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Uncertain and Evolving Regulation: Regulatory and Ethical Challenges in the Electronic Tobacco Industry

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SUMMARY

INTRODUCTION

The main objective of the thesis is to illustrate and analyze the dynamics that arise in contexts of product innovation and possible uncertainty in its regulation. With this purpose, we will delve into the world of the electronic tobacco industry, a sector particularly innovative and subject to constant regulatory changes.

The thesis will first present the well-known case-study of the American company Juul Labs, which will serve as a starting point for examining the legislative process that led to the regulation of the electronic tobacco industry in the United States and in Italy. Finally, the thesis will conclude with a more general discussion on the strategies that companies might adopt to navigate safely in such dynamic and complex environments, where legislation is constantly changing or even absent.

In particular, Chapter I explores the peculiar case of Juul, focusing on the regulatory challenges that a company in this industry may face. Indeed, the electronic tobacco sector, known for its rapid growth and constantly evolving regulations, provides an interesting context for analyzing the issues that companies might encounter operating in an environment without precise and defined rules.

Through the analysis of the Juul case, we will look at how the absence of a defined regulatory framework can affect corporate strategies, products, and even public perception of the company. In the context of this case, we will examine the details of its emergence to public attention in 2019, when North Carolina Attorney General Josh Stein sued Juul Labs, leading to a significant settlement that changed the way the company operates.

Juul's story and its entry into the U.S. market represent the beginning of an important change in the nicotine consumption, which raised numerous ethical and regulatory questions. This provides the foundation for Chapter II, where the legal and regulatory environment that influenced the American electronic tobacco industry will be discussed, guiding the reader through the legal implications that led to the creation of the U.S. regulatory landscape in this sector. The evolution of federal regulation in the United States, with the Food and Drug Administration (FDA) stepping in with concrete measures, will be examined to better understand how U.S. regulators have addressed the challenges of innovation.

Another discussion will then be presented in Chapter III, where we will delve into the

legislative path that led to the regulation of this industry in Italy. Thanks in part to a significant influence of the European Union, a stricter legislative system that balances the interests of society and the companies involved in the sale of electronic tobacco products is currently being developed.

Finally, in Chapter IV, lessons learned from the previous chapters will be presented to better understand how they may influence companies' future practices. The thesis will discuss the importance of proactive regulations to prevent similar problems in the future and the need for companies to adopt Corporate Social Responsibility (CSR) and Human Rights Focus (HRDD) practices to successfully navigate an uncertain regulatory environment. This insight will offer suggestions on how companies can and should operate in high-innovation, low-regulation sectors.

CHAPTER I

THE JUUL CASE: AN OVERVIEW

1.1. Exploring Regulatory Challenges in the Electronic Tobacco Industry

With the purpose of illustrating and analyzing the dynamics that arise in contexts of product innovation and possible uncertainty in its regulation the thesis will have a particular focus on the electronic tobacco industry, a sector characterized by rapid growth and continuous evolution of its regulations.

This environment has been chosen to offer an interesting perspective to analyze the challenges that companies may face when working in a context without precise and defined rules.

Analyzing the Juul case will illustrate how companies face risks and ethical challenges when the boundaries between lawful and unlawful, healthy and harmful, remain undefined.

The analysis finally serves as a starting point for proposing and evaluating possible ethical guidelines and strategies for moving more responsibly and safely through the complex challenges that can arise in this situation.

1.2. The Juul Case

The Juul case came first to public attention in 2019, when North Carolina Attorney General Josh Stein sued e-cigarette company Juul Labs and agreed to a settlement[1] with the well-known electronic cigarette company in the US alleging that Juul targeted through specific marketing strategies young people in order to sell addictive e-cigarettes.[2] Josh Stein announced a settlement on a consent order requiring JUUL to pay $40 million and sharply alter the way it operated its business. With the agreement, North Carolina became the first state in the nation to "*successfully hold JUUL accountable for its role in spiking teen use and dependence on e- cigarettes*".[3]

The State accused the company of consciously targeting teenagers - through its marketing

[1] State of North Carolina v. Juul Labs Inc., settlement agreement, 27 June 2021 (N.C. 2021).

[2] Martinez A., While Juul Settles with North Carolina, Colorado's Suit Goes On, Law Week Colorado (Apr. 11, 2024), https://www.lawweekcolorado.com/article/while-juul-settles-with-north-carolina-colorados-suit-goes-on/.

[3] Press Release, Office of the Attorney General, North Carolina, Statement by Attorney General Joshua H. Stein on Juul Settlement with North Carolina.

and placement campaigns - with its products rich in nicotine and harmful to health. Teenagers were particularly attracted by the e-cigarette trendy design, similar to a USB stick, and by the flavored e-cigarette liquids that made the device particularly attractive. These actions, they allege, helped create an epidemic of addiction among young people, making nicotine "cool" again after years of historic declines in cigarette smoking.[4]

North Carolina Attorney communicated: "*This win will go a long way in keeping Juul products out of kids' hands, keeping its chemical vapor out of their lungs, and keeping its nicotine from poisoning and addicting their brains, I'm incredibly proud of my team for their hard work on behalf of North Carolina families. We're not done - we still have to turn the tide on a teen vaping epidemic that was born of JUUL's greed. As your attorney general, I'll keep fighting to prevent another generation of young people from becoming addicted to nicotine*."[5]

1.3. How Juul Was Created

The story of Juul and its electronic cigarette develops in a particular industrial and social landscape which certainly contributed to the scandal associated with this company. Despite the complex dynamics behind this case, the introduction of Juul into the American market marked the beginning of an innovative era for nicotine consumption.

James Monsees and Adam Bowen, then students at Stanford University, together developed the initiative to launch a start-up with a clear and ambitious mission that if made possible could have been capable of changing the world: preventing smoking through the design of an innovative electronic cigarette, that could not only interrupt nicotine addiction but also mitigate the damage to health caused by traditional smoking.[6]

When Juul was developed smoking was a leading cause of preventable death in the United States, with impacts in terms of public health and economic costs. According to the Tobacco Control State Highlights 2010 report[7] published by the Centers for Disease Control and Prevention (CDC), cigarette smoking and exposure to passive smoke were responsible for approximately 443,000 deaths each year. This figure highlighted the

[4] How Juul Got Vaporized, Time (May 2021), https://time.com/6048234/juul-downfall/.
[5] Press Release, Office of the Attorney General, North Carolina, Statement by Attorney General Joshua H. Stein on Juul Settlement with North Carolina.
[6] Big Vape: The Rise and Fall of Juul (documentary film, Netflix, 2023).
[7] Tobacco Control State Highlights 2010, Centers for Disease Control and Prevention, https://www.cdc.gov/mmwr/preview/mmwrhtml/su6203a14.htm.

human losses caused by smoking and the urgent need for public health interventions with the primary purpose of reducing tobacco use. In addition to the high cost in human lives, tobacco-related diseases were impacting negatively also the US healthcare system, resulting in annual healthcare costs of $96 billion.[8]

In this context, the vaping and electronic cigarette industry in the United States in the early 2000s was growing dramatically in an environment practically without rules, with the FDA (Food and Drug Administration) finding itself powerless to monitor and regulate the products that entered the market without any control and without age limits for purchase.

In 2010, Monsees and Bowen, consistent with their idea developed years earlier at Stanford, launched Ploom's "Model One". The latter was one of the first incarnations of the products developed by Monsees and Bowen's business, which made its entry into the vaping market with this new electronic device. The initial marketing and positioning strategy of the Ploom focused on distributing the product in bars and clubs frequented by young people, offering them the opportunity to try the product and express opinions on potential changes. This experimental phase led to the creation of the first aromas. It emerged that consumer interest was in fact focused both on the intake and distribution of nicotine by the product but also on the unique experience offered by the variety of flavors.[9]

However, Ploom still had some limitations in its ability to effectively diffuse nicotine, making it unattractive especially to regular smokers. This flaw brought James and Adam to completely change the product. The revolutionary goal remained indeed the one of offering a less harmful alternative to traditional cigarettes. With the entry of new investors - including Japan Tobacco International - and a redesign of the production process, Pax was born, a vaporizer for loose tobacco that quickly gained popularity, especially among marijuana consumers, for its ease of use and effectiveness.

The success of Pax, although more significant than Ploom thanks to the ease of use of the product, once again placed the company in difficulty because the primary objective always remained that of defeating smoking. The team was aware that, to achieve this goal, they needed not only a product as intuitive and easy to use as Pax, but also capable

[8] Id.

[9] See note 6 supra.

of providing immediate nicotine gratification, similar to that offered by traditional cigarettes, all things that neither the Ploom nor the Pax were yet able to satisfy. Therefore, even this product would not have been able to direct the company towards its main mission and the primary reason why Monsees and Bowen engaged in this project.

Finally, the solution to this problem arrived thanks to an innovation in the formulation of nicotine: while the first generations of electronic cigarettes were based on free-base nicotine, difficult to inhale and limited in the quantity of nicotine that could be delivered, it was introduced by the company the use of nicotine salts. This "chemical trick" made it possible to solve the problem of little nicotine delivered, revolutionizing the way in which the latter was administered via vaporizer.[10] In December 2014, the Juul was completed and presented to the public. Its simple and essential design, often compared to Apple products for its sophistication and innovation, made it particularly attractive also from an aesthetic point of view for smokers. [11]

1.4. Ethics and Regulation with Juul

Juul offered a comparable amount of nicotine to conventional cigarettes, but in a much more accessible and socially acceptable form. However, the creation of a device capable of delivering the right amount of nicotine directly to the brain, together with the possibility of smoking practically anywhere, posed a fundamental ethical question: was it really a good idea to introduce it onto the market?

Juul at that point was thus faced with the complex task of equilibrating high profit expectations with a firm belief in its social mission. Entering the market with such an innovative and potentially revolutionary product required careful consideration of the ethical and public health implications combined with a launch strategy that took into account the long-term impact on society.

This is why we consider Juul's story as an emblematic example of the complexities and challenges that companies face in innovating responsibly in unregulated sectors.

For properly launching the new developed product into the market, James Monsees and Adam Bowen were aware of the critical importance of having a well-defined marketing strategy. Before Juul, e-cigarettes were perceived by society as gadgets for tech

[10] Id.

[11] Pax Juul: The iPhone of E-cigs?, Men's Journal, https://www.mensjournal.com/gear/pax-juul-iphone-e-cigs

enthusiasts or “nerds”, far from being considered cool or desirable by people. James and Adam obviously wanted to change this narrative, transforming Juul into a luxury product, above the negative stereotypes linked at that time to vaping.[12]

Juul wanted to adopt a marketing strategy based on positioning its target as authentic people with an aspirational lifestyle, shifting the focus from the company main mission to the creation of a "cool" image of the e-cigarette. The use of hashtags and a short "social takeover", even projected in Times Square, aimed to engage influencers and encourage sharing on social media. Additionally, to increase awareness Juul relied on organized events to attract influencers, inviting them to promote the device on their channels. The launch of Juul, which took place in June 2015, was marked by a large celebration in New York, specifically in Manhattan.[13] There, a massive quantity of free Juul vapes were distributed to guests, prompting them to post content and photos online related to that new product. This event, along with a six-month sampling tour in several urban areas of the United States, helped spread the brand, although some internal concerns had already begun to arise about the apparent young age of some users in social media posts. Social media marketing,targeting major influencers and acclaimed celebrities such as Leonardo DiCaprio and Bella Hadid, amplified Juul's visibility and appeal. But growing concerns about the device's popularity among young people and potential health risks remained.[14]

It is reported that no one on the team raised any objections to the proposed marketing strategies, except for one member of the board of directors, who was the only one to express some disapproval for the direction taken by the company with the advertising campaign. In fact, similarities were noted between the Juul ads and old tobacco ads, which had the same emphasis on glamor and sophistication of the product without considering the fact that it was addictive and unhealthy.[15] These similarities soon became noticeable to many, drawing criticism for developing the product and its promotion inspiring from the tobacco industry's worst advertising practices. Moreover, following a critical article in AdAge, Juul was forced to review and modify aspects of its recently launched campaign, finding itself in a difficult position. In September 2015, retailers' resistance to

[12] See note 6 supra..
[13] Id.
[14] The vape company Juul said it doesn’t target teens. Its early ads tell a different story., Vox (January 25, 2019), https://www.vox.com/2019/1/25/18194953/vape-juul-e-cigarette-marketing.
[15] See note 6 supra.

distribute Juul in their shops highlighted all the challenges the company was having in penetrating the market. Low demand as a primary consequence of these concerns led to a temporary halt in production. The controversies arisen led also to an internal reflection and modification of Juul's advertising campaigns and the strategies associated with them, with a change towards communication that emphasized and focused more on the product as an alternative to conventional smoking for adults, trying to reduce the visual appeal to young people.[16]

Despite the company's efforts to tone down its previously damaged product image and targeting, accusations of intentionally attracting young consumers heavily impacted Juul's reputation.

The challenges intensified with the introduction of federal regulation in the e-tobacco industry by the FDA, which until then had no specific expertise in the matter. After years of waiting, companies in the sector, including Juul, had to adapt to the new regulations with the new threatening monitor of the regulatory authority.[17] The overall situation worsened even more when, during a board meeting, James Monsees was removed from leadership of the company and management went directly to investors, who considered the possible liquidation of the company.

However, between June and July 2016, a sudden increase in sales, probably thanks to word of mouth in New York, demonstrated again how the most efficient advertisement is word-mouth generated by the users themselves. Generation Z, defined by individuals born between 1998 and 2010, saw in Juul a product that was particularly connected to their habits and lifestyle, already a lot influenced by highly addictive technologies such as smartphones, social media or video games. Other than the novelty of vaping from an electronic product, the initial attraction to Juul was the innovative design of the device, which was very similar to a USB stick, making it discreet and easily usable in social and academical settings without attracting attention. This feature facilitated rapid adoption and diffusion among teenagers, transforming vaping from an isolated activity to a mass social phenomenon. Juul's commercial success saw a significant peak in early 2017, so much that demand vastly overcame supply, making the device a rare and hard-to-find

[16] Id.

[17] E-Cigarettes and the Burdens of History: Children, Bystanders and the American War on Nicotine, https://link.springer.com/chapter/10.1007/978-3-031-23658-7_4.

item.[18]

1.5. Young People As a Major Target

Although the initial intentions of the company were focused on reducing addiction to traditional cigarettes, Juul's enormous popularity among young people raised important ethical and health questions. At the end of 2019, the Trump administration raised the legal age for purchasing tobacco to 21 years and, shortly after, the FDA (Food and Drug Administration) banned many flavored vaping products, because they were particularly capable of attracting teenagers. As will be further explored later when recent evolution of regulations of this complex industry will be analyzed, the FDA after this scandal evaluated whether to continue to allow the sale of e-cigarette products in the United States, with particular attention to preferred products by teenagers, like Juul itself.

Indeed, back in 2019 it was discovered that Juul was widely used, especially by teenagers, in contexts where smoking was prohibited, thanks to its small dimension and discretion. Research and studies revealed an evident change in the perception and use of nicotine among students, being Juul itself the reason why smoking became popular and "fashionable" again among teenagers, ruining years of efforts for trying to prevent or decrease the problem. The fact that the company collaborated with Altria, one of the giants of the tobacco industry, raised even more concerns. Indeed, this move definitely expanded market opportunities for Juul but also developed other criticism regarding the missing coherence with the company's mission to fight smoking. The collaboration with Altria represented an important change in the public perception of Juul, leading many to view the company as an accomplice rather than a solution to the smoking problem.[19]

At the end of 2019, therefore, the company faced a crisis of image and a series of legal actions against the company were taken, supported by associations of parents of children addicted and damaged by Juul. One example is that of Lisa Marie Vail, mother of a Florida teenager, who filed a lawsuit against Juul Labs over the death of her son, accusing the e-cigarette manufacturer of making the 18-year-old addicted to vaping and nicotine, a habit she claims led to his death.[20] The lawsuit was filed in the U.S. District Court for the Northern District of California, a jurisdiction that includes Juul's San Francisco office.

[18] Big Vape: The Rise and Fall of Juul (documentary film, Netflix, 2023).
[19] Id.
[20] Vail v. Juul Labs, Inc. et al. (N.D. Cal. Dec. 21, 2021).

Daniel David Wakefield, described as "*a healthy teenager whose life tragically and prematurely ended due to injuries directly caused by his addiction to JUUL*," died in his sleep at age 18 after years of using Juul products.[21] In another case, *People v. JUUL Labs, Inc.* presided over by Judge Margaret Chan in New York County Superior Court, the State of New York, represented by Attorney General Letitia James, filed charges against JUUL Labs, Inc. and its executives. The complaint, filed under No. 452168/2019, accused JUUL of engaging in deceptive marketing practices with its electronic nicotine delivery systems, specifically targeting young consumers. [22]

As a consequence, a decline in stock market valuations followed. Juul and the company executives denied targeting the product to adolescents and have repeatedly stated in press releases that they never intended to do so, specifying that the goal had always remained to offer adult smokers an alternative less harmful than combustible cigarettes. They specified that while the product still managed to gain great popularity among teenagers, this was never the company's goal. The data, however, were very clear and raised concerns and criticism against the company, especially from an ethical and sanitary point of view.[23] In 2020, 20% of high school students and 5% of middle school students in the United States reported to have used e-cigarettes in the previous month.[24]

1.6. Juul's Legal Battles

E-cigarette lawsuits are increasing in the United States. Users of Juul and other vaping devices are suing manufacturers because of serious health problems such as seizures, lung injuries, illnesses and strokes. Many of these lawsuits additionally allege that individuals have become addicted to e- cigarettes, worsening their health conditions. Moreover, most of these lawsuits focus on Juul Labs Inc. At the moment, 5,102 cases against Juul have been grouped into a multidistrict litigation (MDL), coming from all over the United States. Recent settlements include a $23.8 million payment to the city of Chicago for false

[21] Juul Labs Faces Lawsuit Over 18-Year-Old's Death, US News (Oct. 16, 2019), https://www.usnews.com/news/healthiest-communities/articles/2019-10-16/juul-labs-faces-lawsuit-over-18-year-olds-death.

[22] People v. Juul Labs, Inc., Index No. 452168/2019, NYSCEF Doc. No. 284 (N.Y. Sup. Ct. filed July 6, 2022).

[23] Juul disregarded early evidence it was hooking teens," Reuters, https://www.reuters.com/investigates/special-report/juul-ecigarette/.

[24] E-cigarette Use Among Middle and High School Students — United States, 2020," Centers for Disease Control and Prevention, MMWR Morb Mortal Wkly Rep, vol. 69, no. 37, pp. 1310-1312, https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e1.htm.

advertising and sales to minors in March 2023, and a $255 million settlement approved by a California judge in a class action lawsuit against Juul in January 2023. Additionally, Juul agreed to pay approximately $440 million to 33 states to resolve allegations that it promoted its products to teenagers.[25] The claims in the Juul-related lawsuits include, as we have seen through an analysis of the case, marketing its products to appeal to minors, promoting the use of nicotine without warning of its harm and addictiveness and the sale of defective and dangerous products. Despite widespread lawsuits alleging respiratory problems and other serious health effects caused by vaping, no trials have yet been scheduled for this litigation. The lawsuits against Juul allege that the products have caused nicotine addiction and serious problems of health, including cases of devices exploding or burning, highlighting the growing concern about the risks associated with vaping especially among young people.[26]

In response, Juul has also developed a new device with the ability to check the age of the user which also prevents the use of counterfeit or unauthorized third-party refill cartridges. It has also submitted various products to the FDA, hoping for approval, which now has control over monitoring the sector.[27] In recent years, Juul has seen its value drop from $38 billion in 2018 to just $1 billion as of October 2022.[28] Juul's story stands as a warning and as an example on the complexities and risks associated with commercializing innovative products in an industry not clearly regulated. The difficulty of balancing innovation, public health and corporate ethics remains a central theme in the debate on the future of vaping and its impact on new generations.

[25] E-Cigarette Lawsuits," Drugwatch, https://www.drugwatch.com/e-cigarettes/lawsuits/.
[26] Id.
[27] Juul seeks authorization on a new vape it says can verify a user's age. Here's how it works, CNN, https://edition.cnn.com/2023/07/31/tech/juul-vape-can-verify-users-age/index.html.
[28] The rise and fall of Juul, Business Insider, https://www.businessinsider.com/juul-timeline-from-startup-to-tobacco-company-challenges-bans-2019-9.

CHAPTER II
REGULATION OF E-TOBACCO PRODUCTS IN THE US: HOW THE INDUSTRY HAS EVOLVED AND CHANGED

2.1. The Regulatory Evolution of E-Cigarettes in the United States

Electronic cigarettes came to the U.S. market in 2006. These products remained federally unregulated until 2022, when the Food and Drug Administration gained control and oversight of this market and ordered Juul Lab., which owned about 75 percent of the vaping market, to be removed from the U.S. market.[29]

The FDA started its battle for obtaining oversight of this sector in October 2008, when the agency detained several shipments of e-cigarettes at Los Angeles International Airport, claiming they violated the Food, Drug, and Cosmetic Act.[30]

The FDA defined e-cigarettes as drugs, since they were able of both affecting body functions through nicotine and mitigating or stopping the addition to combustible tobacco.[31] Importers and manufacturers of e-cigarettes, predictably, had a different view of the devices' function. In fact, they strategically avoided making any claims about the therapeutic effects of e-cigarettes so that they could circumvent FDA controls and not have to follow its regulation on sale. As a matter of fact, the two manufacturers of the e-cigarettes that were detained in 2008 at Los Angeles Airport sued - successfully - the FDA to end the detention of their products. It was consequently decided that the FDA could not regulate tobacco products as drugs or drug delivery devices unless the products were marketed with claims of their therapeutic effects.[32]

Three years later, with sales of e-cigarettes in the United States rapidly increasing up to $1.5 billion,the FDA was seeking more than ever to break into the regulation of this innovative and completely unregulated industry that was rapidly advancing and raising numerous controversies.[33]

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[29] E-Cigarettes and the Burdens of History: Children, Bystanders and the American War on Nicotine," in: Vapors: Essays on the Cultural History of Electronic Cigarettes, edited by Ronald Bayer & Amy L. Fairchild, 2023, pp. 83-119, https://link.springer.com/chapter/10.1007/978-3-031-23658-7_4.

[30] Id.

[31] Wagoner, K.G., Berman, M., Rose, S.W., Song, E., Ross, J.C., Klein, E.G., Kelley, D.E., King, J.L., Wolfson, M., & Sutfin, E.L. "Health claims made in vape shops: an observational study and content analysis," , 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8142343/.

[32] Supra nota 1.

[33] Hildick-Smith, G.J., Pesko, M.F., Shearer, L., Hughes, J.M., Chang, J., Loughlin, G.M., & Ipp, L.S. "A Practitioner's Guide to Electronic Cigarettes in the Adolescent Population," Weill Cornell Medical College,

2.2. The E-Cigarette Debate

In the United States and all over the world the debate about the use of e-cigarettes became a rapidly growing area of interest for various organizations and people. In 2009, for instance, the United States World Health Organization issued a warning stating that e-cigarettes were employed to evade the public smoking bans, critical for controlling tobacco.[34]

The most important concerns raised were on the function of the e-cigarette as a product that would make the way to sociability and relaxation easier, a medium that therefore was anticipated to increase smoking, predominantly among young people.

Other concerns were raised on the role that e-cigarettes were having on increasing awareness of smoking, especially through their endorsement by celebrities or through being depicted in social media. Based on all these issues, in September 2013, 40 U.S. attorneys asked the FDA to quickly regulate e-cigarettes as tobacco products.[35]

The main line of disagreement within those years was between experts and tobacco control activists, both debating on the optimal strategy for the nearest future of e-cigarettes. Many experts pushed forward the precautionary approach, stressing the risks for non-smokers and youth associated with e-cigarette use and advocating for regulation. On the other hand, some organizations such as the Truth Initiative and some researchers initially regarded e-cigarettes not as a threat but as an opportunity to reduce the harm deriving from cigarettes, particularly for adults trying to quit smoking normal cigarettes. However, as time passed and more data were being gathered, even organizations that had spoken for a harm reduction approach changed their role and considered the risks for adolescents, becoming more anti-vape. Such developments would lead to a polarization over the years to the current e-cigarette debate in the US, requiring the immediate regulation of the industry.[36]

Cornell University, New York, New York, Article history: Received April 17, 2015; Accepted July 12, 2015.

[34] World Health Organization (WHO), "WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2009: Implementing smoke-free environments", https://www.afro.who.int/sites/default/files/2017-06/9789241563918_eng_full.pdf.

[35] Supra note 1.

[36] Supra note 1.

2.3. From Municipal Bans to FDA Oversight

In 2011, health officials in Boston, Massachusetts, voted to treat e-cigarettes as tobacco products, banning their use in the workplace and restricting their sale to adults. Boston would later ban all smoking of combustible cigarettes, including the use of e-cigarettes, in outdoor parks, plazas and cemeteries. New York City was the second major city to ban e-cigarettes in all places where tobacco smoking was prohibited, including parks and beaches. Los Angeles unanimously approved a ban on e-cigarettes in parks and beaches in March 2014. Chicago and San Francisco followed, and finally in 2018, 12 states, including California, Massachusetts, New Jersey and the District of Columbia had laws banning the use of e-cigarettes in outdoor settings.[37]

In October 2013 the FDA proposed a draft Notice of Proposed Rule to the Office of Management and Budget's Office of Regulatory Affairs at the White House.[38] The FDA thus finally announced its intention to bring e-cigarettes and a variety of other products under its regulatory authority. The content of the proposed rules, such as product manufacturing standards, testing provisions, and limits on advertising, however, had yet to be determined. The fact that the products were so recently introduced brought with it shortcomings on medical research or epidemiological evidence on the possible harms that e-cigarettes could cause, which made the realization of the regulatory structure very complex, as it could not be based yet on accurate data.[39]

In June 2017, the Commissioner of the Food and Drug Administration Scott Gottlieb announced a new plan to regulate tobacco and nicotine under the Tobacco Control Act: companies that wanted to offer new e-cigarettes on the market were required to use the pre-market tobacco product application process, which is also known as PMTA.[17] Electronic cigarettes already on the market also had to meet this requirement. At the heart of the change was what the agency described as *"an increased awareness that nicotine, though highly addictive. is delivered through products that represent a continuum of risk and is more harmful when delivered through smoke particles in*

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[37] Id.

[38] "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance," Federal Register, vol. 78, no. 176, pp. 55814-55815, September 11, 2013, https://www.federalregister.gov/documents/2013/09/11/2013-22013/agency-information-collection-activities-submission-for-office-of-management-and-budget-review.

[39] Allen, A., & Ozier, C. "FDA's Comprehensive Approach to Nicotine and Tobacco," Food and Drug Law Institute (FDLI), https://www.fdli.org/2017/10/fdas-comprehensive-approach-nicotine-tobacco/.

traditional cigarettes".[40]

The FDA structured a review of evidence and data related to the harm of e-cigarettes together with the National Academies of Science, Engineering and Medicine (NASEM). NASEM's official charge was to review the scientific literature, identify research needed to fill evidentiary gaps, and make judgments about the short- and long-term health effects of e-cigarettes. Growing evidence that e-cigarettes were substantially safer than combustible products was confirmed. However, the report sounded as an alarm when the risks to adolescents and bystanders was examined. NASEM concluded that because e-cigarettes contained and emitted potentially toxic substances, the use of e-cigarettes indoors could unintentionally expose non-users to nicotine and particulate matter.[41] The head of the FDA's Division of Tobacco, Mitch Zeller, interpreted the evidence in light of the NASEM report arguing that for adolescents starting with e-cigarettes there was a large possibility of heavy use of traditional cigarettes.[42] The issue of harm to the adolescent generation was undoubtedly the debate that increased the most controversy. Moreover, the negative light that major newspapers such as the New York Times or the Los Angeles Times put on e-cigarettes contributed to this somber image and focused on addiction and health risks, especially those presented for young people. In addition, this narrative was further amplified by a series of reporting cases of alarming vaping-related diseases, with several states imposing bans or restrictions on the sale of electronic cigarettes.

Nonetheless, there was and still remains data that proved benefit of e-cigarettes. A large clinical trial published in the New England Journal of Medicine in 2019 for example stated that e-cigarettes were significantly more effective than nicotine replacement therapy for smoking cessation. Still, the debate continued to be steeped in concerns on youth addiction and the risks associated, and this turned out to be increasingly more important than the benefits e-cigarettes brought.[43]

The FDA's legal challenges and actions in this context reflect the continuing struggle to

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[40] FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death," Food and Drug Administration (FDA), https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

[41] Supra note 1.

[42] "The E-Cigarette Debate: What Counts as Evidence?" Nicotine Tob Res. 2019 Jun 19;21(7):857-864. doi: 10.1093/ntr/ntz070. PMID: 31038658; PMCID: PMC6603453. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6603453/.

[43] Id.

balance public health concerns with the regulatory framework.

In May 2019, the court has issued a very harsh ruling against FDA guidelines for not fully dealing with the health issues of tobacco use in public and leaving companies to promoting and selling products that were indeed addictive and focused on young people. We have analyzed in the previous chapter how Juul Lab itself portrays a clear example of this phenomenon.

Subsequently, the court imposed that, within a 10 months deadline, tobacco product makers had to submit marketing authorizations (PMTAs) and within one year they had to obtain FDA approval to sell their products. In response to this, FDA went harder against sales of flavored e-cigarettes but still retained enforcement discretion for certain entities as a way of striking a balance between youth vaping prevention and smoking cessation among adult smokers. It was indeed a pivotal moment when the Juul's application for marketing authorization was disallowed by FDA[44]. In 2021,the agency removed more than 1,000,000 products *"that lacked sufficient evidence that the benefit to adult smokers using the flavored products outweighed the public health concern caused by the products' well-documented and considerable appeal to youth".*[45]

2.4. The Menthol Debate

More controversial, however, has been the debate over menthol, after the FDA made clear its intention to ban menthol in combustible cigarettes. Menthol has indeed always been the most unsafe tobacco chemical for both adult and teenage smokers. As an evidence of this, data suggest that 52% of all young people smoke their first cigarette with menthol. [27] Additionally, alarming rates are observed particularly among African Americans, with more than 90% of this community vaping menthol flavored cigarettes. As a matter of fact, US menthol cigarettes have been primarily marketed towards distinct demographic groups, including black neighborhoods, females and juveniles.

The tobacco business used this type of advertisement technique in its quest to consolidate

[44] Food and Drug Administration (FDA), "FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency," https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency.

[45] Food and Drug Administration (FDA), "FDA Proposes Rules Prohibiting Menthol Cigarettes and Flavored Cigars to Prevent Youth Initiation, Significantly Reduce Tobacco-Related Disease and Death," [data di pubblicazione]. Disponibile su: https://www.fda.gov/news-events/press-announcements/fda-proposes-rules-prohibiting-menthol-cigarettes-and-flavored-cigars-prevent-youth-initiation.

its market base and promote nicotine dependence among vulnerable communities. This policy has been carefully monitored and criticized for leading causes of public health disparity in communities already burdened by social and economic inequalities Historically, menthol cigarettes have been sold as milder, cooler and fresher than non-menthols. These characteristics were meant to attract first time smokers, particularly adolescents, who may find normal cigarettes too heavy. The marketing strategy turned out to be very alarming. Data show that many teenagers largely prefer menthol cigarettes. The lure of menthol cigarettes alongside misleading ads - which mainly focused on fake health claims like "organic" and "natural" - created the perception amongst consumers that they are not as dangerous as other smoking products. The US FDA move to ban menthol cigarettes coincides with those of other countries and organizations aimed at recognizing the disproportionate damage caused by these products. In particular, taking these items away from the market is considered a solution for targeted advertising tactics against disadvantaged populations with regard to public disease discrepancies. The FDA plans to prohibit the sales of menthol cigarettes in order to reduce e-cigarette vaping among teenagers particularly, and lower rates smoking-related disorders.[46] Hence, in 2023 the FDA started imposing stricter restrictions on menthol products. For instance, this led to Reynolds' permanent prohibition of its top-most selling menthol items from being sold in the market, noting that the company was not indeed in line with the federal standards demanding for e-cigarettes to be more beneficial than risky on health grounds. Some proponents of e-cigarettes nevertheless condemned such a move, maintaining that flavors like menthol make e-cigarettes a more viable option among smokers who are trying to stop the smoking habit. [47]

It is important to underline that these issues have not been finally resolved in a definitive way. In fact, there are still dissenting voices within this dynamic debate, including those between the Truth Initiative, other leading NGOs and public communities on one hand and those who believe that US regulatory action on these products is too strict,

[46] D'Ardenne, K. "How menthol cigarette ads target Black people, women and teens," Scope, Stanford Medicine, pubblicato il 18 ottobre 2022. Disponibile su: https://scopeblog.stanford.edu/2022/10/18/how-menthol-cigarette-ads-target-black-people-women-and-teens/.

[47] "FDA's Decision To Block Sale of Popular Flavored E-Cigarettes Signals Stricter Tobacco Controls," ACHI.net, https://achi.net/newsroom/fdas-decision-to-block-sale-of-popular-flavored-e-cigarettes-signals-stricter-tobacco-controls/.

denying harm reduction for cigarette smokers. This overview shows how regulation of innovative industries like electronic tobacco is always changing and linked with many ethical and health aspects, thus requiring continuous control and monitoring to create a peaceful equilibrium between firms involved in production of such goods or services and society targeted by them.

CHAPTER III
THE ITALIAN CONTEXT: REGULATION AND IMPACT ON THE NATIONAL MARKET

3.1. Regulating Electronic Cigarettes in Italy

Electronic cigarettes were first introduced into the Italian market in 2006, becoming an interesting and attractive product, especially for all those who were looking for a less harmful alternative traditional cigarette. For this reason, the sale of electronic cigarettes in the Italian market immediately rose to very high peaks, increasing and spreading rapidly. As in the United States, also in Italy the legislative intervention on this type of product was quite contradictory, mainly because of the difficulty in regulating a product that was innovative but also potentially harmful, although there was still no clear scientific data on the harm of electronic-cigarettes.[48]

In 2013, with DL 104/2013[49], the Italian Parliament intervened in Italian tobacco policy by ordering a ban - which had already been introduced in 1965 by Don Luigi Sturzo only for traditional cigarettes - on advertising brands of liquids or refills for electronic cigarettes that contained nicotine, unless accompanied by a warning about the presence of nicotine and the risk of addiction. The ban on advertising was brought directly by the Chairman of the 7th Commission of the Chamber of Deputies as well as Rapporteur of the Law: Hon. Giancarlo Galan of Forza Italia.[50]

3.2. Smokie's Case Study

The case study of Smokie's - an electronic cigarette company in Italy - illustrates how such aninnovative industry quickly became a complex environment for developing a business.

Initially this market was not particularly regulated, allowing companies to thrive and expand rapidly. In fact, Smokie's initially capitalized on the market opportunity offered by electronic cigarettes. Hence, the company had expanded rapidly, also establishing a

[48] Tabacco Endgame, "Sigarette elettroniche in Italia: ambiguità e carenze della attuale regolamentazione," Tabacco Endgame,https://www.tabaccoendgame.it/news/sigarette-elettroniche-in-italia-2-ambiguita-e-carenze-della-attuale-regolamentazione/.

[49] Law No. 104 of September 12, 2013, art. 4, para. 5-quater, https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legge:2013-09-12;104~art4-com5quater.

[50] Supra note 1.

franchise network that included outlets both in Italy and abroad. Core products included vaping devices, flavored liquids and accessories, all aimed at meeting the growing demand for alternatives to traditional smoking.

However, the control imposed in 2013 posed no small obstacle, requiring strict monitoring over the marketing and sale of these products and consequently bringing uncertainty to the industry.

These regulatory changes obviously impacted the success that Smokie's and the industry in general were having. In particular, there has been a major decline in sales, as the new restrictions greatly limited the ability of companies to freely market their products. Increased regulation also raised the barriers to entry into this market, stimulating fiercer competition among companies that were able to comply despite the new regulations.[51]

3.3. Challenges in Enforcing Regulatory Normative

In 2019, the Court of Rome with the Order Nov 5, 2019 - 57714 declared illegal the direct and indirect advertising of electronic cigarettes, including the advertisement on social media. The Court of Rome intervened with this Order because companies continued to advertise the products by trying to circumvent the laws, for example advertising on street billboards but also and especially through influencers.[52]

Enforcing the vaping advertising ban in Italy is a complex task because the tobacco and e-cigarette industries consider advertising a vital activity to increase their sales and to create more awareness among consumers. These businesses, through rather ingenious methods, try to circumvent the bans on advertising. For example, many of these companies, noticing that the law declares it illegal to advertise the product itself, try to promote anything that is not “product” (e.g. vape-shops). The law also allows businesses to sell to minors cigarettes and liquids as long as those are nicotine-free.

Additionally, minors can buy devices and liquids online on domestic or foreign sites. The sale of electronic cigarette liquids via the web was indeed allowed and the problem arose because online sellers check the attainment of age of majority based solely on a self-

[51] Tonino Pencarelli & Giulia Festa, "La Sigaretta Elettronica in Italia: Da Oceano Blu a Oceano Nero? Il Caso Smokie's" (2014), file:///C:/Users/HP/Downloads/aburatti-101_pdfsam_PMI_2_2014%20(1).pdf.

[52] "Portolano Cavallo Inform: Digital & IP - The First Italian Case on Electronic Cigarettes Advertising" https://portolano.it/en/newsletter/portolano-cavallo-inform-digital-ip/the-first-italian-case-on-electronic-cigarettes-advertising.

declaration, so minors can either make a false claim or assume a false identity and eventually make the purchase on a foreign site. The current regulation is therefore insufficient because the ban is easily circumvented.[53]

In 2018, an amnesty and preferential tax regime for electronic cigarette manufacturers was introduced in Italy. The amnesty - which was worth more than 170 million euros to businesses in the sector - was to facilitate the payment of unpaid consumer tax debts until December 31,2018, by paying only 5 percent of the total amount.[54]

As a result, there is now a significant economic advantage for those who vape over those who smoke. Indeed, a smoker of 20 Marlboros per day spends €2000-2150 in a year, while a person vaping with an electronic cigarette an amount of e-liquid that provides the equivalent of nicotine spends about €1350 per year, hence there is a saving of 35 percent.[55]

3.4. Lack of Immediate and Timely Data

Key data on the prevalence of e-cigarette use among youth are collected every four years through the Global Youth Tobacco Survey (GYTS), an initiative led by the National Institute of Health. The latest dataset available for Italy is from 2018. In the period from 2014 to 2018, the percentage of Italian adolescents using e-cigs more than doubled from 8 percent to 18 percent. In addition, the percentage of young people vaping without ever having smoked traditional cigarettes grew from 3% to 8%.[56]

Over the course of just four years in the United States the Juul electronic cigarette captured 75 percent of the market, reaching a value of $35 billion. We have seen in previous chapters how it then took only a few years of more stringent regulations to cause significant difficulties for its business model. Thus, there is a clear need for a data collection system that is more frequent, ideally for example on an annual basis, considering that GYTS does not require excessive resources to implement.[57]

As for adults, data on vaping, other potentially harmful uses of e-cigarettes and combined use of e-cigs and traditional cigarettes are currently provided by the Passi Surveillance

[53] Note supra 1.
[54] Id.
[55] Id.
[56] Id.
[57] Id.

and the annual DOXA tobacco use survey. However, these surveys, administered by the National Institute of Health, are facing significant difficulties due to the Covid-19-related health emergency. It should also be noted that the ISTAT survey, which annually provides data on smoking, does not yet include e-cig use.[58]

The lack of immediate and timely data makes the law rather vulnerable and defenseless in the face of pressure from interest groups, such as precisely the e-cigarette manufacturers themselves, thus ultimately favoring those with potentially harmful intentions and limiting the ability of the government to intervene, which often remains in the dark and with little data on current developments and the harmfulness of these products.[59]

3.5. EU Intervention

However, The European Union is trying to intervene by taking significant steps in the area of tobacco product regulation, with the ultimate goal of restricting the use of heated flavored tobaccos. This step is in fact part of a broader strategy focused on trying to reduce the attractiveness of smoking and, consequently, its negative impact on public health. Health Commissioner Stella Kyriakides emphasized the intention to remove these products from the market to advance toward the goal of a "Tobacco Free Generation" by 2040, with less than 5 percent of the European population using tobacco. This measure also fits into the European Cancer Plan and aims to drastically reduce cases of lung cancer, which are directly related to tobacco use.[60]

Since the European Union perfectly recognizes that tobacco use is the most important cause of premature death and that tobacco causes 90 percent of lung cancer, it is standing firmly against the tobacco industry, seeking to protect the health of European citizens, especially the youngest.[61]

Therefore, a ban on the sale of flavored HEETS was introduced by the European Union in

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[58] Ministero della Salute, "Fumo di tabacco elettronico," Ministero della Salute, https://www.salute.gov.it/portale/fumo/dettaglioContenutiFumo.jsp?lingua=italiano&id=5589&area=fumo&menu=vuoto.

[59] Note supra 1.

[60] European Commission, "Europe's Beating Cancer Plan: Commission proposes to prohibit flavoured heated tobacco products" https://health.ec.europa.eu/latest-updates/europes-beating-cancer-plan-commission-proposes-prohibit-flavoured-heated-tobacco-products-2022-06-29_en.

[61] Agenzia Nazionale Stampa Associata (ANSA), "UE vuole vietare sigarette a tabacco riscaldato aromatizzato" https://www.ansa.it/europa/notizie/rubriche/altrenews/2022/06/29/ue-vuole-vietare-sigarette-a-tabacco-riscaldato-aromatizzato_bc3706b6-3ac4-4fa5-a327-95fcd2d85a56.html.

2023, extending to all flavors such as menthol, vanilla, and strawberry. HEETS are innovative tobacco cartridges exclusively developed by IQOS, a line of tobacco heating devices and e-cigarette liquids manufactured by Philip Morris International. The IQOS device enables the use of heat-not-burn technology. From the very name HEETS, in fact, the cartridges hint at the type of use for which they are intended, playing on the English word heat, which is pronounced almost equally. Heat-not-burn technology allows tobacco to be heated rather than burned, and e-cigarettes use a process of vaporizing flavored liquids.[62]

The ban on flavored HEETS is designed to reduce the attractiveness of smoking, particularly among young people, a target audience considered vulnerable to the appeal of products that look less harmful at first glance but actually contribute to the maintenance of the smoking habit. This perception of electronic tobacco products as less harmful could be misleading, as the products still pose significant health risks.

Linking these policies with ongoing monitoring and regulatory efforts, as suggested by the need for more frequent and detailed surveys on tobacco and related products consumption, is essential and necessary to ensure that the measures taken are effective and based on realistic, up-to-date data. [63]

3.6. The Impact of Stricter Policies on Italy's Electronic Cigarette Market

Thanks in part to the European Union's tightening of electronic tobacco policies, 2023 marks a truly significant turning point in the regulation of vaping-related products in Italy, with the introduction of specific tax measures also for liquids and flavorings used in electronic cigarettes. These new policies, brought forward by the main parties of the center-right governing coalition, aim to extend state taxation - already applied to nicotine and tobacco - to flavorings and shot series or split liquids as well, in addition to traditional ready-to-use liquids with and without nicotine and disposable e-cigarettes. The measures were codified in the amendment added to Article 6 of the budget law, which includes urgent economic and fiscal provisions. As of May 1 2024, therefore, according to Decree Law 145/23 approved by the Chamber of Deputies, all vaping products, including

[62] IQOS Italia, "Stick di tabacco HEETS: caratteristiche" https://it.iqos.com/it/news/prodotto/stick-di-tabacco-heets-caratteristiche.

[63] Il Sole 24 Ore, "Tabacco aromatizzato, UE propone divieto vendita", https://www.ilsole24ore.com/art/tabacco-aromatizzato-ue-propone-divieto-vendita-AEZ7JBjB.

concentrated flavors and split liquids, are subject to variable taxation and will have to be marketed with a tax seal certifying their tax compliance. This new tax regime applies to both end consumers and stores, manufacturers and importers, with different timelines for the disposal of pre-existing stock.[64]

We have therefore seen how the introduction of stricter regulations, starting with DL 104/2013, changed the advancement that the electronic tobacco industry was having in Italy, as it imposed restrictions on advertising and taxed products, ultimately then increasing control over their marketing and sale. Therefore, we can conclude that the future of the Italian electronic cigarette market is directly related to decisions on legislation and the ability of companies to respond to an environment that is constantly changing. Companies in the industry must therefore be able to adapt quickly to changes in the regulatory environment while continuing to innovate and meet customer expectations. Indeed, effective regulatory oversight could ensure consumer safety and create the structures for sustainable and responsible development of the Italian vaping industry.

[64] Svapo Studio, "Tassa su liquidi e aromi per la sigaretta elettronica", https://svapostudio.com/tassa-su-liquidi-e-aromi-per-la-sigaretta-elettronica-2024/.

CHAPTER IV
BUSINESS ETHICS AND SOCIAL RESPONSIBILITY IN AN ERA OF UNCERTAIN REGULATION

4.1. Navigating Regulatory Uncertainty

Today's global environment is part of an era of rapid change, where new innovative products are continuously introduced into a market driven by constant digitization. In this strong dynamic, it is possible that the law and the normative environment is uncertain about the regulation of such products, precisely because of their novelty. The concept of business ethics and social responsibility takes on an increasingly central role in understanding the boundaries that companies are required to respect in contexts of such regulatory uncertainty. Corporate Social Responsibility (CSR) and Human Right Due Diligence (HRDD) emerge as essential tools for companies that aspire not only to survive but, more importantly, to thrive in this dynamic environment.

4.2. Corporate Social Responsibility and Human Right Due Diligence

We can define Corporate Social Responsibility as a form of business self-regulation that has the primary purpose of contributing to the achievement of social and ethical goals of the company. The term can be even further expanded by defining CSR as a way to create shared value, thus with the ultimate goal of conducting a business in a socially responsible manner but also earning profits by improving the company's recognition.[65]

An additional term that comes back of interest in this context is Human Right Due Diligence, which is a process that businesses undertake to identify, mitigate and resolve any negative human rights impacts possibly jeopardized by their operations. This approach is designated to assess the current or possible human rights issues that might arise directly from the activities performed by a business or indirectly through vertical or horizontal connections: from their products, operations, or services.[66]

[65] Investopedia, "Corporate Social Responsibility", https://www.investopedia.com/terms/c/corp-social-responsibility.asp.

[66] United Nations Development Programme, "HRDD Interpretive Guide", https://www.undp.org/sites/g/files/zskgke326/files/2022-10/HRDD%20Interpretive%20Guide_ENG_Sep%202021.pdf

4.3. The Challenge of Managing Social Responsibility in a Rapidly Evolving Regulatory Landscape

We live in an era of constant change and evolution, both from the standpoint of the products that are part of the market and from the standpoint of the regulation behind innovation. Many businesses therefore find themselves in the position of having to manage their social and environmental responsibilities in situations where regulations are changing or even absent, we can think for example of the regulatory evolution that has been taking place in recent months in the context of Artificial Intelligence. In this dimension, concerns have emerged regarding the compliance of current regulations and potential legal liabilities. Artificial intelligence brings with it the risk of amplifying problems related to user privacy and the management of sensitive data. Indeed, the sector is already under the crosshairs of lawsuits, with companies such as OpenAI and Microsoft finding themselves facing allegations related to unauthorized access of protected materials.[67]

It has been identified that the regulatory uncertainty behind this sector is the main obstacle to the adoption of artificial intelligence in companies, and many CEOs are deciding to take strategic pauses in implementation to observe the evolving regulatory environment. Other companies, on the other hand, limit its use to functions of less risk.[68]

4.4. Corporate Boundaries and Social Responsibility

It is here, then, that the discussion that aims to understand what boundaries companies should respect in situations of regulatory or normative uncertainty arises, in order to move toward ethical and social responsibility despite the ambiguity of the context in which they operate.

Several researches have been conducted with respect to the topic. An initial study that we will review examines how companies manage their social responsibilities focusing particularly on how they behave when the regulatory environment is uncertain.

Research explains that governments greatly influence how companies approach Corporate Social Responsibility because they themselves issue the regulations that define

[67] CIO, "L'incertezza normativa mette in ombra l'IA generativa nonostante gli elevati ritmi di adozione" ,https://www.cio.com/article/650713/lincertezza-normativa-mette-in-ombra-lia-generativa-nonostante-glielevati-ritmi-di-adozione.html.
[68] Id.

what businesses can and cannot do. Precisely when laws are not fixed but constantly changing, companies can find themselves struggling with respect to how they should act in order to be considered socially responsible. The study then looked at a group of companies in the United States and measured the difference on how much they were ethically committed to contributing to the economic and social development of the country depending on the regulatory uncertainty under which the companies were working. The results of the research were quite interesting, showing that most of the companies analyzed that found themselves in a climate of regulatory uncertainty tended to make fewer CSR efforts. The research suggests that this happened likely because, when companies are insecure about possible government actions regarding laws and regulations, they are reluctant to engage in these types of projects because they fear wasting resources on something that may not be in line with future regulations. Consequently, the research concludes that if governments could make the regulatory environment more predictable or at least manage uncertainty better, companies might be more encouraged to voluntarily engage in CSR.[69]

4.5. Strategic CSR in Uncertain Times: A Hedging Strategy for Stability and Reputation

In contrast, a second piece of research that will be analyzed offers mixed results that nonetheless broaden the possible different perspectives on this context of uncertainty and corporate behavior with respect to it. The research investigates, as in the previous one, how government policy ambiguity affects companies' decisions to engage in CSR beyond what is required by law. The study revealed that the companies analyzed (part of a large sample of U.S. companies from 2003 to 2018) tended to strengthen their commitment to CSR causes when working in uncertain political environments. The research suggests several possible causes as to why this had occurred. The study talks about a "hedging strategy." This insight is a key for understanding that many companies invest in Corporate Social Responsibility in times of uncertainty precisely as a strategy to help project stability and reliability to stakeholders, making the company appear more resilient and stable in

[69] Lamia Chourou, Darlene Himick, & Samir Saadi, "Regulatory Uncertainty and Corporate Social Responsibility," Finance Research Letters Volume 55, Part B (July 2023), 104020, available at Elsevier, Finance Research Letters ,https://www.sciencedirect.com/science/article/abs/pii/S1544612323003926.

the face of unpredictable times. The study thus suggests that in such scenarios, companies resort to CSR as a strategy to safeguard their interests by aiming for a positive reputation that can protect them from the negative impacts of uncertainty. This research shows how in addition to ethical and moral reasons, companies also engage in CSR for strategic reasons, finally to improve their positioning this uncertainty.[70]

4.6. Corporate Responses to Regulatory Uncertainty: CSR and HRDD Strategies for Ethical and Strategic Alignment

The two studies thus examine the dynamics between regulatory, political instability and corporate engagement in CSR, demonstrating how there can be different reactions of companies. Both studies show how regulatory uncertainty leads businesses to rethink and recalibrate their CSR efforts. Some companies tend to remain very cautious about investing in new initiatives for fear of engaging in actions that may not align with future regulations. Others, on the other hand, view engaging in social responsibility initiatives as genuine strategies, both for protection (basically as a sort of insurance in the face of uncertainty) and as a way for positively enhancing their reputation.

A further study reflects on how HRDD can have an impact on the behavior of companies in similar situations but with respect to their human rights obligations; thus, the dimension of uncertainty here is expanded in the sense that companies may also find themselves in the situation where they should develop rigorous due diligence processes in order to confidently navigate ambiguous terrain when there is an implication of human rights and thus ethics.

In this regard, the research develops by highlighting how companies need always to take proactive steps that align ethical commitments and strategic interests, even when there is an unclear climate with respect to the regulations that protect society in the sphere in which the company works or has connections.[71]

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[70] Daoju Peng, Gonul Colak, & Jianfu Shen, "Lean against the wind: The effect of policy uncertainty on a firm's corporate social responsibility strategy," Journal of Corporate Finance Volume 79 (April 2023), 102376, available at Journal of Corporate Finance, https://www.sciencedirect.com/science/article/pii/S0929119923000251.

[71] Malcolm Rogge, "Risk, Uncertainty and the Future of Corporate Human Rights Due Diligence," Corporate Responsibility Initiative, Harvard Kennedy School, Working Paper No. 81 (December 2022), available on Corporate Responsibility Initiative, https://www.hks.harvard.edu/sites/default/files/centers/m

4.7. Lessons from the Juul Case: The Imperative of CSR and HRDD in Regulatory Uncertainty

To offer a concrete example of how these issues have not been addressed in the proper way in this thesis is reported the Juul case. This legal case, as well as others in the world of the electronic tobacco industry, explained to us how products can negatively impact public health - particularly young people - when there is a climate of absence or uncertainty with respect to the regulation of electronic tobacco products.

Many companies find themselves having to operate in a very uncertain regulatory environment, with innovative products such as e-cigarettes, where regulations are constantly evolving to support the pace of technologies. In contexts such as this, the advice is to always adopt proactive strategies where transparency and early compliance with possible future regulatory decisions is foregrounded, committing to protecting human rights and positioning as true ethical leaders in the industry, thus being able to build an aura of positivity with respect to the social reputation of the company itself. The aim is to consider both Corporate and Social Responsibility and Human Right Due Diligence not only as ethical or legal obligations but as key elements in corporate strategy, especially in contexts of regulatory uncertainty, as a path to long-term sustainability.

CONCLUSION

The Juul case, analyzed in this thesis, highlights the complexities and challenges encountered in regulating the electronic tobacco industry, with a particular focus on regulatory dynamics in both the United States and Italy. The analysis illustrates that the regulatory evolution in under-regulated sectors can have profound implications not only for the companies involved, but also for consumers and society as a whole.

In the United States, the regulation of electronic tobacco has evolved significantly. The Food and Drug Administration over the years applied a stricter control on the market, imposing restrictions on the sale and promotion of e-cig products, especially those that appeal to a young audience. This change has in fact resulted in improved health risk management associated with vaping, imposing higher standards for safety and transparency on companies.

At the same time, in Italy, the regulatory environment has followed a similarly rigorous path. Laws introduced have aimed to restrict the advertising and availability of electronic tobacco products. The introduction of these restrictions has demonstrated the Italian government's commitment to balance innovation in the tobacco market guaranteeing the protection of public health.

Ethical debate on these issues is surely needed and requires continued effort by all stakeholders to develop and implement responsible practices that protect the companies involved but also society and its well-being.

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