining destigmatization processes
(Hampel & Tracey, 2016). The study also contributes to the technology entrepreneurship
literature (Beckman, Eisenhardt, Kotha, Meyer, & Rajagopalan, 2012; Garud & Karnøe, 2003;
Shane & Venkataraman, 2003) by highlighting the distributed nature of entrepreneurship as well
as its inter-temporal nature. Inter-temporality was evident not only on account of prior
stigmatized associations generating a backlash, but also on account of diachrony i.e., the opening
and closing of opportunity spaces over time through the outcomes of the contestations that
ensued.

To sum up, as sustainability considerations related to human health and the environment
become increasingly important, many industries are getting stigmatized. The fossil fuel industry
continues to evoke concerns related to global warming and climate change due to the release of greenhouse gases (Davis et al., 2010; IPCC, 2014), and the beverage industry is being stigmatized due to the potential negative health effects of sugared drinks (Brownell & Frieden, 2009; Malik et al., 2010). These dynamics raise questions about the possibilities that lie ahead for such industries facing stigmatization. Through the findings of this study, I show that stigmatization of an industry is not necessarily a source of constraint, but that it presents opportunities for entrepreneurial action to create new product offerings that address the stigma. This process of new product category emergence has been understudied in a stigmatized industry setting, which is a topic this study contributes to.

The rest of this dissertation, after this introductory chapter, is organized as follows: In chapter 2, I review the existing management literature on categories and stigmatized industries to formulate and situate my research question in the conversations therein. I also develop my inquiry frame using technology entrepreneurship to investigate my research question. In chapter 3, I discuss the research setting, design, and the data collection and analysis methods that I used. Chapter 4 presents the findings from this study. In chapter 5, I discuss the theoretical significance of my findings, and the contributions of these findings to the relevant literature streams examining categories, stigmatized industries and technology entrepreneurship. I close by discussing the limitations of this study and proposing the direction of my future research.
CHAPTER 2
LITERATURE REVIEW

I begin this chapter by reviewing the existing management literature on categories and stigmatized industries. An integration of this literature leads to the research question: *How do new product categories emerge within stigmatized industries?* I then draw on technology entrepreneurship literature to develop an inquiry frame to investigate this research question.

**Categories**

I begin this section by problematizing the conception of categories as configurations with essential stable properties. Next, I review recent perspectives that have critiqued this conception of categories, highlighting instead their dynamic nature (Durand & Paolella, 2013; Garud et al., 2010; Glynn & Navis, 2013). I conclude that categories are dynamic conceptual schemas driven by the interests and goals of multiple social groups (Bijker et al., 1987; Durand & Paolella, 2013; Garud & Rappa, 1994) in interaction with each other, and the underlying material elements (Garud et al., 2010). I close this section by highlighting how such a dynamic perspective of categories can add to existing conversations on category formation (Durand & Khaire, 2017), which is the focus of this study.

Categories are conceptual systems that enable us to order and make sense of our everyday lives (Bowker & Star, 1999; Douglas, 1986). For the most part, categories have been conceptualized as comprising certain essential properties, with items that display prototypical properties belonging to a particular category (Durand & Paolella, 2013; Rosch & Mervis, 1975). For example, the category ‘chair’ defined as a “separate seat for one person, typically with a back and four legs” (Source: Oxford Dictionaries) in accordance with the artifact’s commonly understood form and function, is an example of such categorization. However, such an
essentialist description of categories misses the point that categorization is also a social process based on the inputs of multiple social groups including producers, consumers, regulators, media etc. (e.g., Bijker et al., 1987; Garud & Rappa, 1994; Porac, Thomas, & Baden-Fuller, 1989; Rosa et al., 1999).

Although scholars have acknowledged the role of various social groups in the categorization process, they have focused their attention on studying category properties and features that have stabilized over time, and have then begun to define category membership (e.g., Carroll & Swaminathan, 2000; Dobrev, Ozdemir, & Teo, 2006; Hannan, Pólos, & Carroll, 2007; Hsu, 2006; Hsu, Hannan, & Koçak, 2009; Zuckerman, 1999). A key premise of such investigations is that once social groups arrive at a consensus about certain ‘essential’ category features, they penalize category members and their products that are less ‘pure’. A stream of empirical work has examined this disciplining force of category membership that requires members to conform to existing category prototypes. For example, firms that straddle multiple product categories are ignored by analysts leading to discounted valuations (Zuckerman, 1999), contract brewers that deviate from authentic craft-style production experience increasing mortality (Carroll & Swaminathan, 2000), and films that target multiple genres are less appealing to both critics and consumers (Hsu, 2006).

Recent studies have begun to loosen such a constraining conception of categories by highlighting the fuzziness and leniency of category membership (Pontikes, 2012; Pontikes & Barnett, 2015). Challenging the extant notions that categories should have well-defined properties, scholars have drawn attention to contexts characterized by ambiguity around the category’s meaning. For example, the US software industry is characterized by many ambiguous market categories (Pontikes & Barnett, 2015), which also appeal to social groups such as venture
capitalists prizing innovation and novelty (Pontikes, 2012). Going against the dominant wisdom that membership in multiple categories leads to audience penalties, scholars have also highlighted contexts such as ‘corporate legal services’ where a firm’s membership in multiple law practice categories gets rewarded, as a sign of its ability to handle complex cases (Paolella & Durand, 2016). Indeed, straddling categories could also lead to positive outcomes through creative recombination (Glynn & Navis, 2013). For example, companies engaged in the production of hybrid movies increased their chances of major box office hits (Hsu, Negro, & Perretti, 2012), science-based startups that mixed ‘science’ and ‘technology’ patents were more likely to attract greater venture capital funding (Wry, Lounsbury, & Jennings, 2014), and organizations that combined categories of ‘industry’ and ‘art’ engaged in design innovation (Dalpiaz, Rindova, & Ravasi, 2016). Not limited to recombination of existing category features, category members can also import new features or reinterpret existing category features to formulate new product offerings (e.g., Delmestri & Greenwood, 2016; Negro, Hannan, & Rao, 2011; Rao, Monin, & Durand, 2003; Rao, Monin, & Durand, 2005).

Such a dynamic view of categories informs the nascent stream of research examining the process of new product category formation—the focus of this study (e.g., Granqvist & Ritvala, 2016; Jones et al., 2012; Kennedy, 2008; Khaire & Wadhwani, 2010). Here too, new product categories are not self-evident resemblances with some existing prototype, but shaped by the actions of actors guided by their own goals and interests (Durand & Paolella, 2013). These actors engage in discursive framing tactics such as drawing on schemas of familiar products to legitimize the new product category amongst important audiences such as regulators, critics, and consumers (Hargadon & Douglas, 2001). For example, satellite radio companies in the US situated their new product in relation to existing products such as terrestrial radio and satellite
television (Navis & Glynn, 2010), and auction houses positioned modern Indian art within the existing discourse of Western modernism (Khaire & Wadhwani, 2010).

These discursive framing tactics are also inextricably bound in materiality, with product category descriptions such as labels co-evolving with the technology (Grodal et al., 2015). For example, product category labels such as ‘eBook’ and ‘cloud computing’ not only describe underlying changes in the technology, but also constitute new technology pathways (Grodal et al., 2015). Similarly, the product categories of ‘modern organic’ and ‘modern functional’ architecture have spawned the widespread use of new technological artifacts (such as concrete, steel and glass) within the practice of architecture (Jones et al., 2012). Thus, product categories are formed among the underlying social and material elements that comprise the discourses of producers and other social groups interacting with material technology (Garud et al., 2010).

New product category formation is hence a distributed process involving multiple social groups interacting with the product’s materiality and making sense of the product in different ways. In these interactions, the product’s materiality may also be decomposed into different parts, as social groups focus on different aspects of the underlying materiality to affix different meanings to the category. While the proponents of nuclear energy focused on the material properties that made the technology a potential source of ‘emission-free’ energy, those opposed to it focused on properties related to ‘wartime destruction’ and ‘catastrophic accidents’ (Garud et al., 2010). However, such differences in product category meanings may not necessarily be characterized by closure and convergence towards a dominant meaning (Grodal et al., 2015; Pinch & Bijker, 1987), but could also be subject to ongoing contestations. For example, modernist winemakers continued to face opposition from traditional winemakers, leading to “competing views on authenticity based on different interpretations of categorical schemas” in
the Italian wine industry (Negro et al., 2011: 1460). Such ongoing contestations are also evidenced in the different meanings social groups ascribe to the product categories of ‘foie gras’ (DeSoucey, 2016), ‘GM’ food (Lucht, 2015), and ‘bitcoin’ (Vergne & Swain, 2017) among others. In summary, I conceive product categories to be “materially anchored, institutionally performed, socially relevant, and entrepreneurially negotiated” (Garud et al., 2010) with category meanings being “continually made and refreshed” (Bowker & Star, 1999: 285) in and through these material-discursive interactions (Barad, 2003) in a performative way (Garud et al., 2010; Garud, Gehman, & Tharchen, 2017b).

Reviewing the management literature on category formation processes, Durand and Khaire (2017) distinguished between category creation and category emergence. Category creation takes place when “existing components in a market are rearranged, reinterpreted, and relabeled to generate new meanings and associations” (Durand & Khaire, 2017: 95). Category emergence, on the other hand, takes place through “components and features exogenous to the main categorical system…founded on new, hard-to-classify…attributes of a good” (Durand & Khaire, 2017: 93). While category creation is driven by the efforts of incumbent producers who use discourses to reframe pre-existing offerings, category emergence is driven by the actions of new producers importing “new attributes not part of the current category system” and then theorizing their offerings through new discourses (Durand & Khaire, 2017: 94).

The present study concerns the innovation of electronic cigarettes (e-cigarettes) involving material additions (in the form of flavors and batteries) and subtractions (such as smoke and tar) from traditional cigarettes. Entrepreneurs (and intrapreneurs) have also theorized the category as an alternative to traditional combustible cigarettes. Following Durand & Khaire (2017), e-cigarettes represent a case of new product category emergence, albeit in a stigmatized industry
setting. New product categories in such a context need to not only gain legitimacy and acceptance by social groups as demonstrated in mainstream industry settings (e.g., Hargadon & Douglas, 2001; Kennedy, 2008; Navis & Glynn, 2010), but they also need to address stigma which further compounds their legitimacy challenges. Hence, this is a theoretically interesting context to investigate, as the literature has not yet addressed the emergence of new product categories in response to stigmatization of an industry’s focal product (i.e. tobacco cigarettes in the context of this study). Following this review of the categories literature which situates my study in the conversations therein, I review the literature on stigmatized industries, which serve as the context for my study.

Stigmatized Industries

I begin this section by reviewing the concept of stigma. I then conceptualize stigma as originating from boundary maintenance processes and introduce the topic of stigmatized industries. Next, I review related literature that examines how organizations in such industries deal with stigmatization. Finally, I integrate the reviewed literature on categories and stigmatized industries to revisit and reformulate my research question on new product category emergence within such industries.

Stigma has been conceptualized as a “socially constructed mark that taints and discredits the bearer—particular individuals or groups—within certain sections of society” (Hampel & Tracey, 2016: 5). Being a social construction, stigma is an outcome of the interactions between individuals and groups that are “the target of stigmatization and the audience of perceivers that produce the stigmatization” (Paetzold, Dipboye, & Elsbach, 2008: 186) due to their “conflicting values, ideologies and belief systems” (Hudson, 2008: 254). At the individual level, such differences—which play out because of differences in physical attributes, character or identity—
when viewed negatively by audiences, subject an individual or group to stigmatization (Goffman, 1963). For example, individuals and groups with physical disability, mental illness, drug addiction, and non-heterosexual orientations confront stigmatization from mainstream audiences (Goffman, 1963).

Extended to organizations, stigmatized organizations are “negatively evaluated category of organizations collectively perceived by a specific stakeholder group as having values that are expressly counter to its own” (Devers, Dewett, Mishina, & Belsito, 2009: 157). Thus, in contrast to organizations lacking legitimacy (e.g. newly formed organizations) due to a paucity of recognizable features deemed normatively appropriate (e.g., resources, standardization and certification of practices etc.), stigmatized organizations have features that are “deeply flawed and discredited” in the collective perception (Devers et al., 2009: 155). Stigmatized organizations hence, arise from “negative social evaluation” that “casts the firm specifically as what that group ‘is not’, which leads stakeholders to ‘disidentify’ with the organization … and to actively impose harmful social and economic sanctions on it” (Devers et al., 2009: 157) (emphasis added).

The socially constructed nature of stigma, and its powers of exclusion (Devers et al., 2009; Douglas, 1966; Goffman, 1963), point to stigma as a boundary maintenance process. In her book *Purity and Danger*, Douglas (1966: 208) observed that nothing is inherently dirty except “from a particular system of classification in which it does not fit”. Dirt, she argues, is taboo because it “offends against order”, and hence, its separation is “not a negative movement, but a positive effort to organize the environment” just like the use of any other classification system:

“…ideas about separating, purifying, demarcating and punishing transgressions have as their main function to impose system on an inherently untidy experience.
It is only by exaggerating the difference between within and without, about and below, male and female, with and against, that a semblance of order is created.”
(Douglas, 1966: 4-6)

What is dirty is hence subject to continuous monitoring and sanction, and over time the dirty gets infused with “moral overtones” and becomes stigmatized (Ashforth & Kreiner, 1999: 416).

Douglas’s ideas related to purity and dirt can also be extended to understand why certain industries have become stigmatized. Industries such as tobacco, arms and ammunition, gambling, etc. are engaged in activities considered “incompatible with ordinary standards of organizational accounts” and hence are morally reprehensible (Elsbach & Sutton, 1992; Hudson, 2008: 254). Thus, in contrast to stigmatization on account of some negative organizational events (such as product defects, accidents, bankruptcies), stigmatized industries are characterized by organizations in which permanent blame “concerns the core of the business” (Durand & Vergne, 2015: 1208). Such industries are thus subject to social sanction characterized by “social contestation, hostile audiences, and distancing between industry insiders and outsiders” (Durand & Vergne, 2015: 1205). Besides the traditionally stigmatized industries mentioned above, many industries such as the beverage industry, nuclear energy, fossil fuel industry, genetically modified (GM) food industry among others are also facing stigmatization around considerations related to human health and environmental safety.

Despite such opposition from social groups, stigmatized industries continue to persist and scholars have investigated the various strategies they have adopted in the face of social sanction. In their study, Hudson and Okhuysen (2009) found men’s bathhouses engaged in shielding strategies such as locating their business in deserted neighborhoods and using discreet signage to avoid contact with stigmatizing audiences. Arms and ammunition producers not only diversified in non-stigmatized businesses to lessen their social disapproval (Vergne, 2012), but were also
prone to divesting their assets in the stigmatized industry when faced with media attacks (Durand & Vergne, 2015).

Moving beyond such defensive tactics, recent studies have also shown how organizations in stigmatized industries can lessen the negative evaluations of audiences, and even completely destigmatize their product offerings and activities. Helms and Patterson (2014) found that mixed martial arts organizations engaged in “rulemaking” to reduce negative perceptions of lawlessness and danger, while at the same time also actively promoting their sport. In yet another study, Hampel and Tracey (2016) documented how Thomas Cook’s travel agency successfully eradicated the stigma associated with the tourism business in Victorian Britain by highlighting tourism’s positive contributions to society, and allying with stigmatizing groups through ingratiation tactics. Over time audience perception of Thomas Cook changed from an organization offering “immoral services” to being seen “as a force for good” (Hampel & Tracey, 2016: 37). These findings reiterate that stigma resides “in the eye of the beholder” (Hudson, 2008: 254), and point to the dynamic nature of stigma based on the changing configuration of audiences.

Stigmatized industries also present opportunities for the introduction of new products and practices that address the stigma. For example, the nuclear industry has been adopting better practices and standards of safety (Garud et al., 2010), and the beverage industry has been innovating to address the health concerns posed by sugared drinks and artificial sweeteners, and has introduced new products with natural sweeteners (Source: www.pepsicobeveragefacts.com). These observations suggest that stigmatized industries present opportunities for organizations to address the stigma and move towards social acceptance. Stigmatized industries thus, present an interesting context to examine the dynamics related to the emergence of new product categories.
to scrub away the stigma associated with the focal product, a topic which has been relatively understudied in the management discipline. Next, I combine the reviewed literature on categories and stigmatized industries to formulate and elaborate on my research question.

**Research Question**

The literature on categories and stigmatized industries, when combined, presents opportunities for productive investigations into the emergence of *new product categories within stigmatized industries*—a theoretically underexplored topic.

As reviewed earlier, the categories literature has highlighted how new product categories must build on the familiar schemas and scripts of existing products to gain the legitimacy of important social groups (e.g., Jones et al., 2012; Khaire & Wadhwani, 2010; Navis & Glynn, 2010). The prevailing wisdom is that successful innovation must achieve the delicate balance of neither distinguishing itself too much nor appearing too familiar against existing understanding (Hargadon & Douglas, 2001). In the context of stigmatized industries too, new product categories need to draw on familiar stigmatized products for cognitive legitimacy and comprehensibility (Aldrich & Fiol, 1994; Suchman, 1995). However, in doing so, they might become stigmatized through the stigma transferred (Hudson & Okhuysen, 2009) from associating with the focal stigmatized product.

Paradoxically though, it might not be straightforward to completely eradicate such transferred stigma, as the new product category may need to maintain links with the stigmatized product. Complete dissociation would risk losing association (and hence the market) around the focal stigmatized product, which the new product is seeking to replace. In the case of e-cigarettes—the subject of this study—entrepreneurs sought to dissociate e-cigarettes from tobacco cigarettes as a ‘smoke-free’ alternative, yet maintained an association with the ‘look’
and ‘feel’ of cigarettes to appeal to existing smokers. Hence, new product categories in stigmatized industries may need to maintain tenuous links with the stigmatized product involving both associating and dissociating—residing within an ‘in-between zone’ of being connected yet disconnected—in such a way that the benefits of the new product are accentuated and the negatives minimized. However, having an existing stigmatized product as a comparator, and drawing on the labels of existing stigmatized products can be problematic as such associations may lead to stigma transfer (Hudson & Okhuysen, 2009).

Such a predicament, where on the one hand, new product categories in stigmatized industries need to draw on existing stigmatized products to be recognizable, and on the other hand, they must depart from them due to stigma transfer (Hudson & Okhuysen, 2009) leads to my research question: How do new product categories emerge within stigmatized industries? To investigate this question, I next present my inquiry frame drawing on the intellectual base of technology entrepreneurship literature.

**Inquiry Frame**

Technology entrepreneurship (Beckman et al., 2012; Garud & Karnøe, 2003; Shane & Venkataraman, 2003) is a suitable inquiry frame to examine my research question. First, in line with my conceptualization of product categories as constituted through the interaction of different social groups, technology entrepreneurship also considers the role of multiple social groups in shaping product design and development (Garud & Karnøe, 2003). Second, resonating with the perspective that categories are materially anchored, technology entrepreneurship is concerned with technical developments (Beckman et al., 2012), which brings to bear materiality issues. For example, using the lens of technology entrepreneurship, Garud and Karnøe (2003: 295) showed how the development of wind turbines was the result of the collective effort of
multiple social groups (including designers and producers, users, evaluators and regulators) through their interactions with each other, as well as with the material “technology-in-the-making”.

Thus, going beyond a person-centric focus on the entrepreneur, technology entrepreneurship considers entrepreneurship as distributed across social groups (Garud & Karnøe, 2003) who influence the technology’s development according to their evaluation criteria i.e., their frames of reference and their involvement in the technology’s development i.e., their levels of inclusion (Bijker et al., 1987). Going beyond a purely ‘social’ account of entrepreneurship, technology entrepreneurship also takes into consideration the role of materiality (Garud & Rappa, 1994; Leonardi & Barley, 2010; Orlikowski & Scott, 2008) in the entrepreneurship process. Technology entrepreneurship thus, embraces an ontology of material-semiotic relationality, whereby entrepreneurship is the result of the ‘social’ and ‘material’ elements in semiotic relationality i.e., “a network whose elements define and shape one another” (Law, 2009: 146).

Adopting a technology entrepreneurship perspective is also pertinent for examining entrepreneurial dynamics within a stigmatized industry setting. Such industries are not only characterized by contestation between different social groups over the meaning of new products (as also depicted in mainstream industry settings), but they also provide a context where new products need to contend with the negative externalities (Coase, 1960) of prior stigmatized products which need to be scrubbed off. For example, new product categories in the tobacco and beverage industries need to contend with the stigma related to health risks attached to prior stigmatized products. Thus, new initiatives in such industries must not only address the social groups that stigmatize, but also the signified material elements that are implicated in the
stigmatization (e.g., carcinogens in cigarette smoke, sugar in beverages etc.). Considerations of the social and the material in relation to stigma makes technology entrepreneurship a suitable theoretical lens with which to examine my research question.

My inquiry frame using technology entrepreneurship is illustrated in Figure 1 shown in Appendix B. In line with this framework, I examine the actions of different social groups comprising firms, institutions and the market. I also examine materiality not only by examining the technology’s form and function, but also the affordances (e.g., Faraj & Azad, 2012; Hutchby, 2001; Leonardi, 2011) i.e., the discursive possibilities the technology’s materiality provides various social groups interacting with it. Although I separate the material and the social for the purpose of analytical tractability, my analysis shows the two to be mutually implicated, in line with the ontology of material-semiotic relationality underlying technology entrepreneurship. Next, I will elaborate on each of these elements in my inquiry frame.

Comprising firms are new entrants, incumbent firms and industry and trade associations. Entrepreneurs and intrapreneurs—individuals engaging in “entrepreneurship within an existing organizations” (Antoncic & Hisrich, 2003: 9) drive the creation of new product categories. They function as “cultural operatives” who can develop stories about how their “ideas [and products] will lead to future benefits for consumers and society” (Lounsbury & Glynn, 2001: 559). In new markets consisting of new product categories, entrepreneurs define the category’s collective identity before differentiating their offerings from others (Navis & Glynn, 2010; Santos & Eisenhardt, 2009). Through such discursive work, entrepreneurs legitimize new product categories in the eyes of important social groups and stakeholders to gain continued access to resources in support of their initiatives. Entrepreneurs can also function as skilled actors (Fligstein, 1997) who use “existing cultural and linguistic materials to narrate and theorize
change” to institutionalize new meaning systems (Garud, Hardy, & Maguire, 2007: 962). Given that new initiatives in stigmatized industries are likely to be viewed with hostility and suspicion by stigmatizing audiences (Durand & Vergne, 2015), it becomes vital to examine the strategies entrepreneurs (and intrapreneurs) use to shape the emergence of new product categories in such settings.

I also focus on the actions of scientists and regulators, two important institutional actors whose actions shape the creation of new product categories. As an important social group shaping the product’s development, scientists are not just engaged with technical facts, but also its interpretation according to their technological frames (Bijker et al., 1987; Garud & Ahlstrom, 1997). During the product’s development characterized by uncertainty, scientists use their beliefs and expectations about “what is feasible or at least worth attempting” to shape the product’s future trajectory (Borup, Brown, Konrad, & Van Lente, 2006; Garud & Rappa, 1994: 525). But scientists are not a homogenous group, and different scientific groups use different beliefs and expectations to come up with criteria to evaluate the product, while also actively seeking to influence other social groups to adopt their beliefs and standards (Garud & Ahlstrom, 1997).

Regulators also play an important role in shaping new product categories by certifying the consumption and use of the new products. Regulatory agencies are “complexity-reducing nodes” that are mandated with the task of assessing “products in a neutral, rational and objective way”, keeping in mind the interests of multiple social groups (Bodewitz, Buurma, & de Vries, 1987: 252). While doing this, regulators develop standards guided by science, but also bound by policy objectives and accountability to legal and legislative institutions (Jasanoff, 1995). Hence, in contrast to the standards of ‘research science’ practiced within universities, ‘regulatory science’ standards are “more fluid, controversial, and subject to political considerations”
(Jasanoff, 1995: 282). Once evaluation criteria get institutionalized through regulatory action, they benefit the development of some products while leaving out others (Garud & Rappa, 1994). In stigmatized industries such as the tobacco industry, which are subject to strong policy mandates, regulators should play an important role in determining the standards that shape the emergence of new product categories.

The actions of consumers not only constitute market demand for products, but also actively shape the emergence of new product categories (Pinch & Bijker, 1987; Rosa et al., 1999). For example, the input of women cyclists and elderly men was important in shaping the product category of the modern safety bicycle (Pinch & Bijker, 1987). The product category of mini-vans was also actively shaped by consumer feedback to the producer’s new automobile designs (Rosa et al., 1999). Relatedly, Ansari and Phillips (2011) showed how consumers innovated and diffused the practice of texting much before firms started building functionalities to promote texting in the mobile telephony category. Thus, I will examine the actions of consumers who play an active role in shaping the emergence of new product categories. I will also examine two institutional actors—the media and the judiciary.

The media not only reports on the actions of different social groups, it also plays an important role in shaping the larger public discourse around new business opportunities (Gamson & Modigliani, 1989), which in turn influences the legitimacy of entrepreneurial initiatives among investors and other interested social groups (Pollock & Rindova, 2003; Rindova, Pollock, & Hayward, 2006). Any conflict arising from interactions amongst the different social groups implicated in the category emergence process is arbitrated upon by the judiciary; hence I will also examine the judiciary’s actions.
New product category emergence, as I had previously described, is not just linguistic since it is constituted through the discourses of different social groups and also implicated in materiality. Specifically, materiality such as the use of novel designs and technology (Grodal et al., 2015) provides the discursive possibilities for social groups to engage in categorical work (Bowker & Star, 1999) to legitimize new product categories. For instance, “short menus requiring fresh ingredients and low inventories” shaped culinary discourse that led to the emergence of nouveau cuisine as a new category in French gastronomy (Rao et al., 2003: 798). The development of roll film camera technology also enabled discourse on photography as a “popular social practice” and led to the emergence of cameras for non-experts (Munir & Phillips, 2005: 1672). Similarly, changes to material appearance, such as the use of stylish bottle designs and labels, enabled the once low status spirit grappa to become a new product category associated with the cultured Italian lifestyle (Delmestri & Greenwood, 2016).

However, because affordances are “unique to the particular ways in which an actor perceives materiality…materiality can provide multiple affordances” (Leonardi, 2011: 153), as social groups present competing and even conflicting discourses around the possibilities they perceive with the artifact’s materiality. Cochlear implants, for example, were viewed by competing research groups as either devices aiding the deaf to hear environmental sounds (when temporarily in the hearing world), or as devices to “cure” deafness (and completely transition into the hearing world) (Garud & Rappa, 1994; Lane, 1992).

Overall, the combination of discourses with materiality involved in the constitution of new product categories offers a material-discursive inquiry frame. The material-discursive inquiry frame, considering the actions of various social groups (entrepreneurs, regulators, scientists, media etc.) and the material technology, takes into account both the social and the
material which is in line with actor-network theorists (Callon, 1986; Latour, 1987, 2005) who consider the social and the material to be symmetric. While things have symbolic value, they also have material effects (Müller & Reichmann, 2015). Indeed, scholars have used the material-discursive approach to examine scientific practices (Barad, 2003; Latour, 1987; Pickering, 1993), financial markets (Beunza, Hardie, & MacKenzie, 2006), and technology management (Leonardi & Barley, 2010; Orlikowski, 2007; Orlikowski & Scott, 2008). Such an inquiry frame, when applied to examine the emergence of new product categories in stigmatized industries, also enables one to go beyond the examination of discourse such as labeling strategies (Ellen & Bone, 2008; Granqvist, Grodal, & Woolley, 2013) to explicitly consider the role of materiality in the category emergence process.

To conclude, I have integrated the existing literature on categories and stigmatized industries in this chapter to ask the research question: *How do new product categories emerge within stigmatized industries?* I have also presented my inquiry frame, drawing on technology entrepreneurship to investigate my research question. In the next chapter, I will describe my research site and design, and the methods that I used for this study.
CHAPTER 3  
RESEARCH SETTING, DESIGN, AND METHODS

In this chapter, I describe my research setting, design, and methods. I begin by providing a brief history of e-cigarettes and chart their growth in the US, the research setting for this study. This is followed by a description of the microhistory case study design (Hargadon, 2016; Hargadon & Douglas, 2001) that I used for this study. Next, I provide details of the data that I collected in line with my research design. Finally, I conclude this chapter by describing the multi-method data analysis that I conducted, making use of both grounded theory (Glaser & Strauss, 1967) and longitudinal process analysis (Langley, 1999) techniques.

Research Setting

Herbert A. Gilbert is widely credited with the invention of electronic cigarettes in the year 1963. His patent application for a “smokeless non-tobacco cigarette” sought to provide “a safe and harmless” method of smoking, by replacing tobacco smoke with “heated, moist, flavored air” (Gilbert, 1965: 1). Figure 2 in Appendix B shows Gilbert’s design, comprised of a mouthpiece, a cartridge, and a heating element.

Gilbert designed his device in such a way that the air inhaled through the device’s mouthpiece could pick up flavored moisture on the cartridge. The moist air mixture would then be heated by a heating element to a temperature approximating cigarette smoke, before being inhaled by the user. Gilbert thought the product could help people abstain from smoking, and also be put to medicinal use through “heated medication for respiratory ailments” (Gilbert, 1965: 3). However, except for the prototypes he built for himself, Gilbert’s design did not materialize into production.
The invention of the modern e-cigarette is credited to Hon Lik, a pharmacist in China, who developed the product in 2003. Hon Lik was dissatisfied with the use of nicotine patches as a smoking cessation aid and wanted to develop a substitute that could simulate cigarette smoking. In an interview in 2013, Hon Lik explained the circumstances that led to his invention:

“I used to be a big smoker myself and knowing the harmful effects associated with it very well, I told myself I couldn’t go on like that. I tried nicotine patches but I didn’t care for the idea of slow diffusion of the drug into the organism. I missed the effect of the sudden impact, the act of smoking, the sensation of smoking. So I started thinking of a way to create vapor containing nicotine, similar to cigarette smoke but not as harmful for the organism.” (Excerpt from an interview conducted by Sridi, 2013) (emphasis added)

Hon Lik’s invention was commercialized by Ruyan Investment (Holdings) Limited (henceforth Ruyan), and by 2005, the devices were being exported from China (Source: blu.com).

Figure 3 in Appendix B shows a schematic of the device invented by Hon Lik from a US patent filing for an “Electronic atomization cigarette”. The patent describes the invention as a cigarette “which only contains nicotine without harmful tar” (Lik, 2010: 1) (emphasis added). Hon Lik’s design consisted of a mouthpiece, a sensor, an electronic circuit board, a heating element and a bottle containing nicotine solution. The sensor, upon detecting inhalation through the mouthpiece, would activate the electronic circuit board. The electronic circuit board would power the heating element, which in turn would convert the liquid nicotine solution into vapor inhaled by the user.

Although current e-cigarette designs have evolved beyond Hon Lik’s prototypes, his design was the inspiration behind the 1st generation e-cigarette called ‘cig-a-like’. Figure 4 in Appendix B shows a schematic of a ‘cig-a-like’ e-cigarette sold by NJOY. Mirroring Hon Lik’s design, the ‘cig-a-like’ has a lithium battery which powers a heating element (atomizer) which vaporizes a solution of flavored liquid nicotine (e-liquid) to be inhaled by the user. Following
this brief introduction into the genesis of e-cigarettes, I next describe the US e-cigarette market which is the research setting for this study.

**E-Cigarette Market in the US.** E-cigarettes emerged in the US in late 2006 (The New York Times, 2011, April 26), with the devices mainly being imported from manufacturers based in China (Etter, 2009, June 2). Since then, the e-cigarette market in the US has grown rapidly, with aggregate product category sales amounting to 3.5 billion dollars in 2015 (Euromonitor International, 2016). The product category has also expanded from the abovementioned ‘cig-a-like’ devices to 2nd and 3rd generation open system devices called ‘eGos’ or ‘vape pens’, and ‘advanced personal vaporizers’ or ‘mods’ (please see Figure 5 in Appendix B) (Zhu et al., 2014). These open system devices offer users the advantages of refillable ‘e-liquids’ over a wider selection of flavors and nicotine strengths (starting from zero milligrams), in addition to customization of battery voltage/wattage to produce vapor heated to desired temperatures (Grana, Benowitz, & Glantz, 2013; Zhu et al., 2014). Figure 6 in Appendix B shows the growth of the e-cigarette product category in the US, including the market for ‘cig-a-like’ devices, open system devices and ‘e-liquids’.

Today, numerous players populate the e-cigarette market. While larger independent e-cigarette companies (e.g., VMR, NJOY) and tobacco cigarette manufacturers (e.g., Reynolds American and Altria) dominate the ‘cig-a-like’ market, the market for open system devices comprises many smaller independent e-cigarette companies. Smoke Free Alternatives Trade Association (SFATA), a trade association of independent companies in the e-cigarette business, estimates that there are thirty-five manufacturers and assemblers of e-cigarette hardware, and around 1,200 manufacturers of ‘e-liquids’ in the US (Source: www.sfata.org).
While closed system devices are mainly sold online or in convenience stores, open system devices and ‘e-liquids’ are sold online as well as in brick and mortar vapes shops. Around 70,000 retail stores and close to 10,000 vapes shops are estimated to be selling different e-cigarettes devices (Dai & Hao, 2016; U.S. Department of Health and Human Services, 2016b). Relatedly, in January 2014, 466 e-cigarette websites were selling 7,764 unique e-cigarette flavors (Zhu et al., 2014), and in 2015, an estimated 3.5% of the US adult population were e-cigarette users (CDC, 2016). Thus, the e-cigarette product category in the US has seen rapid growth since 2006, reflected not only in terms of increasing revenues, but also in the number of producers, retailers, and consumers driving the product category’s growth.

This growth of the e-cigarette product category however, must also be seen in the larger context of the tobacco cigarette industry in the US, which experienced a period of rapid growth from the early 1900s onwards (Cummings & Proctor, 2014) and then fell into disrepute after the Surgeon General’s Report published in 1964, highlighted the health dangers of smoking. Since the report’s publication, the tobacco cigarette industry has been stigmatized as smoking, once considered an “acceptable, perhaps even desirable, behavior” (Markle & Troyer, 1979: 612) began to be viewed as a deviant activity.

The accumulating scientific evidence on the health hazards of second-hand smoke (e.g., Steenland, 1992; Wells, 1998) led to the adoption of legislations prohibiting smoking in public places and further stigmatized cigarette smoking (Alamar & Glantz, 2006; Greaves, Oliffe, Ponic, Kelly, & Bottorff, 2010; Stuber, Galea, & Link, 2009). Numerous other initiatives for tobacco control, such as the approval by the US Food and Drug Administration (FDA) of smoking cessation products (e.g., nicotine patches and gum) between 1984 and 1992 (Source: www.fda.gov); the enactment of the 1998 Master Settlement Act mandating tobacco cigarette
companies to make payments to US states to compensate them for the health burdens caused by tobacco use (please see Schroeder, 2004 for additional details); as well as the enactment of the 2009 Family Smoking Prevention and Tobacco Control Act (henceforth Tobacco Control Act), have continued to stigmatize the tobacco cigarette industry and led to the falling consumption and sales of cigarettes.

While the Master Settlement Act also led to the founding of the American Legacy Foundation (now Truth Initiative), an organization committed to making “tobacco use a thing of the past” (Source: www.truthinitiative.org), the passing of the Tobacco Control Act prompted the FDA’s Center for Tobacco Products to “regulate the manufacturing, distribution, and marketing of tobacco products” to protect “children and families from the dangers of tobacco products” (Source: www.fda.gov). Thus, the tobacco industry in the US represents a highly stigmatized industry in which incumbent tobacco companies have to pay reparations and face hostile stakeholders and regulations to conduct their businesses. Figure 7 in Appendix B highlights the dramatic rise and fall of adult cigarette consumption in the US from 1900 to 2012.

Though these anti-smoking initiatives have contributed to the decline in adult smoking rates in the US, estimated to be 15.1% in 2015 (Source: www.cdc.gov), smoking still remains “the leading cause of preventable disease and death in the United States” (Source: www.cdc.gov). It is against this backdrop that e-cigarettes have lately emerged as an alternative to tobacco cigarettes. As e-cigarettes do not burn tobacco but heat liquid nicotine, they contain substantially lower levels of harmful chemicals compared to tobacco cigarettes (e.g., Cahn & Siegel, 2011; Farsalinos & Polosa, 2014; McNeill et al., 2015). Figure 8 in Appendix B shows the risk profile of e-cigarettes vis-à-vis other tobacco and nicotine products.
Hence, e-cigarettes offer the discursive possibility for a new category of products that are less harmful than tobacco cigarettes, and have the potential to remove the stigma associated with smoking. Such discursive efforts can be seen in the coining of new vocabulary such as *vaping* to distinguish e-cigarettes as ‘smoke-free’ alternatives to traditional combustible cigarettes. Additionally, compared to FDA approved nicotine patches and gums, e-cigarettes offer users the behavioral stimulation of smoking cigarettes, which also make them potentially more attractive to smokers by addressing not just the “pharmacologic” but also the “behavioral components of cigarette addiction” (Cahn and Siegel, 2011: 17). Thus, the advent of e-cigarettes in the US provided a strategic research site (Bijker et al., 1987) to generate theoretical insights into my research question on the emergence of new product categories in stigmatized industries.

**Research Design**

I used a microhistory case study design for this study (Bijker et al., 1987; Garud & Rappa, 1994; Hargadon, 2016; Hargadon & Douglas, 2001). A microhistory case study “focuses on the dynamics between larger social and institutional forces and individual cognition and action within a single setting or event” (Hargadon, 2016: 125). Thus, it differs from traditional case study analysis due to its emphasis on “studying individual behaviors in particular moments or events in relational to the institutional … context in which they originate, and which they in turn reify or change” (Hargadon, 2016: 125; Vaara & Lamberg, 2016). Due to its emphasis on the contextualized understanding of phenomenon, the microhistory case study design was considered suitable to develop grounded theory (Hargadon, 2016; Yates, 2014) on the process (Langley, 1999) driving the emergence of new product categories in a stigmatized industry setting.
Using microhistory case study design, I went beyond a realist chronological description of events to develop an interpretive account of how the “actions and meaning” (Vaara & Lamberg, 2016) of different social groups (Bijker et al., 1987) have been shaping the category’s emergence. Also, in keeping with my inquiry frame which took a material-discursive approach (Barad, 2003), I paid attention to both the material and discursive elements throughout my analysis. Although I separated the material and the discursive for the purpose of analytical tractability, the onto-epistemological position that I espouse is relational, which recognizes that materiality and discourse “do not stand in a relationship of externality to one another; rather, the material and the discursive are mutually implicated in the dynamics of intra-activity” (Barad, 2003: 822).

**Research Methods**

**Data collection.** Microhistory focuses on the in-depth analysis of moments, episodes or events over time; hence my primary source of data was longitudinal and archival in nature (Hargadon, 2016; Vaara & Lamberg, 2016). As the news media records such events, I began by gathering articles on e-cigarettes from two leading general newspapers, *The Wall Street Journal*, and *The New York Times*. Using the Factiva database, I collected all the articles on e-cigarettes published in these newspapers from 2006—the year e-cigarettes first made their way into the US—onwards. Reading these articles sensitized me to the context, and also enabled me to identify important social groups relevant to my inquiry frame. These groups included independent e-cigarette entrepreneurs, tobacco companies, regulators, consumers, and public health groups whose actions were being widely reported in these articles. Once I had identified these social groups, I gathered additional timestamped data about them from their websites. In
addition, I also sourced texts authored by these groups, which appeared in regulatory and judicial petitions, scientific journals, as well as in trade journals and magazines.

Because the phenomenon was unfolding even as I was studying it, I supplemented the archival data with observational and interview data (Yates, 2014). I gathered observational data from four conferences that I attended from February to October 2016. Being present at these conferences, which were attended by prominent social groups such as entrepreneurs, regulators, public health agencies and scientists, was important to gain a deeper understanding of the phenomenon. These conferences included: i) two e-cigarette industry tradeshows held in February and July 2016, ii) a scientific conference on nicotine and tobacco research organized by the Society for Research on Nicotine and Tobacco (SRNT) in March 2016, iii) and a public seminar on regulatory issues related to pre-market application for electronic nicotine delivery systems organized by the FDA in October 2016.

In addition, I gained access to one recorded workshop and two webinars. The recorded workshop was on battery safety concerns in electronic nicotine delivery system products (such as e-cigarettes) conducted by the FDA in April 2017. One of the webinars was devoted to e-cigarette advocacy issues and was organized by the National Vapers Club (NVC) in November 2015. The second webinar was on the science around e-cigarettes and was conducted by SRNT in December 2016. Besides, I also conducted thirty interviews with entrepreneurs and experts in the e-cigarette industry. Nine of these interviews (ranging from thirty to ninety minutes each) were conducted telephonically, while twenty-one interviews were conducted at the conferences that I attended. All the interviews were documented and analyzed. In addition, I collected transcripts of interviews of e-cigarette entrepreneurs, scientists, industry experts and officials of
public health groups conducted by other individuals. Table 1 in Appendix A summarizes the data sources and the corpus of data that I collected.

**Data analysis.** I adopted a multi-analytical approach (Garud, Berends, & Tuertscher, 2017a) making use of both grounded theory (Glaser & Strauss, 1967) and longitudinal process methods (Langley, 1999) to examine my data. While grounded theory analysis aimed at uncovering themes that were constitutive of the observed phenomenon through the actions of the social groups involved, longitudinal process analysis enabled me to fully appreciate how the phenomenon was being performatively constituted and de-constituted (Garud et al., 2017b). Such an approach enabled a contextualized understanding of the phenomenon as both observed and experienced by the different social groups in their interactions with each other and the underlying material elements (Garud et al., 2017a). I describe the steps I took for data analysis in greater detail below:

**Grounded theory.** I used grounded theory (Glaser & Strauss, 1967) to analyze the data using both first and second order coding (Gioia & Chittipeddi, 1991). The first order analysis related to coding texts produced by different social groups, staying as close as possible to the language and terms of the informants themselves (Gioia, Corley, & Hamilton, 2012). In the context of this study, first order coding led to the identification of social groups, their ‘category labels’ and the ‘discursive possibilities’ they constituted for the category. Table 2 in Appendix A presents a summary of the various social groups as well as the category labels and the discursive possibilities they constituted. Table 3 in Appendix A is a breakdown of the discursive possibilities that each social group constituted with regard to the different material elements of e-cigarettes.
The second order analysis consisted of collapsing the first order codes across the different social groups into “a workable set of themes and concepts” to describe the phenomenon (Gioia et al., 2012: 20). I identified eight second order themes which I further classified into two aggregate theoretical dimensions namely *categorical work of sanitization*, and *categorical work of stigmatization*. Table 4 and 5 in Appendix A presents a summary of the data structure highlighting the two aggregate theoretical categories, and the underlying first and second order themes and illustrative quotes.

**Longitudinal process analysis.** While the grounded theory analysis spotlighted important theoretical themes related to the phenomenon, to develop a more processual understanding of how the category emerged over time, I conducted a longitudinal process analysis (Langley, 1999), which consisted of the following steps: First, I analyzed the corpus of longitudinal data to code events and tabulate them into an event history database (e.g., Garud & Rappa, 1994; Maguire, 2004; Van de Ven & Poole, 1990). Such a database established a general chronology of events related to the product category’s emergence over time. All the events in the event history database were covered by multiple data sources.

Second, I identified historically significant moments (Yates, 2014) from the database of events for deeper investigation. I define such events as ‘critical events’ i.e. events which (a) received widespread attention and invited reactions from multiple social groups, and (b) influenced (or continue to influence) the process of emergence in important ways. To select these ‘critical events’, I identified events based on the “light of their effects on history” (Hargadon, 2016: 125) i.e. their importance in shaping the category’s emergence till date. Based on my independent analysis of the events, and my discussions with another colleague who was immersed in the phenomenon, I identified eight events as ‘critical events’. To establish face
validity, I approached three knowledgeable industry experts (an entrepreneur, an industry advocate, and a policy scientist) with my list of ‘critical events’. All three confirmed that the events I had identified were both comprehensive and important. Table 6 in Appendix A shows the event history database and the ‘critical events’ that I identified.

These ‘critical events’ comprised of regulatory actions, a legal ruling, a corporate acquisition, the publication of a public health report, and the publication of two scientific reports. I zoomed into (Nicolini, 2009; Vaara & Lamberg, 2016) each and wherever necessary gathered additional data in the form of texts generated by different social groups on these episodes. For example, regulatory rulings by the FDA constituted ‘critical events’ which evoked responses from different social groups such as e-cigarette entrepreneurs (and their trade association and advocacy groups), public health agencies, and intrapreneurs of tobacco companies. I gathered and analyzed texts produced by each of these social groups to reveal themes related to their actions in shaping the category’s emergence.

Besides providing “key moments of contention” to dig deeper into (Funk & Hirschman, 2014: 675), ‘critical events’ also provided breakpoints for temporal bracketing (Langley, 1999) to enable transformation of the “shapeless mass of process data … into a series of more discrete but connected blocks” (Langley, 1999: 703). This is part of the process of zooming out to “better understand the bigger picture” as it relates to the phenomenon under investigation (Nicolini, 2009; Vaara & Lamberg, 2016). I identified three periods (bracketed by three ‘critical events’) as broadly summarizing the emergence process. I next present my findings from the abovementioned analysis using both grounded theory and process analysis techniques.
CHAPTER 4

FINDINGS

I present my findings in four sections in this chapter. I begin by providing a first order description of the different social groups, their category labels, and the discursive possibilities they constituted for the product category. Next, I provide a descriptive narrative (Denis, Dompierre, Langley, & Rouleau, 2011) of how the category emerged through the interactions of these different social groups over the eight critical events that I identified. Following this first order description, I describe the second order themes that emerged from the data, which I then use to present a more analytical account of the emergence process over the three periods (Denis et al., 2011).

First Order Findings: Material-Discursive Possibilities

Table 2 in Appendix A provides a summary of the major social groups (and representative organizations) that surfaced from my analysis of the data. These social groups use different labels and invoke different discursive possibilities for the category. For instance, independent e-cigarette companies (and their trade association and advocacy groups) use labels such as ‘alternative smoking device’, ‘smoke-free alternatives’, ‘vapor’, ‘vaping’, and ‘technology products’ to describe e-cigarettes. Companies comprising this group sell both open and closed system e-cigarette devices, with many of them also selling e-liquids. These companies see e-cigarettes as a disruptive innovation playing an important role in making “combustion cigarette obsolete” (Source: www.njoy.com) by providing consumers with a more enjoyable, convenient, and less harmful alternative to tobacco cigarettes. In line with this belief, they characterize e-cigarettes as ‘vapor’ products that are “not tobacco products” (SFATA, 2014, August 8; VMR, 2014, August 8).
Tobacco cigarette companies such as Altria and Reynolds American, while associating e-cigarettes with the label ‘vapor’, also describe e-cigarettes as “innovative tobacco products” (Source: www.nu-mark.com) that are “transforming tobacco” (Source: www.rjvapor.com). For these companies, which are mainly in the business of selling closed system e-cigarettes or ‘cig-a-like’ devices, e-cigarettes present opportunities for “reimagining the tobacco category” (Source: www.nu-mark.com) by combining their “years of tobacco expertise with innovative technology to provide adult tobacco consumers with great-tasting vapor products” (Source: www.rjvapor.com). Hence, in contrast to independent e-cigarette companies which are now dissociating e-cigarettes from tobacco by calling them ‘vapor’ products, tobacco cigarette companies see e-cigarettes as merely a new category of reduced harm ‘tobacco’ products (Source: www.transformingtobacco.com, www.altria.com).

Another important social group that emerged from my analysis was comprised of the regulators represented by the FDA. The FDA labeled e-cigarettes first as a ‘combination drug device product’ and later as a ‘tobacco product’ (Source: www.fda.gov). For the FDA, e-cigarettes are ‘tobacco’ products which, while offering the possibility for harm reduction, also constitute a public health threat due to their potential for increasing nicotine addiction, reducing the intention to quit smoking, and increasing the likelihood of new user initiation into tobacco, especially among youth (Source: www.fda.gov).

Public health groups in tobacco control also constituted an important social group in my analysis. Organizations such as the Centers for Disease Control and Prevention (CDC), the Campaign for Tobacco-Free Kids, the American Lung Association, the American Heart Association etc., which are part of this social group, are vociferous in their expression of concern for public health because of increasing e-cigarette use. They see e-cigarettes as a ‘tobacco’
product being made especially “attractive to youth” (Source: www.tobaccofreekids.org), hence placing youth at risk of a “lifetime of nicotine addiction” (Source: www.cdc.gov). They also express concern about the presence of “harmful chemicals, including carcinogens” in e-cigarette vapor (Source: www.lung.org).

Scientists engaged in nicotine and tobacco research also surfaced as an important social group. Across scientific articles, e-cigarettes are labeled as ‘electronic nicotine delivery systems’. Scientists are however, not a homogenous group with regard to the discursive possibilities they constitute for e-cigarettes. Depending on whether they take a ‘precautionary’ or a ‘harm reduction’ perspective (please see Fairchild & Bayer, 2015; Fairchild, Bayer, & Colgrove, 2014), scientists either resist or support the use of e-cigarettes as a smoking cessation tool. For example, scientists taking a ‘precautionary’ approach associate e-cigarettes with “significantly less quitting among smokers” (Kalkhoran & Glantz, 2016: 116), and potential exposure to dangerous carcinogenic substances such as formaldehyde and diacetyl (e.g., Allen et al., 2016; Jensen, Luo, Pankow, Strongin, & Peyton, 2015). In contrast, scientists taking a ‘harm reduction’ view associate e-cigarettes with a higher likelihood of continued abstinence from smoking (e.g., Brown, Beard, Kotz, Michie, & West, 2014; Hartmann-Boyce et al., 2016), and perceive them as being substantially less harmful than tobacco cigarettes (e.g., McNeill et al., 2015; Shahab et al., 2017).

Consumers comprised yet another important social group in my study. In testimonials reported on online consumer forums (e.g., www.e-cigarette-forum.com), advocacy group websites (e.g., www.casaa.org, www.vaping.org), and in published focus group studies (e.g., Barbeau, Burda, & Siegel, 2013; Coleman et al., 2016; Simmons et al., 2016), consumers described e-cigarettes as ‘vapor’ or ‘vaping’ products which provided them with a more
enjoyable and healthier alternative to tobacco cigarettes. For e-cigarette consumers who are
mainly current smokers (e.g., Pearson, Richardson, Niaura, Vallone, & Abrams, 2012; Syamlal,
Jamal, King, & Mazurek, 2016), e-cigarettes also constituted the possibility of gaining social
support from an online and physical community of ‘vapers’ to overcome their addiction to
cigarettes (Barbeau et al., 2013; Simmons et al., 2016). Speaking to user driven innovation or
user entrepreneurship (Shah & Tripsas, 2007; Von Hippel, 1986), e-cigarette consumers also
engaged in product innovations that led to the emergence of e-cigarette designs known as ‘mods’
(Brown & Cheng, 2014; Grothaus, 2014). Such innovations were also collective, and took place
through information sharing in user communities (Shah & Tripsas, 2007) such as online e-
cigarette consumer forums (e.g., www.e-cigarette-forum.com).

Besides these groups, other social groups such as the judiciary (including state attorney
generals), and lawmakers were also implicated in the categorization process. Being guided by
legal and legislative precedents related to tobacco cigarettes, these groups labelled e-cigarettes as
a ‘tobacco’ product and sought to bring it under existing statutes for tobacco cigarettes (e.g.,
Durbin et al., 2014; National Association of Attorneys General, 2013, September 24; United
States District Court for the District of Columbia, 2010).

In summary, social groups used different labels for e-cigarettes based on their own
frames of reference (Bijker et al., 1987). These discursive actions of social groups are also
implicated in materiality, and social groups emphasized different elements of the materiality
based on their own frames of reference. For example, while e-cigarette entrepreneurs and
scientists supporting harm reduction emphasized the reduction of harmful carcinogens in e-
cigarette vapor (relative to cigarette smoke), the FDA, public health groups and scientists taking
a precautionary approach emphasized the addition of flavors, nicotine, and the remaining
carcinogens resulting in different implications for the category. Table 3 in Appendix A provides a summary of how social groups emphasized the material elements in e-cigarettes to constitute different possibilities for the emerging product category.

What bearing did the actions of these social groups have on the product category’s trajectory, and what was the nature of the category’s emergence? To answer this question, I next present a descriptive account of how the product category emerged based on my analysis of the eight critical events that I identified.

**First Order Findings: Descriptive Case Narrative**

I present my case narrative in three chronological periods: Period 1 describes the FDA’s regulatory action against e-cigarette shipments being imported into the US, and concludes with a description of a subsequent court ruling against the FDA. Period 2 highlights the entry of tobacco cigarette companies into the e-cigarette market, as well as rising concerns among public health groups regarding increasing e-cigarette use among youth. This period ends with a description of FDA’s draft regulations for e-cigarettes and the reactions of different social groups to the proposed regulations. Period 3 describes two developments in the science around e-cigarettes referenced by social groups supporting or opposing the terms of the FDA’s proposed regulations. I end this period by describing the FDA’s final regulations, and the ongoing unfolding dynamics amongst different social groups in reaction to these regulations.

**Period 1: From ‘drug device combination’ to ‘tobacco’ product (2006-2011).** E-cigarettes entered the US market in late 2006 as imports from overseas manufacturers based in China (Hollander, 2009, 22 February; The New York Times, 2011, April 26). The products, sold at online stores and malls (Zezima, 2009, 2 June), were ‘cig-a-like’ products similar to the ‘look’ and ‘feel’ of conventional cigarettes, and companies promoted them as a healthier alternative to
traditional cigarettes. Speaking to the material-discursive possibilities, consumers also began sharing stories of how they successfully weaned off tobacco cigarettes through testimonials on online forums such as the E-Cigarette Forum mentioned earlier (Source: www.e-cigarette-forum.com). However, the promotion of e-cigarettes as a healthier alternative was not without its problems. Specifically, the FDA took issue with the health claims being made, and began issuing orders to detain the shipments of imported e-cigarettes. Two e-cigarette companies in turn sought legal protection against the FDA’s actions, which led to a legal battle culminating in a ruling against the FDA. I next describe these critical events in greater detail.

**Critical event 1: Detention of imported e-cigarette shipments.** The FDA began detaining imported e-cigarette shipments in 2008 (Kesmodel & Yadron, 2010, August 25). The FDA’s actions were based on its interpretation of the Federal Food Drug & Cosmetics Act (FD&C Act henceforth) which defined drugs or devices as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals” (Source: www.fda.gov).

Citing the content of promotions made by e-cigarette companies, the agency concluded that since imported e-cigarettes were being marketed as a ‘healthier’ alternative to alleviate the ‘medical condition’ of nicotine addiction, they fell under the definition of ‘drug device combination’ products under the FD&C Act:

“"The promotion of E-Cigarettes as satisfying a craving for nicotine and providing the same physical feeling as smoking establishes that the product is intended to affect the structure or function of the body. The assertion that E-Cigarettes provide a “healthier way” to obtain the effects of nicotine establishes that E-Cigarettes are intended to prevent or alleviate nicotine withdrawal symptoms. Accordingly, FDA reasonably concluded that the totality of the evidence demonstrates that E-Cigarettes are intended to affect the structure or function of the body and intended for use in the mitigation of disease.”" (FDA et al, 2009: 21) [emphasis added]
As new drug and device products had to obtain FDA approval regarding ‘safety and efficacy’ which none of the e-cigarettes being marketed and sold had obtained, the FDA proceeded to detain e-cigarette shipments as ‘unapproved’ and/or ‘misbranded’ drug device combination products. By June 2009, the FDA had detained seventeen e-cigarette shipments (Etter, 2009, June 2). In addition, the FDA and public health agencies such as the CDC and Campaign for Tobacco-Free Kids, warned consumers about the presence of potentially toxic ingredients in e-cigarettes, and expressed concerns that the product could initiate new users including youth, into nicotine addiction and tobacco cigarettes (Campaign for Tobacco-Free Kids, 2009, July 22; FDA, 2009, July 22).

FDA’s actions were not without opposition from e-cigarette companies. In April 2009, Smoking Everywhere Inc. (SE henceforth) filed an appeal before the United States District Court for the District of Columbia seeking injunctive relief from the FDA’s actions. In addition to petitioning against the potentially damaging economic consequences of the FDA’s actions on its business, the plaintiff also questioned the FDA’s regulatory authority over e-cigarettes. Specifically, SE argued that since e-cigarettes were sold as an alternative to tobacco cigarettes without any marketing claims related to smoking cessation, they did not fall under the drug and device regulations of the FD&C Act:

“SE [Smoking Everywhere] does not market the E-cigarette for any therapeutic purpose, as a smoking cessation aid, or as a product that is designed to affect the function of the body of man…[but] marketed, labeled and sold solely to provide adult consumers with alternative ‘smoking pleasure’, without the inconveniences of traditional tobacco smoking.” (Smoking Everywhere Inc., 2009: 4) [emphasis added]

Smoking Everywhere Inc.’s promotion of e-cigarettes during this period is shown in Figure 9 in Appendix B. While an association is made with the ‘look’, ‘feel’ and ‘taste’ of cigarettes, problematic materials such as ‘tobacco’, ‘tar’ and ‘smoke’ are dissociated with. The
promotions of Sottera Inc.\(^1\) (later known as NJOY), another company during this time, is also shown in Figure 10 in Appendix B. Here again, e-cigarettes are promoted as a means to “continue smoking” albeit using a less harmful alternative which, according to the company, also generated more “social acceptance” vis-à-vis cigarettes.

In summary, the detention of e-cigarette shipments by the FDA revealed different interpretations of the product. While the FDA classified e-cigarettes as a ‘drug device combination’ product being sold for smoking cessation, e-cigarette companies such as SE and Sottera Inc. qualified e-cigarettes as a less harmful alternative to smoking. To resolve this difference in interpretation, the judiciary was called in to adjudicate. I will next describe its judgment on this issue.

**Critical event 2: District Court ruling against FDA’s actions.** On January 14\(^{th}\), 2010, after deliberating on the appeals of SE and Sottera Inc., District Judge Richard J. Leon concluded that unless e-cigarettes were being marketed or sold with therapeutic or medicinal claims, the FDA had no right to detain or refuse admission to them. Deeming the FDA’s actions as a “tenacious drive to maximize its regulatory power” (United States District Court for the District of Columbia, 2010: 31), the judge called into question the FDA’s interpretation of e-cigarettes as a ‘drug device combination’ product. Judge Leon argued that since the way e-cigarettes were being marketed and sold was no different from tobacco cigarettes, they could not be classified as drugs or devices under the FD&C Act. Citing the FDA’s own arguments and the plaintiff’s promotions of e-cigarettes, Judge Leon noted:

\(^1\) *Sottera Inc.* later joined *Smoking Everywhere Inc.*’s petition against the FDA after its e-cigarette shipments were detained by the FDA in April 2009.
“FDA does not contend that the electronic cigarettes marketed by plaintiffs are intended to affect the structure or function of the body in any way materially different from traditional cigarettes… Indeed, by FDA's own admission, *Smoking Everywhere markets its product as providing ‘the same drug effects on the structure and function of the human body as cigarettes.’*…Likewise, *NJOY markets its product as providing ‘all the pleasures of smoking.’* …Because plaintiffs sell their electronic cigarette products for customary recreational use, those products (just like traditional cigarettes) are properly excluded from the meaning of drug or device under the FDCA.” (United States District Court for the District of Columbia, 2010: 21) [emphasis added]

In arriving at this judgment, Judge Leon also drew upon a 2000 Supreme Court ruling in *FDA v. Brown and Williamson Tobacco Corp.* which had prevented the FDA from regulating cigarettes as drug device combination products. A consequence of that ruling was the creation of a separate regulatory framework for tobacco products under the Family Smoking Prevention and Tobacco Control Act\(^2\) (henceforth Tobacco Control Act). While the FDA had reasoned that the Tobacco Control Act did not extend to new products such as e-cigarettes, Judge Leon opined otherwise. Specifically, the judge noted that the definition of ‘tobacco product’ in the Tobacco Control Act defined as “any product made or derived from tobacco that is intended for human consumption” was expansive enough to include newer products such as e-cigarettes using nicotine derived from tobacco. Thus, Judge Leon noted that in the absence of any therapeutic claims, the Tobacco Control Act precluded the FDA from regulating e-cigarettes as drugs and devices:

“Congress enacted the Tobacco [Control] Act to confer FDA jurisdiction over any tobacco product—whether traditional or not—that is sold for customary recreational use, as opposed to therapeutic use. *As such, the Tobacco Act, in effect, serves as an implicit acknowledgment by Congress that FDA’s jurisdiction over drugs and devices does not, and never did, extend to tobacco products, like electronic cigarettes.*” (United States District Court for the District of Columbia, 2010: 20) [emphasis added]

\(^2\) The Family Smoking Prevention and Tobacco Control Act was signed into law by former US President Barack Obama on June 22\(^{nd}\), 2009. The FDA, through the newly formed Center for Tobacco Products, was given the authority to regulate the manufacturing, distribution and marketing of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products.
Further invalidating the FDA’s interpretation of e-cigarettes as a drug device combination product, Judge Leon remarked that even in the event that e-cigarettes were being marketed as a healthier alternative to tobacco cigarettes, they could still be regulated by the FDA as a “modified risk tobacco product” defined under the Tobacco Control Act as any tobacco product “sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products” (United States District Court for the District of Columbia, 2010: 25-26).

Judge Leon’s ruling evoked mixed reactions from social groups. While e-cigarette companies such as SE celebrated the ruling as a “victory for smokers who want a safer cigarette” (Wilson, 2010, January 15), public health groups such as the Campaign for Tobacco-Free Kids opposed the ruling saying it opened “a gaping loophole” in the FDA’s ability to regulate non-tobacco products containing nicotine (Wilson, 2010, January 15). The FDA in turn, filed an appeal in the US Court of Appeals for the District of Columbia Circuit (Court of Appeals henceforth)3, following which on December 7th, 2010, a three-member bench upheld the district court’s ruling noting:

“FDA cannot regulate customarily marketed tobacco products [including e-cigarettes] under the FDCA’s drug/device provisions… the FDA has authority to regulate customarily marketed tobacco products—including e-cigarettes—under the Tobacco [Control] Act.” (United States Court of Appeals for the District of Columbia Circuit, 2010: 13)

Following another refusal by the Appeals Court to review the ruling (Gleason, 2011, April 26), the FDA decided not to pursue the matter any further, and communicated its intention to regulate

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3 Smoking Everywhere Inc. voluntarily dismissed its complaint against the FDA after Judge Leon’s ruling, which left Sottera Inc. as the sole petitioner in the case against the FDA.
e-cigarettes as a tobacco product under the Tobacco Control Act. An excerpt from the FDA’s letter dated April 25th, 2011, addressed to all stakeholders highlighted the agency’s new position on e-cigarettes:

“The US Court of Appeals for the D.C. Circuit ... held that e-cigarettes and other products made or derived from tobacco can be regulated as ‘tobacco products’ under the Act and are not drugs/devices unless they are marketed for therapeutic purposes. The government has decided not to seek further review of this decision... The Agency intends to propose a regulation that would extend the Agency’s ‘tobacco product’ authorities ...which currently only apply to certain specifically enumerated ‘tobacco products’, to other categories of tobacco products that meet the statutory definition of ‘tobacco product’.” (FDA, 2011, April 25)

This resolved the ambiguity around the classification of e-cigarettes as a ‘drug device combination’ or a ‘tobacco’ product.

**Period 2: From the entry of tobacco companies to regulation as a tobacco product (2011-2014).** The FDA’s decision to regulate e-cigarettes as a tobacco product meant the FDA had to initiate the process of formulating new regulations for these products. This process took three years, and in this interim period, e-cigarette sales enjoyed rapid growth from an estimated 0.3 billion dollars in 2011 to 2.7 billion dollars in 2014 (Euromonitor International, 2016). As mentioned earlier, the product technology also changed rapidly from the closed system ‘cig-a-like’ devices to open system customizable devices called ‘eGos’ and ‘mods’ (Zhu et al., 2014) being sold at numerous brick and mortar ‘vapeshops’ as well as over the internet. However, public health agencies and lawmakers soon raised concerns about ‘smoking renormalization’ and growing youth initiation into nicotine through e-cigarettes, and individual states started banning the sale of e-cigarettes to minors, prohibiting their use in public places as well as levying taxes on them (Esterl, 2012, March 2). I next discuss these developments in greater detail through three critical events.
**Critical event 3: Acquisition of BLU by Lorillard.** The acquisition of the e-cigarette company BLU by Lorillard Tobacco Company (Lorillard henceforth) on April 25th, 2012 marked the entry of a major tobacco cigarette company into the e-cigarette business. BLU, founded in 2009, had grown to be one of the largest e-cigarette companies in the US, and its acquisition by Lorillard, then the third largest tobacco company in the US (for 135 million dollars) signaled the growing importance of the e-cigarette product category to tobacco companies faced with falling cigarette sales (Esterl, 2012, April 26). From being a market comprised of independent startup companies, the e-cigarette market now included a major tobacco cigarette manufacturer.

Lorillard’s then CEO, Murray Kessler, described the acquisition in the following words:

> “BLU ecigs are the perfect adjacency for us to participate in the smokeless market, but in a Lorillard way… e-cigarettes offer many of the benefits of other smokeless products but do so in a way that is familiar and enjoyed by current adult cigarette consumers.” (Excerpt from an interview conducted by EcigAdvanced.com, 2012)

Thus, Lorillard saw e-cigarettes as a promising product, attractive to smokers due to the similarity of experience with smoking, while also providing the lower risk profile benefits of smokeless tobacco products.

Lorillard, anticipating the FDA regulations for e-cigarettes, believed it could take the lead in demonstrating regulatory preparedness over smaller entrepreneurial companies. As Lorillard’s then CEO, Murray S. Kessler remarked:

> “It’s a very fragmented industry and there’s some fly-by-night e-cigarette companies … regulation is coming and we have a lot of regulatory expertise… if somebody large didn’t step in maybe this great category wouldn’t get a fair chance because mistakes would be made … *We decided that we could get in, that our relationship with the FDA and our experience with retailers, etc., that we could help this category reach its full potential.*”

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4 *Lorillard* was acquired by *Reynolds American* in June 2015.
“I want to make sure all that kind of quality is put into place and that I could look to the FDA and say, ‘You want to see how it’s made? Come on in. We’ve nothing to hide. Here it is. Here’s all the test results.’” (Excerpt from an interview conducted by EcigAdvanced.com, 2012) [emphasis added]

An immediate effect of this acquisition was the increased marketing, advertising and distribution of BLU e-cigarettes. BLU’s availability at retail stores increased five-fold after the acquisition and was estimated to have reached 50,000 stores by December 2012 (Nasaw, 2012, December 6). Commenting on these developments, BLU founder Jason Healy mentioned:

“They've [Lollilard] come in and put in their tremendous resources and experience and they've put us on steroids and given us the resources to grow well.” (Jason Healy quoted in Nasaw, 2012, December 6)

Lorillard’s marketing and advertisement campaigns to promote BLU also drew scrutiny from public health agencies. Specifically, the use of celebrity actors and themes such as ‘Take Back Your Freedom’ generated suspicious reactions from public health groups:

“It feels like what they're trying to do is re-establish a norm that smoking is okay, that smoking is glamorous and acceptable.” (Cynthia Hallett, Executive Director, Americans for Non-Smokers' Rights quoted in Nasaw, 2012, December 6) [emphasis added]

“The BLU advert stokes the spirit of rebellion that appealed to smokers when they first started as adolescents…This time around…the ad encourages smokers to rebel against more recent anti-smoking social norms…They're capitalizing on that with adult smokers by basically saying 'don't let society tell you what to do.” (David Abrams, Executive Director, Legacy [now Truth Initiative] quoted in Nasaw, 2012, December 6) [emphasis added]

Public health groups saw Lorillard’s promotions as a means to renormalize smoking through e-cigarettes. These misgivings about Lorillard’s promotions were not surprising given the tobacco industry’s use of misleading advertising campaigns such as those related to ‘light’ and ‘mild’ cigarettes in the past (Hsu & Grodal, 2015; Pollay & Dewhirst, 2002; Shiffman, Pillitteri, Burton, Rohay, & Gitchell, 2001). Figure 11 in Appendix B shows some of the themes from Lorillard’s advertising campaigns to promote BLU.
Such misgivings were also detrimental to e-cigarettes as public health agencies extended their negative perceptions to the e-cigarette product category. As one informant, a former e-cigarette industry trade association executive whom I interviewed mentioned:

“I believe that many in tobacco control have just transferred their belief about combustive tobacco onto the vapor industry. They literally cannot tell the difference between the two. No one can stop big tobacco from entering the space, which they did. On the one hand, it's good because now big tobacco has some of the same concerns [the] vapor industry has. On the other hand, it's very bad because the vapor industry gets painted with the same brush as the tobacco industry. ...They remember the lies by big tobacco. They remember the manipulation by big tobacco and they just assume vapor is an extension of that.” (Interview, Industry Trade Association Executive) [emphasis added]

While tobacco companies Altria and Reynolds American began launching their own e-cigarette brands in 2013 (Esterl, 2013, June 10), the opposition towards e-cigarettes from public health groups intensified in the light of reports about increased youth initiation into e-cigarettes, which I describe below.

**Critical event 4: CDC’s report on e-cigarette use among middle and high school students.** On September 5th, 2013, CDC, in its morbidity and mortality weekly report, disclosed the doubling of e-cigarette “experimentation and recent use” among middle and high school students in the US during 2011-2012 (CDC, 2013). The CDC’s estimates of e-cigarette use amongst youth were based on a National Youth Tobacco Survey (NYTS) which had measured ‘recent use’ (i.e. use “>=1 day in the past 30 days”) of e-cigarettes. The CDC, engaged in tobacco control efforts, interpreted this trend as potentially renormalizing smoking, leading to nicotine addiction among youth. While commenting on the trend, Dr. Tim McAfee, Director of the CDC’s Office on Smoking and Health, observed:

“We are worried that e-cigarettes will help kids overcome their inhibitions and re-normalize smoking and undermine the progress we have made… we do not have direct evidence, but it's likely to increase the risk of smoking…We are
worried about the adolescent use of nicotine, because the adolescent brain is
uniquely susceptible to addiction and nicotine is harmful to their brain
development.” (Dr. Tim McAfee quoted in Reinberg, 2013, September 5)
[emphasis added]

The FDA saw this trend as ‘reinforcing’ the need for regulations that they were in the
process of formulating (Esterl, 2013, September 6). Other public health organizations echoed the
CDC’s concerns, associating the rise in e-cigarette use with the availability of a wide range of
flavors, and the increased marketing of e-cigarettes with themes borrowed from prior cigarette
advertising. In their letter addressed to the US President, sixteen public health organizations
called for immediate regulation of e-cigarettes by the FDA:

“The e-cigarette industry is using a number of marketing techniques originally
employed by the cigarette companies to addict youth, including the use of candy-
and fruit-flavors…Centers for Disease Control and Prevention (CDC) released
alarming new data about e-cigarette use among youth… Given the enormity of the
burden of death and disease caused by tobacco products, the public health of our
nation cannot afford further delay. FDA must issue a rule to regulate all tobacco
products, including cigars, little cigars, e-cigarettes and other tobacco products.”
(American Academy of Pediatrics et al., 2013, September 19)

The CDC’s report and its conclusions were, however, challenged by both cigarette and e-
cigarette trade associations which questioned the CDC’s interpretation of the NYTS survey.

SFATA, representing the interests of independent small e-cigarette businesses, implied the
survey measured experimentation and not continuous use (SFATA, 2013, September 17). The
National Association of Tobacco Outlets (NATO), a trade association for tobacco retailers, also
commented on the use of e-cigarettes and pointed out that the CDC’s claim may be overstated:

“The NYTS statistics relied on by the CDC to estimate how many youth use
electronic cigarettes include middle and high school students who currently use e-
cigarettes and those who have used an e-cigarette just once. This means that the
CDC’s claim that electronic cigarette use has doubled among underage youth is
likely overstated since students who used the product one time may no longer be
using e-cigarettes.” (NATO quoted in Convenience Store News, 2013, September
5) [emphasis added]
One informant, an executive at an e-cigarette advocacy organization whom I interviewed, also had a similar opinion:

“Think about all the products that you interact with. Did you go to a fancy meal in the past 30 days? If that's the case, if you went once in the past 30 days, is it fair to say that you always go out to expensive restaurants? That's very misleading and that's what a lot of these numbers are based on, this meteoric rise in use among young people. That can be a kid experimenting or his friend passed him an e-cigarette and said, ‘Here, try this’. That counts as ever use.” (Interview, Advocacy Organization Executive)

This criticism notwithstanding, the CDC report soon became a reference point for other social groups. State and city legislative bodies began enacting legislation to prevent the sale of e-cigarettes to minors, and their use in public places. For example, in October 2013, the state of New York passed a law prohibiting individuals under the age of twenty-one from purchasing cigarettes, including e-cigarettes (Vilensky & Jackson, 2013, October 31); and in December 2013, the New York City Council extended its ban on smoking in public places to include e-cigarettes (NPR, 2013, December 19). By April 2014, over twenty-four states had implemented regulations to prohibit the sale of e-cigarettes to minors, and over 100 cities had issued a ban against the use of e-cigarettes in smoke-free venues (Burton & Esterl, 2014, April 24).

Law officers and legislators also cited the CDC’s report to put pressure on the FDA to expedite regulations on e-cigarettes. On September 24th, 2013, the National Association of Attorney Generals (NAAG) asked the FDA to “move quickly” to expedite the regulations on e-cigarettes (National Association of Attorneys General, 2013, September 24). Subsequently on April 14th, 2014, eleven US Senators and Representatives, citing the CDC report, published a report titled ‘Gateway to addiction?’ and urged the FDA to immediately regulate e-cigarettes:

“In the absence of FDA using its authority to issue e-cigarette regulations, e-cigarette companies are taking advantage of the regulatory vacuum to market their products to youth. In light of concerns regarding exposure to addictive nicotine and other ingredients in e-cigarettes, the sharp rise in e-cigarette use
among teens, and the marketing of these products to youth, FDA should act quickly to finalize and issue deeming regulations pertaining to e-cigarette.” (Durbin et al., 2014: 22) [emphasis added]

The mounting pressure on the FDA from these social groups led to the FDA issuing draft regulations for e-cigarettes in April 2014. I next describe these regulations proposed by the FDA.

**Critical event 5: FDA proposes regulations under the Tobacco Control Act.** On April 24th, 2014, the FDA proposed regulations for e-cigarettes and other novel tobacco products under the Tobacco Control Act. The proposed regulations required all e-cigarette companies to seek FDA approval before marketing their products. Under the Tobacco Control Act, the FDA could grant premarket authorization to new tobacco products after considering:

> “Risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.” (U.S. Department of Health and Human Services, 2014: 23146) [emphasis added]

Such a ‘population’ standard meant e-cigarette companies would need to demonstrate not only how their products benefited current tobacco users, but also show that non-tobacco users were not being initiated into them. The proposed regulations would also mandate all e-cigarette companies to register their product, provide ingredient listings, include health warnings (related to nicotine addiction), and also refrain from distributing free samples and selling to minors, among other provisions (U.S. Department of Health and Human Services, 2014).

The FDA by no means considered the proposed regulations as complete, and in light of the emerging science and social groups’ contending claims about the potential benefits and harm from e-cigarette use, the agency also invited comments on the proposed regulations:
“Emerging technologies such as the e-cigarette may have the potential to reduce the death and disease toll from overall tobacco product use...[but] FDA is aware that some e-cigarettes are being marketed with flavors that may be attractive to young people. FDA asks for comments, data, and research to determine whether the Agency’s evaluation of the relative risk or potential for harm reduction of such a product should be different...especially if there is evidence that these flavors make the products more attractive to children.” (U.S. Department of Health and Human Services, 2014: 23147-23148) [emphasis added]

Social groups responded to the proposed regulations, guided by their own frames of reference (Bijker et al., 1987). Twenty-five public health organizations, including the Campaign for Tobacco-Free Kids, the American Lung Association, the American Heart Association and others, while welcoming the proposed regulations as a “critical [step] to protecting public health” proposed implementing greater restrictions on the use of flavors and online sales of e-cigarettes (American Academy of Family Physicians et al, 2014, August 8: 4). In their joint letter to the FDA, the group reasoned that marketing of flavors had made e-cigarettes attractive to youth, and expressed concern that initiation into e-cigarettes could be a gateway to other tobacco products:

“FDA’s failure in the proposed deeming rule to address the growing use of characterizing flavors in deemed products, creates a serious regulatory gap that is adverse to public health. FDA should immediately develop rules prohibiting characterizing flavors (other than tobacco) in the deemed products, including ...e-cigarettes... We...urge FDA to [also] include a prohibition on the sale of deemed products over the internet...there also is a legitimate concern that these new nicotine-delivery devices expose youth to nicotine, result in the initiation and addiction of young people and/or function as a gateway to smoking or other tobacco use for kids who otherwise would not have used any tobacco product.” (American Academy of Family Physicians et al, 2014, August 8: 7, 30, 46) [emphasis added]

Mentioning that e-cigarettes “are not free of carcinogens and toxicants”, and highlighting the addictive nature of the nicotine contained in e-liquids, the group extended its full support to the proposed regulations to bring e-cigarettes under the Tobacco Control Act, notwithstanding the lower risk profile of e-cigarettes vis-à-vis traditional cigarettes (American Academy of Family Physicians et al, 2014, August 8: 73).
E-cigarette companies across the board, including both tobacco cigarette manufacturers and independent e-cigarette companies, expressed support for the proposed regulations related to the listing of ingredients, health warnings and the prohibition of sale to minors. However, underscoring the harm reduction potential of e-cigarettes, these groups also rebuffed claims related to youth initiation and smoking renormalization raised by regulators and public health groups as speculation (VMR, 2014, August 8), pointing to the lack of conclusive scientific evidence. According to them, the use of flavors was not harmful, but beneficial because it enabled smokers to continue abstaining from smoking:

“Recent research suggests that e-cigarette flavors assist smokers in moving to e-cigarettes from traditional combustion tobacco products.” (VMR, 2014, August 8: 28) [emphasis added]

“Scientific evidence suggests that flavors in electronic cigarettes do not influence initiation of electronic cigarette use and may aid in smoking cessation.” (Lorillard, 2014, August 7: 16) [emphasis added]

However, these companies differed on other facets of the FDA’s proposed regulations.

Tobacco companies in the e-cigarette business welcomed the FDA regulations under the Tobacco Control Act, but urged the FDA not to apply the provisions related to premarket authorization till the science around the products was more established. For these companies with prior regulatory experience in dealing with the FDA, the proposed regulations presented an opportunity to work with the FDA to understand the requirements needed to eventually obtain premarket authorization under the Tobacco Control Act. As Lorillard remarked in its comments to the FDA:

“Lorillard’s record of compliance with FDA requirements has been demonstrated by…successful FDA inspections and the fact that Lorillard was the first company to obtain orders of substantial equivalence [from the FDA] for two of its conventional cigarette products. Lorillard is proud of this record of compliance and looks forward to continuing to work cooperatively with the [FDA] Center for Tobacco Products (CTP)...Given limitations in the current state of science
surrounding electronic cigarettes, some aspects of the FDCA cannot be implemented at present...Lorillard urges FDA to begin an open dialogue to develop these methodologies, which are a prerequisite to implementing ....premarket review for electronic cigarettes. Absent the ability to compare products to evaluate their constituent deliveries, or to reach conclusions about population-level effects, FDA cannot implement a meaningful and consistent premarket review process for electronic cigarettes.” (Lorillard, 2014, August 7: 0-3) [emphasis added]

In their letters to the FDA, Altria and Reynolds American (through its subsidiary RAI Services Company) also urged the agency not to give differential treatment to independent e-cigarette businesses:

*FDA should not create special rules for small manufacturers and importers of deemed tobacco products* by extending compliance periods or staggering compliance dates...If FDA creates special rules for certain manufacturers and importers based on their size, it should clearly explain its rationale for doing so, including why such special rules are permitted by the FSTPCA, appropriate for the protection of public health, and necessary. (Altria, 2014, August 8: 5-6) [emphasis added]

*FDA should avoid creating compliance loopholes by extending compliance deadlines for small manufacturers.* Even a brief period of non-compliance would increase the danger to the public health. Moreover, because most e-cigarette manufacturers are small, an exemption for small manufacturers would, in this context, swallow the rule. (RAI Services Company, 2014, August 8) [emphasis added]

Thus, as is evident from the above comments, the proposed regulations presented an opportunity for tobacco companies to influence the regulatory standards that would make it difficult for independent e-cigarette companies to comply with.

Echoing these concerns of unsustainable regulatory burden to comply with the proposed regulations, independent e-cigarette companies commented that rigidly applying the guidelines of the Tobacco Control Act (designed for combustible tobacco cigarettes) to non-combustible products (such as e-cigarettes) would only end up protecting the market for incumbent tobacco
companies and their combustible products. In its letter to the FDA, NJOY, a large independent e-cigarette company observed:

“Rigid application of the law [Tobacco Control Act] to ENDS [Electronic Nicotine Delivery Systems] products—as though ENDS had the same harm profile as the combustion products NJOY seeks to obsolete—would not be consistent with the TCA’s public health objectives…regulating ENDS under the TCA [Tobacco Control Act]…includes barriers to commercializing disruptive technologies that might challenge the market domination of incumbent tobacco companies.” (NJOY, 2014, August 8: 6-7) [emphasis added]

VMR, another independent e-cigarette company, echoed similar concerns:

“VMR estimates testing costs would run between $1 million and $4 million per product. Indeed, just the research needed to satisfy… the…approval pathway would be enough to bankrupt VMR and dozens of similarly-sized producers… The end result would be less choice for consumers looking for an alternative to smoking. In fact, adopting the Proposed Rule would effectively eliminate all small and moderately-sized e-cigarette producers, leaving large, legacy tobacco companies as the only players in the e-cigarette market… In short, adopting the Proposed Rule would benefit those companies that the TCA was designed to reign in.” (VMR, 2014, August 8: 32, 35) [emphasis added]

SFATA, in its comments to the FDA, also called for differential regulatory treatment of e-cigarettes. SFATA contended that given the lower risk profile of e-cigarettes, extending regulations designed for cigarettes to e-cigarettes was akin to jamming a ‘round peg’ into a ‘square hole’, which would surely drive small companies out of business:

 “[E-cigarettes] are…products that allow users to inhale…vapor without fire, smoke, ash, or carbon monoxide…there is no evidence of which we are aware…which would suggest that the risks and public health costs of e-cigarettes are in any way comparable to that of tobacco products… Because the Tobacco [Control] Act was not intended to regulate e-cigarettes…the Tobacco Act does not work either legally or practically to regulate e-cigarettes. E-cigarettes are the ultimate ‘round peg’ which the current proposal is seeking to jam into a ‘square hole’.” (SFATA, 2014, August 8: 5, 10)

“If the Tobacco [Control] Act…are applied to e-cigarettes…the economic impact will amount to making small and medium-sized companies like SFATA’s members obsolete, as they are unable to absorb the significant cost of such applications.” (SFATA, 2014, August 8: 12)
CASAA (Consumer Advocates for Smoke-Free Alternatives Association), a consumer advocacy group, also pointed out that the proposed regulations were detrimental to consumers seeking access to e-cigarettes:

“The [proposed] regulations would make e-cigarettes far less available and attractive compared to smoking, and the resulting higher rate in smoking would be a major public health loss.” (CASAA, 2014, August 7: 5)

Overall, the proposed deeming regulations marked the dawn of e-cigarette regulation as a tobacco product, which as I described, held different implications for different social groups. I next detail two developments, around science and around FDA’s deeming regulations.

**Period 3: From proposed regulations to final regulations (2014-2016).** In its proposed regulations, the FDA had expressed uncertainty about the health risks from e-cigarettes and called for the need for more scientific investigations to inform its regulatory policy. Indeed, after the publication of the proposed regulations, the FDA conducted three public workshops between December 2014 and June 2015 to “gather scientific information and stimulate discussion among scientists about electronic cigarettes” (Source: www.fda.gov). Science, which makes specific material facets (such as carcinogens) salient, came under the spotlight to provide answers to impending regulatory questions. I focus on two scientific reports in this period, which suggested different regulatory approaches. I will end this period by describing the FDA’s final deeming regulations, a ruling which continues to shape the emergence of the e-cigarette product category.

**Critical event 6: Study finds “hidden formaldehyde in e-cigarette aerosols”**. In January 2015, a study published in the *New England Journal of Medicine* found formaldehyde releasing molecules in e-cigarette aerosols (Jensen et al., 2015). While the authors found no formaldehyde in aerosols produced by e-cigarettes at low voltages (3.3V), at higher voltages (5V) formaldehyde was detected. Comparing the observed formaldehyde levels in higher voltage e-
cigarettes with tobacco cigarettes, the authors’ estimated the risk of cancer from long-term use of
e-cigarettes to be “5 times as high…or even 15 times as high…as the risk associated with long-
term smoking” (Jensen et al., 2015: 392). Although prior studies had reported the presence of
formaldehyde and other carcinogens in e-cigarette vapor, they had concluded that the risks from
e-cigarettes were substantially lower than those from smoking cigarettes (e.g., Goniewicz et al.,
2014).

The results of this study were widely reported in the news media, with headlines linking
e-cigarette use to cancer. While CBS news carried an article with the headline “E-cigarette vapor
filled with cancer-causing chemicals” (Thompson, 2015, January 21), another article in the Wall
Street Journal proclaimed, “Study links e-cigarettes to formaldehyde, cancer risk” (Mickle,
2015, January 21). Commenting on the study’s findings, public health groups reiterated the need
for immediate regulations. Eric Jacobs, director of pharmacoepidemiology, American Cancer
Society observed:

“This study shows how little we know about toxic exposures that can result from
using any one of the many different available types of e-cigarettes at different
heating levels...Until these things are monitored and regulated, there's a real
potential risk for unexpected exposure to toxic chemicals.” (Eric Jacobs quoted in
Thompson, 2015, January 21)

However, scientists and groups advocating for e-cigarettes challenged the study’s
findings criticizing it for using experimental conditions that were unrelated to the normal use of
e-cigarettes. For instance, Nitzkin, Farsalinos, and Siegel (2015) commented that the use of high
voltage might have produced overheating leading to the production of more formaldehyde than
in regular e-cigarette use. They mentioned that in such conditions, e-cigarette users would
experience “dry-puff” characterized by an “unpleasant burning taste” and would stop using their
e-cigarette devices (Nitzkin et al., 2015: 1575). Greg Conley of the American Vaping
Association (AVA), an e-cigarette advocacy group, shared the same observation while commenting on the study’s findings:

“Contrary to the authors’ mistaken belief, these are not settings that real life vapers actually use, as the resulting dry puffs are very unpleasant.” (Greg Conley quoted in Thompson, 2015, January 21)

Michael Siegel, an expert in tobacco control at Boston University, published an article in the Wall Street Journal titled “The misbegotten crusade against e-cigarettes”, which pointed out how the study’s unrealistic conclusions had created unfounded fears about e-cigarettes:

“Last month a New England Journal of Medicine article reported extremely high levels of formaldehyde in the aerosol of an electronic cigarette and concluded that vaping may therefore be more harmful than smoking. But the study was carried out under unrealistic conditions in which the e-liquid was severely overheated. Under more realistic conditions, the study failed to detect any formaldehyde. Unfortunately, the e-cigarette cancer scare had already been spread through the media.” (Siegel, 2015, February 25) [emphasis added]

Indeed, confirming these observations, a subsequent study published in the journal Addiction in May 2015, found minimal levels of aldehyde emissions (such as formaldehyde) under normal e-cigarette use conditions and at levels “far lower” than cigarette smoke (Farsalinos, Voudris, & Poulas, 2015). However, the study received little coverage except amongst e-cigarette advocates.

**Critical event 7: Report concluding e-cigarettes were 95% less harmful than tobacco cigarettes.** In August 2015, Public Health England (henceforth PHE) published a report authored by McNeill et al. (2015) which concluded that e-cigarettes were 95% less harmful than combustible tobacco cigarettes. The authors of the report noted:

“While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger…EC [electronic cigarettes] are around 95% safer than smoking. This appears to remain a reasonable estimate.” (McNeill et al., 2015: 12) [emphasis added]
Reviewing the available scientific literature on e-cigarettes, the report’s estimation of the relative risk of e-cigarettes was based on the assessment of an expert panel of twelve individuals. These individuals had rated different nicotine products on a continuum of risk using a multi-criteria decision model (Nutt et al., 2014). Based on these considerations, the PHE report endorsed e-cigarettes as a viable harm reduction alternative for cigarette smokers who had difficulties quitting:

“Encouraging smokers who cannot or do not want to stop smoking, to switch to EC could be adopted as one of the key strategies to reduce smoking-related disease and death.” (McNeill et al., 2015: 13)

Speaking to the negative media messaging around e-cigarettes, the PHE report also called for greater publicizing of its findings to counter the worsening public perception of e-cigarettes:

“Recent worldwide media headlines asserted that EC use is dangerous. These were based on misinterpreted research findings...The ongoing negative media campaigns are a plausible explanation for the change in the perception of EC safety...There is a need to publicise the current best estimate that using EC is around 95% safer than smoking.” (McNeill et al., 2015: 12)

The PHE report, however, received its share of criticism. Scientists criticized the study for lacking conclusive evidence in support of its claims (McKee & Capewell, 2015) and also for being guided by the “opinions of a small group of individuals” constituting an expert panel selected without “formal” criteria (The Lancet, 2015: 829). In response to this criticism, and underscoring ideology shaping scientific inquiry, Professor Ricardo Polosa, a member of the expert panel, observed:

“The nature of these problems is simply ideologic, with harm reductionists versus precautionary principle supporters presenting opposing views on e-cigarettes.” (Polosa, 2015: 1238)

The PHE report received mixed reactions from social groups in the US. Gregory Conley of AVA welcomed the report describing it as a “major win for public health” and expressed
optimism that public health groups opposed to e-cigarettes in the US would reassess their actions in light of the report’s findings:

“In light of this new report, the AVA is calling for US organizations and government agencies like the American Cancer Society, American Lung Association, Campaign for Tobacco-Free Kids, and Centers for Disease Control & Prevention (CDC) to reassess their views on vaping. Additionally, the AVA is calling on these groups to issue corrective statements clarifying prior misleading or inaccurate statements [on e-cigarettes]... This report should change the debate about vaping in the US for the better.” (AVA, 2015, August 19) [emphasis added]

In the midst of impending FDA regulations (under review at the US White House’s Office of Information and Regulatory Affairs—OIRA), e-cigarettes’ trade associations engaged in advocacy work to publicize the report’s findings to prevent ‘over-regulation’ of the e-cigarette product category. For example, in November 2015, SFATA incorporated the findings of the PHE report in its guidance statement to e-cigarette companies interested in meeting OIRA officials to effect a more favorable regulatory framework. In December 2015, the American E-Liquid Manufacturing Standards Association (AEMSA) also brought to OIRA’s attention the PHE report to "compel FDA to rethink the manner in which it has proposed to regulate e-vapor products" (AEMSA, 2015: 58). However, the recommendations of the PHE report were largely ignored by public health agencies in the US based on their precautionary frame of reference, and the report also received relatively lower coverage in major news media articles in the US around that time. Next, I describe how these scientific perspectives were brought to bear in the final regulations issued by the FDA.

**Critical event 8: FDA issues final deeming regulations.** On May 5th, 2016, the FDA published its final deeming regulations. In the face of science highlighting potential harm (such as the abovementioned Jensen et al., 2015 study), and reports by public health groups on increasing e-cigarette use among youth (such as the CDC reports), the FDA, while not
dismissing the potential benefits from e-cigarettes, adopted a precautionary approach requiring e-cigarettes to undergo a rigorous pre-market authorization process similar to tobacco cigarettes before being sold. As the FDA noted in its final regulations:

“The Agency has concluded, based on scientific data, that the newly deemed products [including e-cigarettes] should be regulated due to their potential for public harm…and regulation is necessary to learn more about that potential…Even if a category of products were to prove generally beneficial, individual products within that category might raise concerns. For example, some products may be particularly attractive to youth or deliver unexpected high level of toxicants…implementation of the requirements [under the proposed regulations]…will increase product consistency and help protect the public from adverse impacts.” (U.S. Department of Health and Human Services, 2016a: 28983-28984) [emphasis added]

Besides requiring premarket authorization, the regulations also prohibited the sale of e-cigarettes to minors, sales through vending machines (unless located in adult-only facilities), and the distribution of free samples. In addition, the regulations stipulated age verification of all customers who were less than twenty-seven years old, and put in place requirements of health warnings related to nicotine addictiveness to be displayed on e-cigarette product packaging and advertisements. E-cigarette manufacturers were also prohibited from making lower risk claims, unless such claims had been approved by the FDA (U.S. Department of Health and Human Services, 2016a).

Although the regulations did not include a ban on characterizing flavors and online sales of e-cigarettes as desired by many public health groups, e-cigarettes of different flavors would henceforth require separate premarket authorization from the FDA, and online sales would similarly be subject to age verification. E-cigarette businesses had up to three years from August
Public health groups welcomed the regulations as another step towards eliminating tobacco use. For this group, e-cigarettes were no different from the other tobacco products they were opposed to:

“We are glad that the extended wait for this final rule is over and applaud the FDA for establishing a tighter grip on these products. These new regulations will …move us closer to becoming a tobacco-free nation.” (American Heart Association, 2016, May 5)

“The American Lung Association welcomes this long-awaited step to protect public health. At last, the Food and Drug Administration will have basic authority to make science-based decisions that will protect our nation’s youth and the public health from all tobacco products, including e-cigarettes.” (American Lung Association, 2016, May 5)

The group also demanded stronger regulatory action prohibiting the use of flavors and online sales, as well as restrictions on e-cigarette marketing:

“[The rule]…falls short in protecting kids from e-cigarettes. It does nothing to restrict the irresponsible marketing of e-cigarettes or the use of sweet e-cigarette flavors such as gummy bear and cotton candy, despite…data showing that flavors play a major role in the skyrocketing youth use of e-cigarettes…This proposal should be strengthened to prohibit e-cigarette flavors…restrict e-cigarette marketing…[and] prevent online sales of e-cigarettes and refill liquids to [the] youth.” (Campaign for Tobacco-Free Kids, 2016, May 5) [emphasis added]

Opposing the regulations, independent e-cigarette companies (and their trade association and advocacy groups) argued that subjecting e-cigarettes to the same level of regulatory oversight as cigarettes imposed unreasonable regulatory burdens on products that were less harmful. Nicopure Labs, LLC (henceforth Nicopure), an independent e-cigarette company, filed

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5 Similar to tobacco products, e-cigarettes could obtain FDA premarket authorization through three pathways: premarket tobacco product applications, substantial equivalence or exemption from substantial equivalence.
a lawsuit against the FDA petitioning that the regulatory burden would put small e-cigarette companies such as theirs out of business:

“The Deeming Rule subjects vaping devices and e-liquids to the same extensive regulatory regime designed for cigarettes and smokeless tobacco…imposes severe regulatory burdens on manufacturers, including small businesses such as Nicopure, by requiring compliance with extensive premarket approval…These costs vastly outweigh the benefits…particularly given that vaping devices and e-liquids do not contain tobacco and/or do not pose the public-health risks associated with products that contain tobacco.” (Nicopure Labs LLC, 2016, May 10: 11-13) [emphasis added]

Trade association SFATA estimated that 99% of e-cigarettes would be removed from the market due to the inability of independent small businesses to go through the premarket authorization process required for approval:

“FDA today issued its final rule classifying vapor products as tobacco, essentially banning 99 percent of all vapor products on the market…These new regulations create an enormously cost-prohibitive regulatory process for manufacturers to market their products to adult smokers and vapers.” (SFATA, 2016, May 5)

Similarly, consumer advocacy group CASAA described the regulations as being informed by an ‘abstinence only’ approach in contrast to the ‘harm reduction’ approach adopted by PHE and other UK organizations such as the Royal College of Physicians. For CASAA, the regulations in their present form represented a departure from the agency’s mandate to protect public health:

“In blinding contrast, the FDA’s deeming regulation comes on the heels of two monumental reports released by Public Health England and the Royal College of Physicians in the UK. Both organizations recognize the significant contribution that electronic cigarettes can make toward improving public health as an alternative to smoking that is at least 95% less harmful than combustible cigarettes. Conversely, the FDA is sending a clear but misleading message to 42 million smokers in the US that abstinence is the only acceptable option. Such an irresponsible and reckless recommendation from an agency with a mandate to protect public health is an appalling breach of ethics and public trust.” (CASAA, 2016, May 6)
On May 10th, 2016, FDA published further details on the regulatory requirements for premarket authorization of e-cigarettes. In its ‘draft guidance’ document for companies preparing applications for their products, the agency recommended that companies submit data from clinical and non-clinical studies on their product including (but not limited to):

“…health risks (e.g., toxicological testing outcomes) of the product, the product’s effect on tobacco use behavior among current users, the product’s effect on tobacco use initiation among nonusers, and the product’s effect on the population as a whole.” (U.S. Department of Health and Human Services, 2016c: 22-23)

Given the cost and expertise required to prepare such an application, the draft guidance document inviting comments from the e-cigarette industry generated a low response (it received forty comments) (Source: www.regulations.gov), many of which were disgruntled comments from small businesses on the regulatory burdens imposed by the new regulations:

“As a small eliquid manufacturing company and long time advocate for vaping, I can assure you that this will effectively stifle and could even shut down many small business owners in this community.” (Source: www.regulations.gov) [emphasis added]

“The vapor industry is comprised of small micro businesses not big tobacco companies...Please consider this when finalizing this ruling... My business will be forced to close under this ruling.” (Source: www.regulations.gov)

Even established tobacco cigarette manufacturers such as Altria expressed concern that the regulations in their present form would stifle innovation and put many e-cigarette products out of the market. In their comments on the draft premarket application guidance document, Altria noted:

“FDA’s Deeming Rule and the Draft Guidance together create an onerous PMTA [Premarket Tobacco Applications] process within a time frame that, as a practical matter, may be difficult for many ENDS product manufacturers to meet… The result is that many existing ENDS products may be removed from the market… By creating an accelerated or modified PMTA pathway and/or performance standards system for ENDS, FDA could meet its public health obligations, which include ensuring potentially reduced risk products can get to market.” (Altria, 2016, July 11: 4-7) [emphasis added]
Implicit in Altria’s comments was the demand for more reasonable regulations for the e-cigarette product category, given its lower risk profile and potential harm reduction benefits vis-à-vis other tobacco products.

While Altria’s comments to the FDA suggested modifications to the premarket authorization requirements within the tobacco control framework, independent e-cigarette companies such as Nicopure and Lost Arts Liquid have resorted to legal action against the FDA. E-cigarette trade associations and advocacy groups such as CASSA and SFATA have also been engaged in efforts to garner legislative support for bills that would enable all e-cigarettes on the market before the effective date of the new regulations (i.e., August 8th, 2016) to remain, without having to go through the premarket authorization process (Source: www.casaa.org; www.sfata.org). Such initiatives, however, continue to face opposition from public health groups that have appealed to legislators not to pass bills that would weaken FDA’s regulatory jurisdiction over e-cigarettes (Academy of General Dentistry et al, 2016, September 7). Thus, the product category’s emergence in the post regulation world continues to be contested among different social groups, and it is the outcomes of these contestations that will shape the category’s emergence.

**Second Order Findings: Categorical Work**

The first order findings related to the category labels used by different social groups, and the descriptive case narrative that followed suggests that social groups were engaged in categorical work (Bowker & Star, 1999) of sanitation and stigmatization. Table 4 and 5 (shown in Appendix A) summarizes the various strategies undertaken by the different social groups in their initiatives to sanitize or stigmatize e-cigarettes. Following the descriptive accounts, I present a more analytical second order account of these sanitization and stigmatization strategies.
**Categorical work of sanitization.** The strategies constitutive of the *categorical work of sanitization* included *establishing contrast (with the stigmatized product)*, *highlighting detachment possibilities*, *surfacing harm reduction*, and *claiming differential regulations*.

*Establishing contrast (with the stigmatized product)* involved highlighting the similarities and differences with stigmatized tobacco cigarettes. During the first period, e-cigarette companies highlighted how similar their products were in ‘look’, ‘feel’ and taste’ with tobacco cigarettes, yet were devoid of all the ‘troubles’ and ‘inconveniences’ associated with smoking. Such contrasting with cigarettes was necessary to place e-cigarettes in existing “schemas and scripts” i.e., within the “familiar world” (Hargadon & Douglas, 2001: 480) of smoking while introducing the product as a more convenient ‘smoke-free’ alternative to cigarettes. Comparisons with cigarettes were also invoked in the appeals by e-cigarette companies SE and Soterra Inc. against the FDA’s actions to regulate e-cigarettes as ‘drug device combination’ products. Specifically, by successfully arguing that e-cigarettes were not ‘drug device combination’ products but were similar to cigarettes in providing an alternative to smoking, the category was also able to escape regulatory action under the FD&C Act.

Over time, during the second and third period, as e-cigarettes evolved from ‘cig-a-likes’ to open system devices such as ‘eGos’ and ‘mods’ that resembled less like cigarettes, entrepreneurs and consumers alike began to dissociate e-cigarettes from tobacco cigarettes through the use of new vocabulary around ‘vapor’ and ‘vaping’. Such dissociation from tobacco cigarettes was also necessary in the wake of the FDA’s proposed regulations for e-cigarettes as a tobacco product. For example, in response to the FDA’s proposed regulations, NJOY, a large independent e-cigarette company, stated it was not a ‘tobacco company’ but instead was committed to making tobacco products such as cigarettes obsolete:
“NJOY is not a tobacco company… NJOY is committed…its corporate mission to obsolete the combustible cigarette.” (NJOY, 2014, August 8: 4)

Thus, *establishing contrast (with the stigmatized product)* was a sanitization initiative used by entrepreneurs to first enable the recognition of e-cigarettes as a recognizable ‘convenient’ alternative to tobacco cigarettes, and then to distinguish e-cigarettes as a new category of products that were not tobacco products.

**Highlighting detachment possibilities** involved characterizing e-cigarettes as a ‘gateway out’ of tobacco cigarettes. Social groups, including entrepreneurs and consumers, pointed to the effectiveness of e-cigarettes over other FDA approved products such as nicotine patches and gums. These initiatives gathered force during the second and third period, as innovations made the product more appealing to consumers as a substitute for tobacco cigarettes. Countless testimonials of consumers on the websites of advocacy groups such as CASAA and AVA highlighted how they successfully quit smoking using e-cigarettes. One such testimonial from an ex-smoker in August 2013 states:

“I had been smoking a pack a day since I was 16 years old. During that time I had tried to quit multiple times. *I used gum, patches, lozenges, anything out there. Unfortunately it was to no avail.* I would always end up back smoking...In February of this year I tried my first ecig. *From that moment I haven’t touched a cigarette.*” (Source: www.casaa.org) [emphasis added]

An entrepreneur in the e-cigarette business, whom I interviewed, also mentioned to me the effectiveness of e-cigarettes over other smoking cessation products:

“The power of the product [e-cigarettes] is to be able to deliver somebody away from smoking and to provide that alternative to nicotine, that they couldn't get from nicotine patches or nicotine gum.” (Interview, Entrepreneur)

Scientific articles also began to attest to the detachment possibilities from tobacco cigarettes, which e-cigarettes could provide smokers. For example, in one study Brown et al.
(2014) found e-cigarettes were more effective in enabling smokers to abstain from cigarettes than nicotine replacement therapy (NRT) products such as nicotine patches and gums:

“Respondents who reported having used an e-cigarette in their most recent quit attempt were more likely to report still not smoking than those who used NRT bought over-the-counter or nothing.”

The materiality of e-cigarettes such as the flavors being used, also played an important role in the detachment process by enabling smokers to quit ‘tasteless’ cigarettes. One advocacy organization executive whom I interviewed, mentioned how the “flavor experience” led him to switch to e-cigarettes and quit smoking (Interview, Advocacy Group Executive). AEMSA also noted in its submission to OIRA that flavors were “the primary reason why vapers continue to vape rather than smoke” (AEMSA, 2015: 32), a fact also acknowledged in scientific studies (e.g., Barbeau et al., 2013; Farsalinos et al., 2013). To sum up, highlighting detachment possibilities sanitized e-cigarettes by drawing attention to the product’s ability to release individuals from the addictive grip of tobacco cigarettes.

**Surfacing harm reduction** consisted of strategies to discursively frame e-cigarettes as a reduced harm alternative to tobacco cigarettes. Harm reduction discourse gained ground during the second and third period as scientific texts highlighting the lower risk profile of e-cigarettes vis-à-vis tobacco cigarettes got published (e.g., Cahn & Siegel, 2011; Goniewicz et al., 2014; McNeill et al., 2015; Polosa, Rodu, Caponnetto, Maglia, & Raciti, 2013). Such discourse constituted e-cigarettes “as a means to limit the toll of smoking-related morbidity and mortality” (Fairchild & Bayer, 2015: 375). Viewed through such a frame of reference, social groups advocating e-cigarettes saw the product not as a public health problem but as a ‘solution’ to mitigate the problem of tobacco cigarettes. As Dr. Michael Siegel of Boston University, an expert in the area of tobacco control, stated in an interview:
I believe that this technology [e-cigarettes] has the potential to transform the nicotine market in a dramatic way—away from combustible tobacco products and toward a much safer alternative. Vaping products have the potential to be a true game changer. They could potentially save more lives than any previous strategy in tobacco control. There are risks that need to be addressed, but if properly managed, these products could play a role in saving more lives than almost any previous anti-smoking intervention. (Excerpt from an interview conducted by Mt Baker Vapor, 2015, October 12) [emphasis added]

SFATA, in their comments to the FDA’s proposed regulations, also noted:

“Given the potential for harm reduction that e-cigarettes may offer, it would be a serious mistake in public health policy and contrary to FDA’s commitment to reduce tobacco harm, to take any regulatory action that would have the reverse effect.” (SFATA, 2014, August 8: 11)

E-cigarettes as a harm reduction alternative gained increased currency during the third period with the publication of the PHE report (McNeill et al., 2015: 80) concluding e-cigarettes to be around “95% safer than smoking”, a phrase widely used by social groups advocating for e-cigarettes in the US. This discourse of harm reduction was also implicated in materiality, as the nicotine delivery mechanism (employing a heating device to vaporize liquid nicotine) used in e-cigarettes enabled a cleaner means of nicotine delivery vis-à-vis tobacco cigarettes. In summary, surfacing harm reduction sanitized e-cigarettes by presenting the product as a substantially cleaner alternative to tobacco cigarettes, and constituted the possibility of significant reductions in disease and mortality associated with cigarette smoking.

Finally, claiming differential regulation consisted of actions initiated by e-cigarette entrepreneurs seeking different regulatory treatment of e-cigarettes compared to combustible tobacco cigarettes. These actions gained steam at the end of the second period, after the FDA proposed regulations to regulate e-cigarettes as a tobacco product. Social groups called for differential regulation of e-cigarettes highlighting fundamental differences in the technology and risk profile of e-cigarettes vis-à-vis tobacco cigarettes. For example, Purebacco, an independent
e-cigarette company commenting on the FDA’s proposed regulations, observed the regulations were “not designed to address a technology based solution to combustible tobacco” (Purebacco, 2014: 2). Other independent e-cigarette companies pointed to the prohibitive costs of complying with the proposed regulations, which according to them, only benefitted tobacco companies selling ‘cig-a-like’ devices. E-cigarette trade associations and advocacy groups such as SFATA and CASAA also invoked metaphors such as ‘technology products’ and ‘vapor products’ to problematize the proposed regulations for e-cigarettes as a tobacco product. Arguing that e-cigarettes were being “shoehorned into Tobacco Control” (Source: Notes taken during advocacy session at an industry trade show), this group issued business and consumer ‘calls to action’ to petition legislative and federal officials to prevent ‘over-regulation’ of the product category under the Tobacco Control Act (Source: www.sfata.org; www.casaa.org).

Such calls for differential regulations are also implicit among scientists advocating harm reduction. For example, at SRNT’s 2016 Annual Meeting in Chicago, Dr. Ann McNeill, the lead author of the abovementioned PHE report, presented a themed lecture titled “A failure of mission—distinguishing nicotine from tobacco” (Source: Scientific conference notes). In her lecture, Dr. McNeill called upon the scientific community to “work in partnership” despite their differences, by encouraging the use of less harmful devices such as e-cigarettes towards the end goal of making tobacco cigarettes obsolete. Given that science informs regulatory policy, this was a significant appeal to consider differential regulatory treatment of e-cigarettes vis-à-vis tobacco cigarettes. Such initiatives for differential regulation continue to be undertaken by e-cigarette entrepreneurs and advocacy groups through recourse to legislative and legal actions,

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6 One such initiative is the FDA Deeming Authority Clarification Act of 2017 (also called Cole Bishop Amendment) seeking to change the predicate date of the Tobacco Control Act to enable all e-cigarettes on the market as on August 8th 2016 (i.e. the effective date of the FDA’s regulations) to be grandfathered, and hence exempt from
even as the FDA has issued regulations for e-cigarettes as a tobacco product. Thus, *claiming differential regulation* was a sanitizing initiative aimed at dissociating e-cigarettes from the regulatory framework for stigmatized tobacco cigarettes in the pursuit of more ‘reasonable’ regulations for the emerging product category.

Overall, the abovementioned four sanitization initiatives constitutive of the *categorical work of sanitization*, worked to discursively establish e-cigarettes as a sanitized substitute to combustible tobacco cigarettes. *Comparing and contrasting* with tobacco cigarettes initially enabled e-cigarettes to gain acceptance amongst smokers as a ‘convenient’ alternative to tobacco cigarettes; this was followed by dissociation as a new category of ‘vapor’ products. *Highlighting detachment possibilities* and *surfacing harm reduction* established e-cigarettes as a product to wean smokers from tobacco cigarettes, towards a healthier alternative. During the third period, in the wake of looming regulations of e-cigarettes as a tobacco product, sanitization initiatives also sought to claim *differential regulations* for e-cigarettes vis-à-vis tobacco products. These sanitization initiatives were also inextricably linked to the underlying materiality of e-cigarettes. The delivery mechanism of e-cigarettes, including the use of liquid nicotine and flavors enabling nicotine delivery in a cleaner and more appealing form vis-à-vis tobacco cigarettes, opened up the discursive possibilities for the abovementioned sanitization initiatives by social groups.

**Categorical work of stigmatization.** Offering contrasting arguments to the sanitization initiatives discussed above, I identified four stigmatization initiatives, namely *illegitimating category, highlighting addiction and initiation possibilities, advocating precaution*, and *enfolding into existing regulations (for stigmatized products).*

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FDA’s regulatory approval process. However, at the time of writing, this initiative has not met with success (Source: www.vapingpost.com)
**Illegitimating category** comprised of actions calling attention to the ‘unauthorized’ and ‘unregulated’ status of e-cigarettes. During the first period, the FDA issued ‘import alerts’ and detained e-cigarette shipments calling them ‘unauthorized’ ‘drug device combination’ products (Source: www.fda.gov). Enforcement action by the agency against five e-cigarette companies in September 2010 for ‘violating’ provisions of the FD&C Act, was another instance of illegitimating the emerging category (FDA, 2010, September 8). In a letter to the Electronic Cigarette Association, an early trade associations of the e-cigarette industry, the FDA called upon e-cigarette companies to ‘lawfully’ market their products in the US:

“Firms which introduce these products into the marketplace will have to comply with the FDCA, including the drug approval process as explained below. FDA invites electronic cigarette firms to work in cooperation with the agency toward the goal of assuring that electronic cigarettes sold in the United States are lawfully marketed.” (FDA, 2010, September 8: 1)

During the second and third period, public health groups yet again drew attention to the ‘unregulated’ status of the e-cigarette market calling it the “wild, wild West”, characterized by activities such as the rampant promotion of e-cigarettes using themes reminiscent of tobacco cigarette promotion. As Matthew Myers, president of Campaign for Tobacco-Free Kids, observed:

“In the absence of any meaningful regulation, the e-cigarette manufacturers have acted as if it's the wild, wild West, with no rules and no restraints...Their advertising is exactly the same type of advertising that made cigarettes so appealing to young people.” (Dennis, 2014, April 24) [emphasis added]

Highlighting another facet of the unregulated market implicating user safety issues, and speaking to the materiality of e-cigarettes, including the batteries being used, Mitch Zeller, Director of the Center for Tobacco Products, FDA, observed:

“But when it comes to e-cigarettes, it's the wild, wild West. We have e-cigarettes that are exploding in car chargers and wall sockets…it's buyer beware.” (FDA, 2014, April 24)
The metaphor ‘wild, wild West’ used by public health groups and the FDA to describe the product category, was picked up and widely used in the news media, further illegitimating the category. Indeed, Tan and Bigman (2014) point to the media attention given to the unregulated status of e-cigarettes, as a possible explanation for the worsening perception of e-cigarettes, even as awareness of these products continued to rise in the US. Thus, illegitimating category was a stigmatization initiative which distanced e-cigarettes from both normative and regulatory approval (Scott, 1995), and also strengthened the grounds for other stigmatization initiatives discussed below.

**Highlighting addiction and initiation possibilities** was a stigmatization initiative associating e-cigarettes with initiation into nicotine and other tobacco products. While this theme surfaced across the three periods, it gained much resonance during the second and third periods with the publication of reports by the CDC raising concerns on increasing e-cigarette use among youth (Source: www.cdc.gov). The CDC and other public health groups associated the trend of rising e-cigarette use among youth with the potential for nicotine addiction and cigarette use, and used metaphors such as ‘gateway to smoking’ and ‘Trojan horse’ of nicotine to describe e-cigarettes (Esterl, 2013, December 19, 2013, September 25; Gara, 2014, March 4). CDC Director Tom Friedan, in a media briefing in 2015, noted:

“We’re concerned that there are multiple aspects of e-cigarette use that are concerning that includes addiction to nicotine...and the significant likelihood that a proportion of those who are using e-cigarettes will go on to use combustible-cigarettes.” (CDC, 2015, April 16) [emphasis added]

Despite data from the 2014 National Youth Tobacco Survey also reporting falling cigarette use among youth, public health groups continued to stigmatize e-cigarettes. Matthew L. Myers, President, Campaign for Tobacco-Free Kids, called e-cigarettes a “new generation of
tobacco products” that was threatening tobacco control efforts by addicting new users, especially youth:

“The dramatic decline in youth cigarette smoking is terrific news for our nation’s health and shows that the fight against tobacco is winnable if we do what we know works. However, the skyrocketing use of e-cigarettes is frightening and threatens this progress…We cannot allow the tobacco industry to keep addicting kids and create another epidemic with a new generation of tobacco products.”

(Campaign for Tobacco-Free Kids, 2015, April 16) [emphasis added]

In October 2015, the CDC further declared e-cigarettes an “emerging public health challenge” that could “promote nicotine addiction, and lead to sustained tobacco use” (Source: www.cdc.gov).

Countering the material-discursive possibilities constituted by those engaged in sanitization efforts, social groups also highlighted the addictive nature of nicotine on the adolescent brain and demanded a ban on flavors, identifying them as the leading cause for increasing youth uptake of e-cigarettes. In their letter to the FDA, twenty-five public health agencies, citing the 2014 CDC report on the doubling of e-cigarette use among high-school students, pointed to “the use of sweet and fruity flavors in e-cigarettes” as a major reason for increasing e-cigarette use among youth (American Academy of Family Physicians et al, 2014, August 8: 48). Scientists advocating precaution also found youth experimentation with e-cigarettes related to the availability of a large selection of flavors (Ambrose et al., 2015; Kong, Morean, Cavallo, Camenga, & Krishnan-Sarin, 2015; Pepper, Ribisl, & Brewer, 2016).

These stigmatization initiatives are still ongoing with the US Surgeon General declaring e-cigarettes “an emerging public health threat among youth and young adults” (Source: www.surgeongeneral.gov) even as studies have also found high school kids mainly using “just flavoring” without nicotine in their e-cigarettes (Miech, Patrick, O’malley, & Johnston, 2016).
To summarize, highlighting addiction and initiation possibilities stigmatized e-cigarettes by countering claims of detachment and surfacing possibilities for addiction to nicotine and other tobacco products, among a new generation of users, especially youth.

*Advocating precaution* comprised stigmatization initiatives to reveal the potential dangers from e-cigarette use. During the first period, laboratory examination of e-cigarette samples by the FDA found “detectable levels of known carcinogens and toxic chemicals” (FDA, 2009, July 22). Based on these findings, the FDA and public health groups warned consumers that e-cigarettes “may contain ingredients that are known to be toxic to humans” (FDA, 2009). During the second and third periods, scientists cautioned that e-cigarette emissions were “not merely “harmless water vapor”” (Grana, Benowitz, & Glantz, 2014: 1983), and reported the detection of harmful chemicals such as formaldehyde (Jensen et al., 2015) and diacetyl (Allen et al., 2016) in e-cigarette aerosols. The CDC, analyzing data from calls to poison centers (between September 2010 and February 2014), also warned the public that e-cigarettes had the “potential to cause acute adverse health effects” even though calls related to e-cigarettes were at lower levels than calls for cigarette poisoning (Chatham-Stephens et al., 2014). Thus, unlike harm reduction discourse which was associated with the removal of carcinogens, the precautionary discourse emphasized other harmful carcinogens present in e-cigarettes.

These studies and reports advocating precaution were also widely carried in the news media with titles such as “Before you vape: High levels of formaldehyde hidden in e-cigs” (NBC News, 2015, January 21); “Calls to poison centers about e-cigarettes have surged” (Dennis, 2014, April 3); “Selling a poison by the barrel: Liquid nicotine for e-cigarettes” (Richtel, 2014, March 24) etc., further amplifying the potential health dangers associated with e-cigarettes. Indeed, (Majeed et al., 2017: 335-336) found that between 2012 and 2015, perceptions that e-
cigarettes were “equally or more harmful” than tobacco cigarettes, increased among US adults surveyed. They attributed this trend, among other factors, to confusing “relative risk” because of the frequent reporting of adverse incidents in the media.

While groups advocating harm reduction recommended the use of e-cigarettes, social groups adopting a precautionary frame of reference recommended the use of FDA approved nicotine replacement therapies (such as nicotine patches and gums) deemed “safe and effective” to “quit” smoking (Source: www.lung.org). A policy scientist in the area of tobacco control mentioned to me that those advocating a precautionary approach resisted the idea of harm reduction using e-cigarettes due to their “abstinence-only” viewpoint characterized by:

“…a very strong moralistic orientation…seeing the world in black and white, right and wrong, absolutes…[and] wanting everybody to totally quit [smoking]… afraid that if you offered them an alternative they might not totally quit.”
(Interview, Policy Scientist) [emphasis added]

Another informant, a tobacco policy consultant, mentioned to me that prior misleading claims of tobacco cigarette companies, such as the lower health risks from ‘light’ and ‘ultra-light’ cigarettes (Hsu & Grodal, 2015; Pollay & Dewhirst, 2002; Shiffman et al., 2001), had made public health agencies adopt a precautionary approach towards e-cigarettes. He noted:

“A lot of the problems that exist are historic. Tobacco companies deceived the American public. They denied that their products killed people… Even though the mounting evidence was so clear that what they were doing was producing products that killed people. This goes back decades… So what you’re talking about with the development of potentially less harmful products, one thing that many in public health will say is, ‘We've been down that road.’ The companies duped us with the concept with low tar and low nicotine cigarettes and we will never allow that to happen again… So what you can show, the company is developing e-cigarettes and talking about non-combustible tobacco products, which are lower in risk, there’s a resistance on the part of my colleagues in public health to accept that or to trust the companies in those endeavors… My colleagues in the public health community just can't let go of the past.” (Interview, Tobacco Policy Consultant)
Thus, not just developments in the present but also “past encumbrances” (Garud, Gehman and Karnøe, 2010) informed the precautionary approach. For these groups, accepting harm reduction claims meant “being duped by the industry...to take back lost ground in the long battle over smoking” (Fairchild & Bayer, 2015: 375). Such a precautionary approach has also influenced FDA regulations on e-cigarettes “due to their potential for public harm” (U.S. Department of Health and Human Services, 2016a: 28983). In summary, advocating precaution stigmatized e-cigarettes by emphasizing their potential for harm going beyond any possible benefits.

Finally, enfolding into existing regulations comprised of actions by social groups to regulate e-cigarettes in the category for tobacco products, under the Tobacco Control Act. These initiatives took off during the second period after the judiciary advised the FDA to regulate e-cigarettes as a tobacco product. Following this mandate, public health groups engaged in stigmatization initiatives to urge the FDA to apply the “full scope of statutory provisions applicable to ‘tobacco products’” to e-cigarettes (American Academy of Family Physicians et al, 2014, August 8: 5), and state lawmakers continued to pass legislation extending tobacco cigarette smoke-free laws to e-cigarettes (Dennis, 2014, April 24). Scientists advocating precaution also made a case for extending smoke-free policies to e-cigarettes (e.g., Gourdet, Chriqui, & Chaloupka, 2014; Grana et al., 2014). These calls to treat e-cigarettes as a conventional ‘tobacco product’ collectively informed the FDA’s actions, and the agency in its final regulations, adopted the tobacco products’ premarket authorization standards, for e-cigarettes. Thus, enfolding into existing regulations stigmatized e-cigarettes by bring them under the purview of existing regulations designed for tobacco cigarettes.
Overall, the abovementioned four stigmatization initiatives constitutive of *categorical work of stigmatization* sought to stigmatize e-cigarettes. *Illegitimating category* problematized the ‘unregulated’ status of e-cigarettes. *Highlighting addiction and initiation possibilities* stigmatized e-cigarettes as potentially leading to nicotine addiction and the use of tobacco products. *Advocating precaution* countered the discourse of harm reduction by highlighting the potential dangers from e-cigarette use and advocating an ‘abstinence only’ approach towards e-cigarettes. Finally, *enfolding into existing regulations* stigmatized e-cigarettes by regulating them as a tobacco product. Here too, the materiality of e-cigarettes opened the discursive possibilities for these stigmatization initiatives. However, in marked contrast to the sanitization initiatives undertaken, the materiality of e-cigarettes was problematized by social groups highlighting the potential for nicotine addiction, exposure to carcinogens, and ‘gateway’ into tobacco products.

Building on the second order themes related to the sanitization and stigmatization initiatives being undertaken, I next present an analytical account of how the interactions amongst the different social groups shaped the product category’s emergence across the three periods.

**Second Order Findings: Analytical Summary of Emergence Process**

The category’s emergence over the three periods was characterized by three analytically distinct phases of category contestation, category growth and backlash, and category enfolding into stigmatized category. I next describe each of these three phases in terms of the second order themes related to the categorical work of sanitization and stigmatization, which in interaction shaped the product category’s emergence.

**Category contestation (Period 1).** During the first period, entrepreneurs engaged in the categorical work of sanitization by first *contrasting* e-cigarettes as a convenient ‘smoke-free’ alternative to tobacco cigarettes. They did so to legitimize e-cigarettes among smokers as a
recognizable alternative to cigarettes. Entrepreneurs also indicated the product’s potential for *harm reduction*, and consumers began sharing stories of *detachment possibilities* from cigarettes. These initiatives at sanitization were, however, countered by the FDA which took steps for *illegitimating* the category as unauthorized ‘drug device combination’ products. Public health groups also highlighted *addiction and initiation possibilities* into nicotine and cigarettes from e-cigarette use, and started *advocating precaution*, warning consumers about the potential health risks from products yet to be proven safe. Amidst these developments, a categorization battle ensued between the FDA and entrepreneurs who challenged the FDA’s framing of e-cigarettes. The judiciary, weighing in on this issue and guided by precedents, opined that e-cigarettes be regulated as a tobacco product.

**Category growth and backlash (Period II).** The settlement provided by the judiciary was only temporary, as it led to further categorical work of sanitization and stigmatization during the second period. Given the defeat of the FDA’s attempt to regulate e-cigarettes as a ‘drug device combination’ product, the category remained unregulated. The absence of regulation spurred material innovation in the form of new designs and flavors, and entrepreneurs engaged in *contrasting* e-cigarettes with cigarettes to establish a distinct framing for e-cigarettes as ‘vapor’ products. Sanitization initiatives also continued through consumer testimonials and scientific studies highlighting *detachment possibilities* from e-cigarette use. The discourse of *harm reduction* also found support in scientific studies which emerged during this period, furthering support for entrepreneurial claims of reduced risk from e-cigarette use. The product category’s growth was however, met with a backlash from social groups which yet again opposed these sanitization initiatives through the categorical work of stigmatization. Regulators, public health groups and lawmakers together stigmatized e-cigarettes by *illegitimating* the category as an
unregulated ‘wild, wild West’, and attributed possibilities of youth *addiction and initiation* into nicotine and other tobacco products. In addition, scientists *advocating precaution* cautioned about the presence of dangerous carcinogens in e-cigarettes. These stigmatization initiatives culminated in the FDA proposing regulations towards *enfolding* e-cigarettes *into existing regulations* for stigmatized tobacco products. In response, social groups engaged in sanitization mobilized forces for the *differential regulation* of e-cigarettes as a ‘vapor’ product.

**Category enfolding into stigmatized category (Period III)**. During the third period, the categorical work of sanitization and stigmatization became increasingly deployed through science. Science was called upon by the FDA to provide “more information on e-cigarettes and the public health” (Source: www.fda.gov). However, scientists were themselves divided on this issue depending on whether they took a precautionary or harm reduction approach. Scientists committed to *advocating precaution* emphasized the potential dangers of e-cigarettes due to the exposure to dangerous carcinogens, while those committed to *harm reduction* emphasized the potential benefits from e-cigarettes as a reduced risk alternative. Other social groups sided with the science that aligned with their own frames of reference. Social groups engaged in stigmatization initiatives echoed studies *advocating precaution*, and continued to stigmatize e-cigarettes *illegitimating* the category over its unregulated status, focusing on its potential for youth *addiction and initiation* into nicotine and tobacco products. These groups urged the FDA to apply the ‘full scope’ of the Tobacco Control Act to e-cigarettes, recommending that smokers use FDA approved nicotine patches and gums to quit smoking. E-cigarette entrepreneurs, on the other hand, highlighted the science of *harm reduction*, and continued to sanitize e-cigarettes.

*Contrasting* with cigarettes was undertaken by entrepreneurs to distinguish e-cigarettes as a ‘vapor’ product different from ‘tobacco’, and consumers and scientists also continued to
highlight the *detachment possibilities* offered by e-cigarettes. Entrepreneurs also engaged in sanitization efforts to claim *differential regulation* for e-cigarettes. The FDA however, guided by the concerns of public health groups, wrote regulations *enfolding e-cigarettes into existing regulations* for tobacco products, thereby constituting the market in favor of larger intrapreneurial firms.

Thus, the category’s emergence across the three periods was driven by interactions between social groups engaged in the categorical work of sanitization and stigmatization. Social groups deployed various strategies associated with sanitization and stigmatization across the three periods, and the outcomes of their interactions at each period shaped future initiatives and interactions.
CHAPTER 5
DISCUSSION

I began this study by asking: *How do new product categories emerge within stigmatized industries?* To answer this question, I studied the emergence of e-cigarettes as a new product category in the stigmatized US tobacco cigarette industry. My analysis of the data highlighted the participation of multiple social groups with different frames of reference (Bijker et al., 1987) driving the category’s emergence. However, such interactions among social groups did not produce a consensus about the category, but instead generated a process fraught with contestation. It was through such contestations that the new product category emerged.

Illustrating the category’s equivocality, social groups attached different labels to the category based on their own frames of reference (Bijker et al., 1987). Entrepreneurs labelled the e-cigarette as a ‘smoke-free’, ‘vapor’ alternative to the traditional combustible cigarette. For regulators, the product was an unauthorized ‘drug device combination’ or a ‘tobacco’ product. This interpretive flexibility (Pinch & Bijker, 1987) was on account of social groups making sense of the emerging category by contextualizing the phenomenon (Pepper, 1942) from their own experience within their communities of practice (Lave & Wenger, 1991; Wenger, 1998). Thus, at one level, the labels used by social groups functioned as ‘constative utterances’ (Austin, 1962), i.e., naming the category from within their own unique contexts.

Such constative utterances however, also had performative implications (Austin, 1962) as they implicitly or explicitly took on evaluative connotations (Bowker & Star, 1999) by infusing the category labels with different dimensions of worth (Boltanski & Thévenot, 2006). For example, because it was labelled as a ‘smoke-free’, ‘vapor’ product, evaluative claims of reduced risk vis-à-vis tobacco cigarettes became attached to it. The labels ‘drug device combination’ or
‘tobacco’ product similarly invoked evaluation considerations related to ‘safety and efficacy’ or ‘public health’ protection. Thus, the descriptive labels used by social groups also functioned to qualify and imbue the category with signification (Callon, Méadel, & Rabeharisoa, 2002) based on their own evaluative considerations.

In the process of such signification, social groups directly or indirectly engaged in categorical work (Bowker & Star, 1999) of sanitization or stigmatization. They did so by associating and dissociating with different material-discursive elements (Callon, 1991; Garud et al., 2010) to either sanitize or stigmatize the new product category. Entrepreneurs sanitized e-cigarettes by associating them with material properties such as the reduction in carcinogens, and by engendering discourses around smoking cessation and harm reduction among smokers. The actions of regulators and public health groups, on the other hand, stigmatized e-cigarettes by associating them with the material flavors being used, and the discourses they engendered with regard to potential youth initiation and smoking renormalization. Thus, each group selectively associated with (and dissociated from) the different material-discursive elements involved to either sanitize or stigmatize the product.

In this regard, Douglas (1966) observed that what is clean or dirty and hence sanitized or stigmatized does not always depend on ‘objective’ material properties and ‘rational’ considerations about hygiene. For example, Douglas (1966) noted that cow-dung is considered a pollutant in most contexts, but it is used in Indian villages to wash and purify the feet of holy men. However, adding to Douglas’s observations, such sanitization or stigmatization may not necessarily be dichotomous within a given context, as interacting social groups may create multiple contexts drawing on different material-discursive elements, thereby simultaneously sanitizing and stigmatizing the category in a kaleidoscopic way.
As a consequence, any framing offered by one social group generates its own overflows (Callon, 2010), compelling other social groups to respond, thereby leading to contestation. Such contestations, however, are spread out over time, inviting the participation of other social groups, such as the judiciary and scientists, to adjudicate on the claims and counter-claims being made.

However, groups such as the judiciary and scientists are themselves not ‘objective’ arbitrators since they are guided by their own frames of reference. The judiciary, for example, guided by legal precedents, called for regulation of e-cigarettes as a tobacco product, thereby limiting the capacity to bring the category under regulation as a drug. While this formed the basis of a temporary settlement, it also led to the anticipation of tobacco control regulations which then became a source of further contestation.

Opinions were also divided among the scientists called in to inform the regulatory process, depending on whether they took a ‘precautionary’ or a ‘harm reduction’ approach. Those advocating harm reduction claimed e-cigarettes to be ‘95% safer than smoking’ (McNeill et al., 2015), while those advocating precaution pointed to the presence of harmful chemicals such as formaldehyde and diacetyl (e.g., Allen et al., 2016; Jensen et al., 2015). Instead of resolving conflicts, such contending claims generated further contestation by offering ‘scientific’ support to both groups engaged in sanitizing or stigmatizing the category, and it was in their interactions that the category emerged over time.

After zooming into the dynamics of new category emergence through the interactions amongst different social groups, I will now zoom out to discuss a more general model of new product category emergence in stigmatized industries.
Process Model of New Product Category Emergence in Stigmatized Industries

Externalities emerge in the use of products in any industry (Coase, 1960), which can then lead to their stigmatization. This was the case with the tobacco cigarette industry, which became stigmatized due to the negative health consequences associated with smoking. This is also the case with many other industries such as the fossil fuel industry on account of environmental concerns, and the beverage industry which produces sugared carbonated drinks deemed to be unhealthy.

Such stigmatization of an industry is problematic as it can lead to its demise. However, as the tobacco cigarette industry case that I have examined illustrates, the associated stigma can also serve as an opportunity for new product categories such as e-cigarettes to emerge that address the stigma. But these initiatives to sanitize also do not go uncontested, as countervailing forces of stigmatization get activated to stigmatize the new product category.

Figure 12 in Appendix B presents a generalized model for new product category emergence in stigmatized industries that has resulted from this study. As the figure illustrates, a dialectical model of change (Van de Ven & Poole, 1995) drives the emergence of new product categories in stigmatized industries. This model of change is characterized by the participation of multiple “entities espousing opposing thesis and antithesis that collide to produce a synthesis, which in time becomes the thesis for the next cycle of a dialectical progression” (Van de Ven & Poole, 1995: 520-521). Going beyond the recognition of a dialectical model at play, the findings from this study also throw light on when and how the model operates and the underlying mechanisms.

As illustrated in the figure, stigmatized industries present opportunities for forces of sanitization (thesis) through categorical work to sanitize and constitute a new product category to
address the stigma. However, such initiatives face opposition in the form of countervailing forces of stigmatization (anti-thesis), which engage in categorical work to stigmatize the new product category. The outcomes of these contestations (new-thesis) over time determine the category’s emergence. These outcomes, as this case illustrated, are not stable settlements, but instead set the stage for renewed contestations over other critical events shaping the category’s trajectory. Thus, the dialectical model of new product category emergence in stigmatized industries is not a one-shot process but is ongoing in a performative sense, involving multiple cycles of interactions between different social groups engaged in categorical work of sanitization and stigmatization emphasizing different material-discursive-discursive elements. Any settled state of affairs regarding the category’s meaning and status is temporary, as associations with existing material-discursive-discursive elements get refreshed, and associations with other material-discursive-discursive elements get forged over such interactions (Garud et al., 2010; Garud et al., 2017b).

Figure 13 in Appendix B is an application of this general model to the tobacco cigarette industry case. As previously described, the new product category has been emerging over cycles of contestation between the ongoing forces of sanitization and stigmatization. As shown in Figure 13, these contestations led to different outcomes for the category, which in turn prepared the ground for further categorical work of sanitization and stigmatization in the ensuing period. These relational and temporal interactions were not just limited to social groups but also implicated materiality, as the material additions and subtractions provided the discursive possibilities for social groups to engage in their categorical work. Social groups emphasized different material-discursive elements to either sanitize or stigmatize the new product category resulting in polyvocality around the category’s meaning, which led to continued contestation. Overall, the dialectical model of new product category emergence in stigmatized industries is a
model of relational and temporal emergence. The category’s emergence involved the participation of multiple social groups and material elements. The product category’s designation as either sanitized or stigmatized by opposing social groups became the basis for contestation and drove ongoing interactions shaping the category’s trajectory over time.

*How do these mechanisms differ from new product category emergence within mainstream industry settings?* The findings from this study suggest that in stigmatized industries, drawing on the schemas of existing products poses a paradox. While on the one hand, linking with schemas of existing products is necessary to appeal to existing users of the stigmatized product (it seeks to attract by offering an alternative product), on the other hand, such associations once initiated lead to stigma being transferred to the new product category itself. As the tobacco cigarette industry case illustrated, entrepreneurs were initially successful in comparing and contrasting e-cigarettes with tobacco cigarettes to appeal to current smokers. However, such associations with cigarettes also became problematic. The rapid growth of the e-cigarette product category was perceived by regulators and public health groups alike, to potentially lead youth into the use of other tobacco products including cigarettes. The new product category of e-cigarettes thus became a contentious dialectical object invoking contradictory forces of sanitization and stigmatization.

This dialectical model of new product category emergence could also be used to explain category emergence in other settings that are getting stigmatized. One such example is the beverage industry which has been stigmatized for the negative health effects from sugared carbonated drinks. To address the stigma, the industry created new product categories such as the ‘diet’ brand of sodas. However, such offerings are also being re-stigmatized due to the use of artificial sweeteners such as aspartame. Now, companies are engaged in initiatives to sanitize by
removing these contentious material elements. But such actions are also generating a backlash for other reasons such as unpalatable taste (Taylor, 2016). Indeed, these dynamics of sanitization and stigmatization are ongoing.

**Contributions**

The findings from this study hold several implications for management literature on categories, stigmatized industries and technology entrepreneurship. In the next part of this chapter, I discuss these implications. I will conclude by highlighting some of the boundary conditions and limitations of this study.

**Contribution to the literature on categories.** Management scholars studying categories have recently emphasized the need to go beyond the conceptualization of categories as stable systems, and to pay attention to its dynamic structuring (e.g., Garud et al., 2010; Glynn & Navis, 2013; Kennedy & Fiss, 2013). In this stream of research, scholars have studied the importance of processes such as linguistic recombination of previously unconnected familiar labels (such as ‘mini’ van, ‘personal’ computer, ‘electronic’ books etc.) in the category formation process (Grodal et al., 2015; Navis & Glynn, 2010). Scholars have highlighted how such a recombination may lead to “optimal distinctiveness” (Brewer, 1991) of the new category by conveying to stakeholders “both the novelty of the category and its relationship to preexisting ones” (Grodal et al., 2015: 429; Hargadon & Douglas, 2001; Navis & Glynn, 2010).

E-cigarettes also brought together two familiar and previously unrelated symbols, ‘e’ and ‘cigarettes’. However, the association with stigmatized labels such as ‘cigarettes’, while effective in making the product recognizable and acceptable among consumers, also invoked suspicion and hostility among other social groups such as regulators and those involved with public health. Hence, these findings suggest that cognitive legitimacy (Aldrich & Fiol, 1994; Suchman, 1995)
by way of increased recognition may not be necessarily beneficial, but may create negative perceptions as associations with prior stigmatized products become more salient. In the context of stigmatized industries, optimal distinctiveness of the new product category by drawing on existing stigmatized products might not be possible, as the new product category needs to contend with opposing stigmatization forces as soon as any association with the focal stigmatized product gets invoked. These findings also highlight the stigmatizing effects of product labelling (Ellen & Bone, 2008). While, Ellen and Bone (2008) found that labelling a product as ‘No GM’ contributed to stigmatizing the GM product category, in the context of e-cigarettes, the label ‘cigarettes’ in ‘e-cigarettes’ transferred stigma to the new product category. Perhaps on account of these considerations, de novo labels such as ‘vapor’ are now being used to label the e-cigarette product category as different from ‘tobacco’ products.

Scholars examining category emergence processes have also studied how social groups import new material elements to theorize their new product offerings (e.g., Durand & Khaire, 2017; Jones et al., 2012; Rao et al., 2005). For example, while the category of nouvelle cuisine imported new culinary ingredients (Rao et al., 2005), modern architecture imported new building materials (Jones et al., 2012). The present study adds to this conversation by highlighting how the import of new materials can not only be the basis of opportunity for the category’s growth, but can also lead to unintended undesirable consequences. For example, the use of flavors in e-cigarettes to make the product more palatable among smokers, also led to unintended consequences of under-age youth use and experimentation of these products, inviting a backlash from powerful social groups. Thus, the findings of this study present a more nuanced understanding of the role of materiality in providing both ‘resistance and accommodation’ to the category emergence process (Pickering, 1993).
Overall, the findings from this study contribute to the categories literature by revealing a dialectical model of category emergence through the forces of sanitization and stigmatization. The findings showed how category emergence was distributed, involving the participation of multiple social groups who imbued the constituent material elements with different meanings. As these meanings were evaluative with regard to the product’s sanitization or stigmatization, social groups faced insurmountable challenges in translating (Callon, 1986) their initiative to opposing groups, and the category’s emergence was shaped by continued contestation. Hence, in contrast to mainstream settings where opposing social groups might recant their positions to arrive at a consensus (Jones et al., 2012), the findings from this study in the context of stigmatized industries show that because such contestations are also “fraught with moral weight” (Bowker & Star, 1999: 6) they become more acute and difficult, if not impossible, to resolve. The findings from this study consequently problematize notions that category meanings converge to stability (Grodal et al., 2015), highlighting instead the contested nature of categorization processes with any settlements being at best temporary and the basis for renewed contestation (Bowker & Star, 1999; Garud et al., 2010; Garud et al., 2017b).

**Contribution to the literature on stigmatized industries.** The findings of this study also contribute to the growing management literature on stigmatized industries (e.g., Durand & Vergne, 2015; Hampel & Tracey, 2016; Vergne, 2012). In prior studies, scholars have focused on how organizations in stigmatized industries manage the consequences of stigma through tactics such as shielding the stigmatized activity (Hudson & Okhuysen, 2009), straddling multiple categories (Vergne, 2012) or co-opting stigmatizing labels (Helms & Patterson, 2014). The present study contributes to the recent work focused on understanding initiatives to eradicate stigma (e.g., Hampel & Tracey, 2016). E-cigarettes represented a new product category to
eradicate the stigma associated with tobacco cigarettes. Entrepreneurs attempted to scrub away the stigma associated with cigarettes through categorical work of sanitization highlighting harm reduction benefits, the possibilities for quitting cigarettes, as well as associating with new schemas around ‘vapor’ products. These findings are in line with recent studies that have suggested the use of more active strategies to encounter stigma by refusing to “accept any wrongdoing or shame about its activities, and instead focus[ing] on why it is virtuous” (Hampel & Tracey, 2016: 41). Indeed, in the case of e-cigarettes too, social groups revealed positive social benefits such as the product enabled smokers to quit, and was ‘95% safer’ than tobacco cigarettes (McNeill et al., 2015).

However, such destigmatization initiatives also gave rise to opposing stigmatization initiatives. For example, attempts at destigmatization through the discourse on harm reduction were countered with the discourse on precaution. Arguments for differential regulation of e-cigarettes on account of its lower risk profile were resisted by regulators who formulated regulations for the product as a ‘tobacco’ product. These findings suggest that destigmatization initiatives may not be a straightforward process, and initiatives such as allying with stigmatizers (Hampel & Tracey, 2016) or correcting the stigma held by audiences (e.g., Helms & Patterson, 2014) may be much more difficult to achieve, especially when tenuous links with the focal stigmatized product need to be maintained. As the e-cigarettes case illustrated, the process of being attached to the stigmatized product, while at the same time scrubbing away stigma being transferred, soon becomes an uphill task.

Stigma ultimately crystallizes in the form of social sanctions. While acknowledging this, the study also highlights the underlying material basis for stigmatization. The materiality of e-cigarettes manifested in the nicotine and flavorings used contributed to stigmatizing the category
as much as any ‘social’ initiatives from opposing groups. Indeed, materiality was also central to
the sanitization initiatives being carried out through the removal of many harmful carcinogens in
cigarette smoke. Hence, this study also contributes to the literature on stigmatized industries by
making salient the role of materiality in the unfolding dynamics of stigmatization and
sanitization.

Overall, the findings from this study highlight the social and material basis of stigma.
Opposing social groups coupled with (and decoupled from) different material-discursive
elements, and in the process attached stigma to (or scrubbed stigma from) the new product
category. The findings thus present a contextualized understanding of stigma, going beyond a
binary understanding, as being either completely present or absent. E-cigarettes, as this case
illustrated, were neither completely stigmatized nor sanitized, as interacting social groups
emphasized different material-discursive elements to both simultaneously stigmatize and sanitize
the new product category.

Contribution to the literature on technology entrepreneurship. The findings from this
study contribute to the technology entrepreneurship literature (Beckman et al., 2012; Garud &
Karnøe, 2003; Shane & Venkataraman, 2003) that views entrepreneurship as a distributed
process. In line with this perspective, the findings show that entrepreneurial opportunity resides
neither in the discursive actions of entrepreneurs nor in the material properties of the technology.
Instead, it is constituted through the interactions of multiple social groups and the material
elements that become implicated. For example, this study showed that entrepreneurs, regulators,
scientists, and public health groups among others, played an important part in constituting the
new product category through their interactions with each other and the material artifact. Overall,
these findings speak to the relational dimension of entrepreneurial opportunity.
Related to the observation above, the study also highlights the dynamic interplay between entrepreneurs and regulators. Indeed, the study shows that entrepreneurs did not attend to preexisting regulatory gaps to comply with regulatory expectations (Huising & Silbey, 2011), but continued to exploit regulatory voids, which invited regulatory action from the Food and Drug Administration (FDA). Such actions were also further contested by entrepreneurs, and in the ensuing contestation, regulatory oversight for the category was forced to shift from a ‘drug device combination’ product to a ‘tobacco’ product, buying more time for entrepreneurs to grow the product category. Thus, rather than ‘mindful governance’ of regulatory gaps, the dynamics highlight the contested shaping of regulatory gaps and the spillovers involved during the process of opportunity constitution. These dynamics between entrepreneurs and regulators are still continuing; the advent of regulations, which now favors intrapreneurs (i.e., tobacco cigarette companies) over small businesses, continues to be contested through lawsuits and legislative initiatives as was mentioned earlier.

The study also highlighted that opportunity constitution was not just relational but also temporal. Specifically, entrepreneurial claims generated reactions from various social groups, which influenced subsequent actions. I highlighted these dynamics through the analysis of critical events over time, and documented how such critical events shaped future entrepreneurial initiatives in important ways. Thus, entrepreneurial opportunities resided not in markets waiting to be discovered or created (Alvarez & Barney, 2007; Shane & Venkataraman, 2000), but instead were constituted in and through the interactions of different social groups over time. Hence, entrepreneurial opportunities arise not just from relational but also from temporal interactions.

Speaking about temporal issues, I also observed diachrony i.e., dynamic variations in outcomes over the entrepreneurship process. Diachrony was a result of the varying degrees of
success entrepreneurs achieved while providing a solution to the stigma associated with
smoking. The entrepreneurs’ sanitization initiatives initially met with success and opened up
entrepreneurial opportunities, resulting in the category’s growth through product innovation and
the rapid entry of small businesses. However, this opportunity soon became so widespread that
social groups perceiving threats started stigmatizing it. What was a success soon turned into a
problem because it was so successful, highlighting diachrony in the entrepreneurship process.
These dynamics call attention to the conception of entrepreneurial opportunity not as something
enduring forever, but rather residing in pockets and windows of opportunity. Pockets of
opportunity may evaporate as contexts change, as was the case with many small e-cigarette
businesses with the advent of the FDA’s regulations.

**Conclusion**

I investigated the emergence of new product categories within stigmatized industries by
conducting an in-depth analysis of the emergence of e-cigarettes in the US tobacco cigarette
industry. My findings show that the stigmatization of the tobacco cigarette industry served as a
source of opportunity for entrepreneurs to engage in categorical work of sanitization and realize
a sanitized substitute in the form of e-cigarettes, for tobacco cigarettes. However, such initiatives
at sanitization also led to categorical work to stigmatize the new product category by making
links with existing stigma-producing elements. These dynamics were also not a one-shot process
but spread out over time as a dialectic between the opposing *forces of sanitization* and the *forces
of stigmatization*. The periodic outcomes of the interactions between these two forces were not
‘stable’ resolutions but set the stage for renewed contestations; and it is in and through such
contestations that the category has been emerging.
**Limitations.** This study has its limitations which provide opportunities for future research. First, although the use of a single case study design provided the opportunity for in-depth analysis, the generalizability of the findings from this study to other core-stigmatized settings might be limited given the idiosyncrasies of each industry. It would be interesting to examine how sanitation strategies undertaken in other core-stigmatized industries such as alcohol and gambling differ from the ones discussed in this study. The study’s findings might also have limited applicability in other stigmatized industry settings such as arms and ammunition, meat processing, pornography etc. In such settings, sanitization initiatives might be impossible to carry out due to the deeply morally contentious nature of the activities in such industries. Indeed, prior work has indicated that organizations in industries such as arms and ammunition may prefer to remain ‘discreet’ and engage in tactics to dilute the stigma such as diversifying into non-stigmatized businesses rather than engage in destigmatization initiatives (e.g., Durand & Vergne, 2015; Vergne, 2012).

Second, the present case also highlighted a context where sanitization initiatives were initially driven by smaller entrepreneurial players and consumers seeking an alternative to tobacco cigarettes. The low entry barriers, in addition to the regulatory limbo that prevailed, provided opportunities for unencumbered entrepreneurial action which led to the category’s rapid growth. These contexts were very unique to the present case, and might be very different for other industry contexts which future studies could also examine.

Third, my choice of microhistory methods focusing on the actions of various social groups at critical events, while enabling a parsimonious analysis of a complex phenomenon over time, has limitations because of the exclusion of other events. To address this limitation, I triangulated across multiple sources of data (Jick, 1979), supplementing my longitudinal time-
stamped archival data with data obtained from participant observations and interviews. These participant observations and interviews enabled me to get a more ‘lived experience’ (Patton, 2002) of the phenomenon, and I also engaged in member checks (Lincoln & Guba, 1985) by seeking input from three industry experts who verified my selection of critical events as being comprehensive. Besides, I also engaged in peer debriefing (Lincoln & Guba, 1985) corroborating emerging themes at regular intervals with another researcher who is an expert in process methodology and is himself immersed in the phenomenon. In addition, I also presented my emerging themes to other scholars disinterested in the phenomenon, for feedback and review. Through these interactions, I was able to get a more complete understanding of the phenomenon, which also enhanced the credibility of the findings that I have presented here.

**Future Research.** The findings from this study present opportunities for future research in many other industry contexts that are getting stigmatized. For instance, as mentioned before, the beverage industry is becoming stigmatized because of the association between sugared beverages and diabetes. In my future research, I would like to explore the strategies that soft drink manufacturers are deploying in their attempts to dissociate their products from stigmatized elements, even while associating with other elements that are appealing to customers.

Another interesting example is the fossil fuel industry which became stigmatized due to environmental considerations related to the emission of greenhouse gases. Natural gas emerged in this industry as a cleaner alternative to coal and oil-based fossil fuels, but it is also facing scrutiny due to the leaking of greenhouse gases such as methane in its production process (The Economist, 2016). Consequently, the fossil fuel industry is yet another context in which to examine the arguments being made of associations and dissociations from stigmatized elements,
and how they are shaping the category’s emergence. This is also a topic I would like to examine in my future research.

While investigating the emergence of new categories in such industries, researchers may like to pay particular attention to the mediating roles that science and the judiciary play. For instance, how is science deployed to make arguments in favor of stigmatization or sanitization? What is the role of the judiciary in mediating the battles that play out between different social groups? Answering these and other related questions would generate a deeper understanding of the categorical dynamics that unfold as industries become stigmatized. In future studies, I also envision further examination of the strategies used by scientists and the judiciary in both shaping and changing the conceptions of what is sanitized and stigmatized.

Future research can also examine how the dynamics related to category emergence can play out differently across different institutional contexts. For example, in the UK, public health agencies such as Public Health England have endorsed e-cigarettes as a harm reduction alternative to addicted smokers who have difficulties quitting tobacco cigarettes. This is in marked contrast to the US context, where e-cigarettes have been called an “emerging public health concern” by the CDC. This raises the question of why the same product category is being seen as so dramatically different across different institutional contexts—in one context an opportunity for public health, and in another context a concern for public health. I also see my future research examining this question through a comparative study of the emergence of e-cigarettes in the UK and the US.
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## Appendix A

### TABLES

#### Table 1: Data Sources

<table>
<thead>
<tr>
<th>Description</th>
<th>News media articles</th>
<th>Regulatory</th>
<th>Judicial</th>
<th>Scientific</th>
<th>Entrepreneurs/Intrapreneurs</th>
<th>Public health groups</th>
<th>Consumers</th>
<th>Interview</th>
<th>Observational</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 plus news articles on e-cigarettes from <em>The New York Times</em> and <em>The Wall Street Journal.</em></td>
<td>FDA’s regulatory rulings, press releases, industry communiques, judicial petitions, and archived webinars and public workshops</td>
<td>Court rulings on the petitions of different social groups</td>
<td>Numerous articles published in scientific journals and reports</td>
<td>Product descriptions, press releases, and regulatory and judicial petitions (in addition to texts produced by trade associations and advocacy groups)</td>
<td>Press releases, articles, and regulatory petitions</td>
<td>Testimonials published on consumer and advocacy forums, and with regulatory petitions</td>
<td>Entrepreneurs and members of industry trade association and advocacy groups, and industry experts (in addition to transcripts of interviews conducted by other individuals)</td>
<td>Notes taken during trade shows, scientific conference and regulatory workshops</td>
<td></td>
</tr>
</tbody>
</table>

#### Use in analysis

| Identify various social groups involved and the issues at play | Surfaces regulatory frame of reference informing their actions | Provides microcosm of the issues at play | Surfaces different scientific frames of reference | Surfaces frame of reference informing entrepreneurs actions | Surfaces social group’s frames of reference | Surfaces consumer’s frame of reference | Provide lived account of phenomenon | Triangulation of themes emerging from analysis of archival data | Provide lived account of phenomenon | Triangulation of themes emerging from analysis of archival data |
| Establish general chronology of events | Highlights historical precedents | | | | | | | | | |
However, companies indirectly point to the potential health benefits from e-cigarettes. For example, Mistic electronic cigarettes claim e-cigarettes as containing far less harmful chemicals vis-à-vis cigarettes (Source: www.misticecigs.com), and NJOY advertises its stated mission as ending “smoking-related death and disease” (Source: www.njjoy.com)

<table>
<thead>
<tr>
<th>Social Groups</th>
<th>Representative Organizations</th>
<th>Category labels</th>
<th>Discursive possibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cigarette entrepreneurs (and their trade association and advocacy groups)</td>
<td>Independent companies in the e-cigarette device and e-liquid business (such as NJOY, VMR, Johnson Creek, Gilla Inc. etc.), industry trade associations such as Smoke Free Alternatives Trade Association (SFATA), and advocacy organizations such as American Vaping Association (AVA), etc.</td>
<td>Alternative smoking device, smoke-free alternatives, vapor, vaping, technology products etc.</td>
<td>Disruptive innovation offering consumers a more convenient and enjoyable alternative to traditional cigarettes without the “inconveniences” associated with smoking7.</td>
</tr>
<tr>
<td>Tobacco companies</td>
<td>Tobacco companies and their subsidiaries such as Nu Mark owned by Altria, Reynolds American Vapor owned by Reynolds American, and Fontem Ventures owned by Imperial Brands</td>
<td>Innovative tobacco products, digital vapor cigarettes, e-vapor, vapor etc.</td>
<td>Emerging category of innovative tobacco products that are transforming the tobacco industry, and part of their portfolio of tobacco products (such as smokeless tobacco) with reduced risk profile.</td>
</tr>
<tr>
<td>Regulators</td>
<td>US Food and Drug Administration (FDA)</td>
<td>Drug device combination product, tobacco product, electronic nicotine delivery systems (ENDS)</td>
<td>E-cigarettes are tobacco products which raise significant public health concerns at the population level in relation to new user initiation into them and other tobacco products especially among the youth.</td>
</tr>
<tr>
<td>Public health groups</td>
<td>Centers for Disease Control (CDC), Campaign for Tobacco Free Kids, American Lung Association, American Heart Association etc.</td>
<td>Drug device combination product, tobacco product, electronic nicotine delivery systems (ENDS)</td>
<td>E-cigarettes are a public health concern. They have the potential to turn back tobacco control efforts due to their potential to addict youth into nicotine and other tobacco products. E-cigarettes are also a distraction from other legitimate means to quit smoking such as using FDA approved nicotine gums and patches.</td>
</tr>
<tr>
<td>Scientists</td>
<td>Society for Research on Nicotine and Tobacco (SRNT)</td>
<td>Electronic nicotine delivery systems (ENDS)</td>
<td>E-cigarettes constitute different possibilities among scientists. Scientists advocating harm reduction recommend its immediate use as reduced harm alternative for addicted smokers. Scientists advocating precaution point to the presence of carcinogens in e-cigarette vapor, in addition to the lack of evidence regarding its long term health effects.</td>
</tr>
<tr>
<td>Consumers</td>
<td>Individual consumers and advocacy organizations such as Consumer Advocates for Smoke-Free Alternatives Association (CASAA) representing their interests</td>
<td>Smoke free alternative, vapor, vaping</td>
<td>Consumers using e-cigarettes view the product as a more effective and enjoyable means to quit/reduce smoking cigarettes vis-à-vis FDA approved nicotine patches and gums. They also regard e-cigarettes as a reduced harm alternative to traditional cigarettes.</td>
</tr>
<tr>
<td>Other social groups (Judiciary, State legislators)</td>
<td>US District Court for the District of Columbia, and State legislators and Attorney generals in various US states</td>
<td>Tobacco product</td>
<td>Guided by legal and legislative precedents related to tobacco cigarettes, e-cigarettes are tobacco products that could be regulated under existing tobacco control statutes.</td>
</tr>
</tbody>
</table>

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7 Companies selling e-cigarettes are not allowed to make health claims related to smoking cessation and harm reduction unless such claims have been approved by the FDA. However, companies indirectly point to the potential health benefits from e-cigarettes. For example, Mistic electronic cigarettes claim e-cigarettes as containing far less harmful chemicals vis-à-vis cigarettes (Source: www.misticecigs.com), and NJOY advertises its stated mission as ending “smoking-related death and disease” (Source: www.njjoy.com)
### TABLE 3: Discursive Possibilities Provided by Constituent Material Elements

<table>
<thead>
<tr>
<th>Social Groups</th>
<th>Carcinogens</th>
<th>Nicotine</th>
<th>Flavors</th>
<th>Batteries</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cigarette entrepreneurs (and their trade association and advocacy groups)</td>
<td>Emphasize the removal of many harmful carcinogens found in cigarettes, and implicitly promote e-cigarettes as a reduced harm alternative</td>
<td>Customizable nicotine concentration levels offer users flexibility to choose desired nicotine strength in their e-liquids</td>
<td>Offers users a wide selection of e-liquid flavors to customize to their taste, which also enables them to abstain from cigarettes</td>
<td>Customization of battery voltage/wattage in open system devices enables users to heat e-liquid at user desired temperatures</td>
</tr>
<tr>
<td>Tobacco companies and their subsidiaries</td>
<td>Acknowledges the lower risk profile of e-cigarettes, and the potential for reduced harm</td>
<td>Mainly sell closed system devices which provide users with a more limited range of nicotine concentration levels to choose from</td>
<td>Closed system devices come with prefilled e-liquids in a relatively limited range of flavors</td>
<td>-</td>
</tr>
<tr>
<td>Regulators and Public health groups</td>
<td>Emphasize the presence of carcinogens, and their unknown long term health risks</td>
<td>Nicotine is an addictive substance, which is dangerous to the adolescent brain and could lead to youth initiation into other tobacco products. Nicotine in e-liquids can also expose individuals especially children to poisoning</td>
<td>E-cigarette flavors are attractive to youth resulting in the rising use and experimentation of these products, which could in turn also serve as a gateway into other tobacco products</td>
<td>Batteries used in e-cigarettes are prone to overheating, and explosion</td>
</tr>
<tr>
<td>Scientists</td>
<td>Emphasize the presence of additional carcinogens, and their unknown long term health risks</td>
<td>Nicotine can lead to addiction and initiation into other tobacco products</td>
<td>Flavors can lead to youth experimentation, with no conclusive evidence that they help in quitting cigarettes</td>
<td>Batteries used in e-cigarettes may be prone to overheating and explosion</td>
</tr>
<tr>
<td><strong>Precaution</strong></td>
<td>Lower levels of carcinogens make e-cigarettes a less harmful alternative for smokers who have difficulties quitting through prescription products such as nicotine patches and gums</td>
<td>Emphasize that it is not the nicotine in cigarettes that kill but the delivery mechanism. Nicotine using a more cleaner delivery mechanism such as e-cigarettes is a much safer alternative</td>
<td>Flavors in e-cigarettes enable addicted smokers to abstain from cigarettes and prevent relapse into tobacco cigarettes</td>
<td>-</td>
</tr>
<tr>
<td><strong>Harm reduction</strong></td>
<td>Testify to positive health benefits using e-cigarettes such as breathing better, and recovering taste and stamina</td>
<td>Nicotine used to deal with nicotine withdrawal condition, with some consumers also testifying they gradually reduced nicotine concentration levels over time</td>
<td>Flavors make e-cigarettes more enjoyable and prevents relapse into tobacco cigarettes</td>
<td>Customization of battery voltage/wattage in open system devices enables users to heat e-liquid at user desired temperatures</td>
</tr>
<tr>
<td>Illustrative Quotes</td>
<td>First-Order Codes</td>
<td>Second-Order themes</td>
<td></td>
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<td>-----------------------------------------------------------------------------------</td>
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<tr>
<td>“…a pure way to smoke. It gives the feeling of smoking along with the oral fixation of inhaling and exhaling smoke/vapor, but without all the carcinogens, tar, and side effects of regular tobacco smoke.” (Source: <a href="http://www.puresmoker.com">www.puresmoker.com</a>)*</td>
<td>Statements highlighting similarities and differences with tobacco cigarettes, and promoting e-cigarettes as an alternative to tobacco cigarettes</td>
<td>Establishing contrast (with stigmatized product)</td>
<td></td>
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<tr>
<td>“Smoking Everywhere Electronic Cigarette looks like a traditional cigarette, feels like a traditional cigarette, taste like a traditional cigarette, But it isn’t a traditional cigarette. It’s just a much better way to smoke!” (Source: <a href="http://www.smokingeverywhere.com">www.smokingeverywhere.com</a>) (emphasis added)</td>
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<tr>
<td>“Njoy performs similarly to traditional smoking. It looks, feels and tastes like a cigarette or cigar, and delivers all the pleasures of smoking, without all the problems.” (Source: <a href="http://www.njoy.com">www.njoy.com</a>)</td>
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<tr>
<td>“Vapor products contain zero tobacco and are significantly different from combustible cigarettes. Vapor products are technology products comprised on metal and electronic circuitry. Vapor products use heat from battery to vaporize e-liquids rather than combustion to burn tobacco.” (Source: <a href="http://www.sfata.org">www.sfata.org</a>) (emphasis added)</td>
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<tr>
<td>“They are more convenient, and efficient – gives more draw into the lungs, more enjoyable and memorable flavor as opposed to smoking” (Interview, Entrepreneur at trade show)</td>
<td>Statements about e-cigarettes as a means to quit smoking cigarettes</td>
<td>Highlighting detachment possibilities</td>
<td></td>
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<tr>
<td>“Delicious, easy, better – in comparison to tobacco cigarettes” (Interview, Entrepreneur at trade show)</td>
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<tr>
<td>“I smoked my last cigarette the day that I bought my first personal vaporizer. That was four years ago. Vaping saved my life! I now run a small vape shop in a small town in hopes of helping others to stop smoking.” (Source: <a href="http://www.vaping.org">www.vaping.org</a>)</td>
<td>Statements as an alternative really is a good thing – we know, people who switch stay switched, patch not very effective, substituting smoking for vaping is a good thing” (Interview, Trade association executive)</td>
<td></td>
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<tr>
<td>“I haven’t picked up a cigarette since that day [I tried e-cigarettes], and I haven’t smoked for over 3 years now...The big thing is that I love vaping, I don’t smoke...Success!” (Source: <a href="http://www.e-cigarette-forum.com">www.e-cigarette-forum.com</a>)</td>
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<tr>
<td>“Vape as an alternative really is a good thing – we know, people who switch stay switched, patch not very effective, substituting smoking for vaping is a good thing” (Interview, Trade association executive)</td>
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<tr>
<td>“The variety of [e-cigarette] flavors are not only enjoyable for adults, they also help a significant number of adults distance themselves from their former smoking habit” (CASAA, 2014, August 7: 14) (emphasis added)</td>
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<tr>
<td>“…prolonged use of e-cigarettes is associated with a higher smoking cessation rate, independent of the effect of baseline intention to quit smoking” (Zhuang, Cummins, Sun, &amp; Zhu, 2016: i93)</td>
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</table>

* Texts retrieved using www.archive.org
“Electronic cigarettes are designed to mitigate tobacco-related disease by reducing cigarette consumption and smoking rates. The evidence reviewed …suggests that electronic cigarettes are a much safer alternative to tobacco cigarettes.” (Cahn & Siegel, 2011: 27) (emphasis added)

“Encouraging smokers who cannot or do not want to stop smoking to switch to EC could be adopted as one of the key strategies to reduce smoking related disease and death.” (McNeill et al., 2015: 6) (emphasis added)

“ECs are a revolutionary product in tobacco harm reduction. Although they emit vapor, which resembles smoke, there is literally no fire (combustion) and no …suspicion or evidence that they may be the cause for disease in a similar way to tobacco cigarettes.” (Farsalinos & Polosa, 2014: 81) (emphasis added)

“Smokers with asthma switching to ECs experienced a better control of respiratory symptoms with less asthma attacks and better quality of sleep…Smokers with high BP or hypertension switching to vaping felt more relaxed and less anxious, with significant improvement in their psychological and social life.” (Excerpt from an interview with Riccardo Polosa conducted by E-Cigarette Direct, 2016, November 24)

“Health professionals may consider advising smokers unable or unwilling to quit through other routes to switch to EC as a safer alternative to smoking and a possible pathway to complete cessation of nicotine use.” (Hajek, Etter, Benowitz, Eissenberg, & McRobbie, 2014: 1801)

“As a new category of technology product, vaporizing products deserve a new and distinct set of regulations.” (SFATA, 2014, April 25) (emphasis added)

“The electronic cigarette / vapor products industry is not the “Cigarette Lookalike” products this deeming proposal is designed to regulate… a new category of regulatory framework must be devised.” (Purebacco, 2014: 4-5) (emphasis added)

“What we could be looking at [with e-cigarettes] is that this is a transformation of the market away from combustion-based delivery. I think we need a law that … makes it more likely that the people will transition to the less hazardous products, and things like differential taxation …different approaches to advertising, distribution, points of sale, …things that make it more likely that the less hazardous products are the ones that consumers are likely to gravitate toward.” (Interview, Policy Scientist) (emphasis added)

“The net effect of the deeming rule, which now subjects products known to be less harmful [including e-cigarettes] to the same onerous burdens placed on cigarettes, is to solidify the stability of “big tobacco” and traditional products, namely cigarettes. New companies, like [us] and thousands of other small entities, will struggle to survive the flood of administrative …burdens.” (Lost Arts Liquid LLC, 2016, May 19: 26)
Table 5: Data Structure: Categorical Work of Stigmatization

<table>
<thead>
<tr>
<th>Illustrative Quotes</th>
<th>First-Order Codes</th>
<th>Second-Order themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>“As an unapproved drug or device, distribution of E-Cigarettes in commerce in the United States is prohibited. Thus, FDA properly concluded that the shipments of E-Cigarettes at issue here may be refused admission into the United States.” (FDA et al, 2009: 1) (emphasis added)</td>
<td>Statements drawing attention to the unauthorized and unregulated status of e-cigarettes</td>
<td>Illegitimating category</td>
</tr>
<tr>
<td>“[The] unregulated presence [of e-cigarettes] on the market must be viewed as a threat to the public health…[it] will also encourage other companies to endrun the regulatory process, leading to the marketing of other potentially unsafe and/or ineffective products used and advertised as tobacco alternatives.” (American Academy of Pediatrics et al, 2010, May 24: 2) (emphasis added)</td>
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<tr>
<td>“[We] write to highlight the need for immediate regulatory oversight of e-cigarettes…Consumers are led to believe that e-cigarettes are a safe alternative to cigarettes….and there is no regulatory oversight ensuring the safety of the ingredients in e-cigarettes.” (National Association of Attorneys General, 2013, September 24: 1-2) (emphasis added)</td>
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</tr>
<tr>
<td>“So, nicotine gum, nicotine patch, nicotine lozenge, the prescription nicotine inhaler, is safe and effective when used according to the label to help smokers quit. But when it comes to e-cigarettes, it's the wild, wild west.” (FDA, 2014, April 24) (emphasis added)</td>
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<tr>
<td>“[E-cigarettes] could serve as a pathway to nicotine addiction for children, leading them to smoke cigarettes and use other tobacco products to satisfy their addiction.” (Campaign for Tobacco-Free Kids, 2009, July 22) (emphasis added)</td>
<td>Statements suggesting the possibilities of ‘nicotine addiction’ and ‘gateway’ into other tobacco products through the use of e-cigarettes, especially among the youth</td>
<td>Highlighting initiation and addiction possibilities</td>
</tr>
<tr>
<td>“…if a 13-year-old is experimenting with an e-cigarette, we have reason to be very concerned that this could increase his or her chances of eventually experimenting with conventional cigarettes.” (Excerpt from an interview with Tim McAfee, Director, Office on Smoking and Health, CDC conducted by McMullen, 2013, September 5) (emphasis added)</td>
<td></td>
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<tr>
<td>“Most e-cigarettes deliver nicotine, which …is a dangerous and highly addictive chemical….AHA is also concerned that e-cigarettes could be a gateway to tobacco use for non- or former smokers, sustain dual use, or promote or maintain nicotine addiction. Acceptance of e-cigarettes also has the potential to re-normalize smoking behavior. We are especially concerned that e-cigarettes may lead to increased initiation among youth.” (American Heart Association, 2014, August 8: 9)</td>
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<tr>
<td>“E-cigarettes are tobacco products that deliver nicotine. Nicotine is a highly addictive substance, and many of today’s youth who are using e-cigarettes could become tomorrow’s cigarette smokers. Nicotine exposure can also harm brain development in ways that may affect the health and mental health of our kids.” (U.S. Department of Health and Human Services, 2016b: v) (emphasis added)</td>
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</tbody>
</table>
“FDA conducted a preliminary analysis on some samples of electronic cigarettes and components from two leading brands... analysis of the electronic cigarette samples showed that the product contained detectable levels of known carcinogens and toxic chemicals to which users could potentially be exposed.” (FDA, 2009) (emphasis added)

“the particle size distribution and number of particles delivered by e-cigarettes are similar to those of conventional cigarettes, with most particles in the ultrafine range ... The thresholds for human toxicity of potential toxicants in e-cigarette vapor are not known, and the possibility of health risks to primary users of the products and those exposed passively to their emissions must be considered.” (Grana et al., 2014: 1977) (emphasis added)

“...the public should be aware that e-cigarettes have the potential to cause acute adverse health effects and represent an emerging public health concern.” (Chatham-Stephens et al., 2014) (emphasis added)

“...given the existence of toxic chemicals in at least some e-cigarettes and the fact that most contain nicotine, FDA believes that its oversight of these products ...is appropriate for the protection of the public health.” (U.S. Department of Health and Human Services, 2014: 23157) (emphasis added)

“Recent studies...have found high levels of toxicants and carcinogens in large numbers of e-cigarette flavorings and have concluded that inhalation of such chemicals at the levels present in these products could have adverse health consequences.” (American Heart Association, American Lung Association, & Campaign for Tobacco-Free Kids, 2016, July 11: 6) (emphasis added)

“The FDA must act without delay to assert jurisdiction over e-cigarettes ... under the 2009 law granting the agency authority over tobacco products...It is also important that states apply their laws governing cigarettes and other tobacco products to e-cigarettes.” (Campaign for Tobacco-Free Kids, 2013, September 5) (emphasis added)

“There are reasonable concerns and reasons for folding them into the existing clean-air framework for cigarettes.” (Tim McAfee, Director, Office on Smoking and Health, CDC quoted in Esterl, 2013, December 19) (emphasis added)

“It is critical to public health for FDA to apply to the deemed products [including e-cigarettes] all provisions of the tobacco control act applicable to ‘tobacco products’” (American Academy of Family Physicians et al, 2014, August 8: 17) (emphasis added)

“The Tobacco Control Act gave FDA the statutory authority to regulate e-cigarettes, which would subject them to evaluation and marketing restrictions... FDA should act quickly to finalize and issue deeming regulations pertaining to e-cigarettes.” (Durbin et al., 2014: 22)

| Statements highlighting the presence of carcinogens in e-cigarettes, and the potential for adverse health effects | Advocating precaution |
|---|---|---|

<p>| Statements supporting regulation of e-cigarettes under the tobacco control act | Enfolding into existing regulations (for stigmatized products) |</p>
<table>
<thead>
<tr>
<th>Year</th>
<th>Events and Critical Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006/07</td>
<td>E-cigarettes begin to be imported into the United States from overseas manufacturers mainly based in China</td>
</tr>
<tr>
<td>2008</td>
<td><strong>FDA starts detaining imported e-cigarette shipments</strong></td>
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<tr>
<td>2009</td>
<td>World Health Organization warns against e-cigarette marketing claims related to smoking cessation</td>
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<tr>
<td>2009</td>
<td>FDA’s tests of e-cigarette samples finds low quality controls and detectable levels of known carcinogens</td>
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<tr>
<td>2009</td>
<td>Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act.) enacted into law</td>
</tr>
<tr>
<td>2010</td>
<td><strong>Judge Richard J. Leon grants injunctive relief to Smoking Everywhere Inc. and Sottera Inc. against FDA’s detention of their e-cigarette shipments</strong></td>
</tr>
<tr>
<td>2010</td>
<td>New Jersey Smoke Free Law amended to include e-cigarettes. New Jersey becomes the first state to ban the use of e-cigarettes in public places, and prohibit its sale to minors.</td>
</tr>
<tr>
<td>2010</td>
<td>FDA sends warning letter to five e-cigarette companies and their industry association seeking compliance with regulations for drug delivery products under Federal Food, Drug, and Cosmetic Act (FD&amp;C Act.)</td>
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<tr>
<td>2010</td>
<td>Three member US Court of Appeals upholds Judge Richard J. Leon’s decision</td>
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<tr>
<td>2011</td>
<td>FDA announces plan to regulate e-cigarettes as a tobacco product under the Tobacco Control Act.</td>
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<tr>
<td>2012</td>
<td><strong>Lorillard Inc. acquires BLU electronic cigarettes for 135 million dollars</strong></td>
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<tr>
<td>2012</td>
<td>E-cigarette commercials begin to appear on television networks in the US</td>
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<tr>
<td>2013</td>
<td>More than dozen US states have implemented bans regarding e-cigarette sales to minors</td>
</tr>
<tr>
<td>2013</td>
<td><strong>CDC reports doubling of e-cigarette use among both middle and high school students in 2012 over 2011</strong></td>
</tr>
<tr>
<td>2013</td>
<td>Attorney Generals of 40 US states urge FDA to expedite e-cigarettes regulations under the Tobacco Control Act.</td>
</tr>
<tr>
<td>2013</td>
<td>Lorillard Inc. acquires UK based Skycig for 60 million pounds</td>
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<tr>
<td>2013</td>
<td>New York City council extends public smoking bans to e-cigarettes</td>
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<tr>
<td>2014</td>
<td>Altria acquires e-cigarette company Green Smoke Inc. for 110 million dollars</td>
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<tr>
<td>2014</td>
<td>CDC reports dramatic increase in calls to poison centers from e-liquid poisonings</td>
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<tr>
<td>2014</td>
<td>Eleven US Senators and Representatives publish report titled “Gateway to addiction?” urging FDA to immediately issue regulations on e-cigarettes</td>
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<tr>
<td>2014</td>
<td><strong>FDA proposes draft regulations to regulate e-cigarettes and other electronic nicotine delivery system (ENDS) product under the Tobacco Control Act</strong></td>
</tr>
<tr>
<td>2014</td>
<td>US state attorney general’s urge the FDA to impose restriction on e-cigarette advertising, online sales and use of e-liquid flavors appealing to the youth</td>
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<td>2014</td>
<td>Study published in Nicotine and Tobacco Research finds formaldehyde at levels equal to that of tobacco smoke in high voltage e-cigarette vapor</td>
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<td>2014</td>
<td>Industry analyst Well Fargo estimates vaporizer sales approaching 50% of e-cigarette sales</td>
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<td>2014</td>
<td>Reynolds American rolls out its VUSE brand of e-cigarettes nationally</td>
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<tr>
<td>2014</td>
<td>Altria rolls out its Mark-Ten e-cigarettes nationally</td>
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<tr>
<td>2014</td>
<td>Reynolds American acquires Lorillard Inc. for 25 billion dollars</td>
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<tr>
<td>2014</td>
<td>Twenty-nine US state attorney general’s urge the FDA to impose greater restrictions on the use of flavors and the advertising and marketing of e-cigarettes</td>
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<tr>
<td>2014</td>
<td>World Health Organization calls for restriction of e-cigarette advertising, and curbs on its indoor use and in public places</td>
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<tr>
<td>2014</td>
<td>CDC reports continued increase in e-cigarette use among both middle and high school students in 2013 over 2012</td>
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<tr>
<td>2014</td>
<td>University of Michigan’s Monitoring the Future study finds e-cigarette use among high school and middle school students to surpass the use of regular cigarettes</td>
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<td>2015</td>
<td>California Department of Public Health declares e-cigarettes a public health threat</td>
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<tr>
<td>Year</td>
<td>Event Description</td>
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<td>2015</td>
<td>CDC includes e-cigarettes in its anti-smoking campaign “Tips From Former Smokers”</td>
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<tr>
<td>2015</td>
<td>CDC reports tripling of e-cigarette use among US high school and middle school students from 2013 to 2014</td>
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<tr>
<td>2015</td>
<td>The Federal Trade Commission grants approval to Reynolds American’s acquisition of Lorillard</td>
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<tr>
<td>2015</td>
<td>FDA invites comments for rulemaking related to nicotine exposure warnings and child-resistant packaging for liquid nicotine and nicotine-containing e-liquid(s)</td>
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<tr>
<td>2015</td>
<td>Japan Tobacco Inc. acquires US e-cigarette company Logic Technology Development LLC</td>
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<tr>
<td>2015</td>
<td>Public Health England (PHE) publishes report concluding cigarettes are 95% less harmful than tobacco cigarettes</td>
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<tr>
<td>2015</td>
<td>CDC declares e-cigarettes an emerging public health challenge</td>
</tr>
<tr>
<td>2016</td>
<td>Royal College of Physicians UK publishes report “Nicotine without smoke: tobacco harm reduction” endorsing e-cigarette as a harm reduction alternative</td>
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<tr>
<td>2016</td>
<td>FDA passes final deeming regulations to regulate e-cigarettes and other ENDS products under the Tobacco Control Act</td>
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<tr>
<td>2016</td>
<td>US Department of Transportation bans e-cigarettes from being carried in the checked baggage of commercial flights</td>
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<td>2016</td>
<td>A Billion Lives, a documentary advocating for e-cigarette use as a harm reduction alternative is produced</td>
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<tr>
<td>2016</td>
<td>US Surgeon General publishes report on rising e-cigarette use among youth and young adults</td>
</tr>
<tr>
<td>2017</td>
<td>British American Tobacco offers 49 billion dollars for acquisition of Reynolds American</td>
</tr>
<tr>
<td>2017</td>
<td>FDA organizes public workshop on battery safety concerns in e-cigarettes and other ENDS products</td>
</tr>
</tbody>
</table>

*Critical events are marked in bold*
Figure 1: Technology Entrepreneurship Inquiry Frame

- **Firms**
  - Incumbent firms
  - New entrants
  - Industry and trade associations

- **Institutions**
  - Scientists
  - Regulators
  - Judiciary
  - Media etc.

- **Technology**
  - Form and function
  - Discursive possibilities

- **Market**
  - Consumers
  - Consumer associations
  - Whole sellers/Retailers
Figure 2: “Smokeless non-tobacco cigarette” Invented by Herbert A. Gilbert

Source: www.uspto.gov

Figure 3: “Electronic atomization cigarette” Invented by Hon Lik

Source: www.uspto.gov
Figure 4: ‘Cig-a-like’ E-cigarette Sold by NJOY

Light-up tip. A carefully designed simulated ash tip. When you inhale, a vacuum switch signals to an IC controller chip and switches on a tiny LED light, so the tip glows orange like a traditional tobacco cigarette. When you’ve depleted your e-cig, this tip is smart enough to blink 10 times and let you know it’s cut.

Faux filter. Looks like a filter, feels like a filter — but isn’t. Why feel like you’re puffing on a ball point pen when the NJOY King replicates the squishy feel of a traditional tobacco cigarette filter? We think that’s an easier switch.

Battery. A lithium-ion battery, sort of like the one in your electronic gadgets — but way smaller. When you puff, the battery activates the atomizer and the light-up tip.

Atomizer. The interface between the electricity and the liquid. This is what literally “atomizes” the liquid and turns it to vapor. This is where the magic happens!

E-liquid. A mix of propylene glycol (to turn the liquid to vapor), glycerin (to keep the taste lasting), nicotine (duh) and flavor (so it tastes better than a tobacco cigarette). We soak it in a cotton swab and coil it around the atomizer.

Source: www.njoy.com

Figure 5. Open System E-cigarettes

‘eGo’ e-cigarettes/Vape pens

Advanced personal vaporizers/mods

Source: www.vapes.com
Figure 6: E-cigarette Product Category Sales (in million USD)

Source: Data obtained from Euromonitor International (2016)
Figure 7: Adult Per Capita Cigarette Consumption and Smoking Prevalence in the US (1900-2012)

Source: Cole and Fiore (2014)
Figure 8: Relative Risk Profile of E-cigarettes

Source: McNeill and Munafò (2013)
“Smoking Everywhere E-Cigarette has no tobacco, no tar, no real smoke and no other chemicals like traditional cigarette…However, It looks like a real cigarette, feels like a real cigarette and tastes like a real cigarette, yet it isn’t a real cigarette.” (emphasis added)

Source: smokingeverywhere.com (image and text retrieved using archive.org)

“The essence of the NJOY brand and products ... give tobacco smokers the opportunity to continue smoking with minimized health risk, greater freedom, lower cost and more social acceptance.”

Source: www.njoy.com (images and text retrieved using archive.org)
Figure 11: Advertising Themes from Lorillard’s Promotions of BLU E-cigarettes

Source: www.tobaccofreekids.org
Figure 12: General Model of New Product Category Emergence in Stigmatized Industries

<table>
<thead>
<tr>
<th>Initial conditions</th>
<th>Stigma as Constraint</th>
<th>Stigma as Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Constrains the emergence of new product categories due to stigmatization</td>
<td>Opportunities for the emergence of new product categories that address the stigma</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initiatives that are the outcome of initial conditions</th>
<th>Forces of stigmatization (anti-thesis)</th>
<th>Forces of sanitization (thesis)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Social groups engage in <em>categorical work of stigmatization</em></td>
<td>Social groups engage in <em>categorical work of sanitization</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consequences of these initiatives</th>
<th>Leads to stigmatization of the new product category</th>
<th>Leads to sanitization of the new product category</th>
</tr>
</thead>
</table>

Outcomes of these interactions (*new-thesis*) will set the stage for further sanitization and stigmatization initiatives.
Figure 13: Dynamics of New Product Category Emergence in the Case Study

<table>
<thead>
<tr>
<th>Period 1: From ‘drug device combination’ to tobacco product (2006-2011)</th>
</tr>
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<tbody>
<tr>
<td><strong>Initial conditions</strong></td>
</tr>
<tr>
<td>Tobacco cigarettes stigmatized in the US</td>
</tr>
<tr>
<td><strong>Initiatives that are the outcome of initial conditions</strong></td>
</tr>
<tr>
<td>Categorical work of stigmatization</td>
</tr>
<tr>
<td>-Illegitimating category</td>
</tr>
<tr>
<td>-Highlighting addiction and initiation possibilities</td>
</tr>
<tr>
<td>-Advocating precaution</td>
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<tr>
<td><strong>Consequences of these initiatives</strong></td>
</tr>
</tbody>
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<thead>
<tr>
<th>Period 2: From the entry of tobacco companies to regulation as a tobacco product (2011-2014)</th>
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<tbody>
<tr>
<td><strong>Initiatives that are the outcome of prior conditions</strong></td>
</tr>
<tr>
<td>Categorical work of stigmatization</td>
</tr>
<tr>
<td>-Illegitimating category</td>
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<tr>
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<tr>
<td>-Advocating precaution</td>
</tr>
<tr>
<td>-Enfolding into existing regulations</td>
</tr>
<tr>
<td><strong>Consequences of these initiatives</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Period 3: From proposed regulations to final regulations (2014-2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initiatives that are the outcome of prior conditions</strong></td>
</tr>
<tr>
<td>Categorical work of stigmatization</td>
</tr>
<tr>
<td>-Illegitimating category</td>
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<tr>
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</tr>
<tr>
<td>-Advocating precaution</td>
</tr>
<tr>
<td>-Enfolding into existing regulations</td>
</tr>
<tr>
<td><strong>Consequences of these initiatives</strong></td>
</tr>
</tbody>
</table>

Category contestation

Category growth and backlash

Category enfolding into stigmatized category
VITA
THINLEY THARCHEN

EDUCATION

2012-2017  Smeal College of Business, Pennsylvania State University, USA
            Ph.D. in Business Administration

2009-2010  London School of Economics and Political Science, UK
            MSc in Finance and Economics

2002-2004  Faculty of Management Studies, University of Delhi, India
            Master of Business Administration

1997-2001  Birla Institute of Technology, Ranchi, India
            Bachelor of Engineering (Electrical and Electronics)

RESEARCH INTERESTS

My research interests lie at the intersection of organization theory, entrepreneurship and strategy. I take an interpretive approach in my research employing the use of both grounded theory and qualitative process methodology. I am also interested in scientometrics tools such as bibliometric analysis. In my research, I have examined topics related to category emergence, institutional change, design and sustainability.

PUBLICATIONS

Garud, R; Gehman, J; & Tharchen, T. 2017. Performativity as ongoing journeys: Implications for strategy, entrepreneurship and innovation, Long Range Planning. (forthcoming)


PRIOR PROFESSIONAL EXPERIENCE

2011-2012  Indian School of Business, Hyderabad, India
            Academic Associate

2004-2009  Power Finance Corporation Ltd., New Delhi, India
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