The Federal Government's Controversial Impact on American Public Health: A Review of the FDA's Attempted Actions to Regulate the Rogue Tobacco Industry

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Abstract: At the beginning of the 20th century, technological innovations in the ability to mass-produce rolled cigarettes resulted in the creation of a multi-billion-dollar industry in the United States. As the popularity of combustible tobacco products grew exponentially, scientific research on their potential harmful effects began being made public. By the 1960s, the research was brought into the public eye by the federal government's Surgeon General Advisory Committee. Although there were countless conclusive studies and organizational warnings, the tobacco companies that led the industry acted practically uncontrolled for the better part of a century. With minimal regulation by Congress, the Food and Drug Administration (FDA) attempted to intervene in 1996 with the intention of regulating the industry and ultimately improving the welfare of the American population. The Supreme Court, however, denied the FDA the ability to implement advertising regulations that would have strongly limited the influence the tobacco industry had over the population. The reasons for denial are not that the proposed regulations were unconstitutional, but that the regulations came from the wrong branch of the federal government. As a result of this controversial Supreme Court ruling in 2000, the tobacco industry was able to continue its successful and manipulative tactics until Congressional legislation granted the FDA authority to regulate the industry in 2009. Once granted authority, the FDA implemented guidelines that have directly contributed to the lowest cigarette consumption rates since the 1920s. Although the federal government is now better handling the tobacco epidemic, conflicting precedents between branches were taken advantage of by big tobacco and were the direct cause for the prolongment of this national threat to public health.

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Introduction

The philosophical concept of separation of powers has been basic to the foundations of American history and is clearly displayed in everyday governmental activity. Designed to ensure no single sector of government gains more power than another, the system of checks and balances has contributed to the United States government functioning rather efficiently in the past few centuries. What is clear is that the branches coexist well when interests and power are clearly defined, transparent and identifiable. However, there are particular instances in which there is an extreme lack in cohesion amongst the branches of government. This unorganized behavior, while uncommon, can result in rather large inefficiencies in government conduct. Such poor activity can have detrimental effects on the population because the few individuals who have a say within the political sphere impact the entire country and all residents.

One topic that has remained a hot-button issue since the early 1900s is tobacco usage and control. What was once a highly prized product that bolstered the American economy, tobacco and, in particular cigarettes, have been more restricted in the United States due to findings on its harmful effects on the human body. Annually, more than 480,000 Americans deaths (roughly a fifth of deaths annually) are from complications from cigarettes and other tobacco-related products. Currently, more than 16 million Americans are living with an illness that has been caused by using tobacco products (U.S. HHS, 2014). The consumption of these products has been linked to many cancers, heart diseases, stroke, diabetes and other diseases and illnesses. The burden extends beyond physical disease and death, as smoking carries with it an economic cost of more than 300 billion dollars annually for the United States (Xu et al. 2014).

Although there are many factors that have contributed to the tobacco epidemic in the United States, the most crucial one has been the ability of the tobacco companies to creatively implement profit margin expansion strategies. These strategies have maximized revenues for over a century and have helped to create a very large and loyal consumer base ranging across many age, racial and socioeconomic groups. Part of their creativity is illustrated by the ability to constantly stay ahead of government regulation and scientific advancement. Since the rise of the industry, tobacco companies have had very few rules to abide by and have been able to successfully shift their campaigns and strategies when needed. These resources and capabilities have also allowed them to alter the perception of their products despite overwhelming amounts of scientific evidence linking cigarettes to major health complications.

Overtime, different parties within the federal government have had the authority to intervene and regulate the tobacco industry in order to improve the general welfare. However, it has been a rather arduous process for the government to gain a firm grip on the industry. The primary reason for the existence of this struggle can be attributed to the fact that the federal government has never been on the same page regarding who has the authority over the issue. Throughout the previous century, leadership has shifted multiple times for who is responsible for controlling the industry. As a result, tobacco consumption amongst the American public has declined at a rate much slower than what would be considered ideal. One of these agencies that has tried to regulate the industry since the 1990s was the Food and Drug Administration (FDA). The FDA was acting in the best interests for the American public when attempting to intervene within the tobacco industry. However, the FDA was wielded powerless in 2000 due to the Supreme Court ruling of *FDA vs. Brown and Williamson Tobacco Corp.* This resulted in another decade in which the tobacco industry was acting practically uninhibited and, consequently, prolonged the possibility for making widespread reform to benefit American public health.

It was not until Congress passed the Family Smoking and Tobacco Prevention Act in 2009 that the FDA could regulate the tobacco industry. This change of authority was met with an immediate impact and currently, tobacco consumption rates are the lowest they have been since 1920. What this change in consumption illustrates is the fact that the federal government has the power and influence to incite change to benefit American public health; however, it took almost a decade for these actions to be taken. It was very clear that the FDA, a federal department, had a defined interest in the welfare of the people and knew the precise actions needed in order to protect such interest. However, due to conflicting precedents and a clear lack of understanding between branches of government, they were unable to initiate progressive reforms of the tobacco industry. This inability to act revealed undeniable deficiencies in communication and organization within the federal government that have contributed to the prolonged epidemic of nicotine usage amongst the American public.

American History Rooted in Tobacco Production

Tobacco has been an integral part of the American infrastructure since before the country was founded. The native groups of the Americas used tobacco for centuries for a number of purposes. Among them were medicinal, ceremonial and, recreational purposes (Ravenholt, p. 215). As European explorers were becoming introduced to the plant, the demand began to grow back overseas. At the time, the European countries, primarily Great Britain, decided to import production from the colonies across the Atlantic Ocean to Europe. This was done for multiple reasons. First, the tobacco plant was native to the Americas and thrived in the warmer climates that were present year-round. Second, the crop was generally thought to be recreational and thus, was deemed less of a priority to cultivate than many vegetables and clothing materials. As a result, tobacco became the top commodity export of the colonies by an overwhelming margin. At the beginning of the American Revolution, the colonies were producing roughly one million dollars of tobacco annually. When adjusted for an inflation, this number equals roughly thirty-one million dollars a year as of 2019 (Alchin, 2017). Following the United States victory over Great Britain in the American revolution, tobacco remained as one of the top exports for the country.

Although the United States capitalized on its established global tobacco industry, U.S. residents began to increase their usage of the plant domestically. The primary form of tobacco consumption in the U.S. was via a mixture of the plant and molasses that could be chewed (Institute of Medicine, 2007). The act of smoking tobacco became popular in Europe among the soldiers fighting wars. In particular, the act of smoking the plant was introduced in Great Britain following military campaigns in the Iberian Peninsula. The soldiers were told that this form of using tobacco was not only more effective than chewing the plant, but also healthier. It was believed that because the tobacco only remained in the mouth and technically not entering the body (the smoke does), it was a safer substitute when compared to snuff-taking or chewing. However, the real boom in tobacco smoking came following the British involvement in the Crimean War in the 1850s. Not long after, the practice became extremely popular in the United States amongst its citizens. All forms of tobacco use became so prevalent that the country placed a federal excise tax on cigars in 1862 in order to fund the Civil War. This was followed by a federal tax placed on cigarettes in 1864. Following the war, taxes on tobacco products increased three times from 1865 to 1875 in order to pay off the debts incurred from the war (Ravenholt, p. 218).

The impact of tobacco on the American public and economy was tremendous. By 1880, Americans were consuming approximately 6 pounds of tobacco per legal adult. Of these 6 pounds, only one percent of it took the form of manufactured hand-rolled cigarettes (Giovino, 2002).

However, the United States public still smoked roughly 1.3 billion cigarettes annually by this time. With a population of 50 million people, this equates to 26 cigarettes per each American citizen. (Ravenholt, p. 219). American hand-rolled cigarette consumption was at this low percentage for a number of reasons. Primarily, it was inefficient to manufacture the product because of the long time it took to roll each individual one. This high cost of labor per unit, coupled with a large demand, resulted in high prices for the products. However, a large turning point for the tobacco industry came in 1881. James Bonsack, a craftsman in Virginia, invented a machine that automatically rolled cigarettes. The machine, which was patented in 1884, was able to produce thirteen cigarettes for every cigarette produced by a hand roller (Burns, p. 134). This caused domestic cigarette production to boom. Specifically, most of the tobacco manufacturing successes can be seen with Duke's American Tobacco Company. The company went from producing 9.8 million cigarettes in 1881 to almost 750 million cigarettes only five years later (Ravenholt, p. 219).

The sales revenue incurred from cigarettes grew at incredibly high rates. Duke's American Tobacco Company had sales of 316 million dollars in 1903, which was thirteen times larger than they were in 1890 (Porter, p. 59). These high revenue numbers contributed to the eventual paying off of all Civil War debts. Once this was accomplished, the federal excise taxes were lifted from cigarettes purchases. As a result of the tax removal and increased manufacturing capabilities, the price of cigarettes was cut in half (Chaloupka et al. 2002). In doing so, cigarettes became available to a larger proportion of the population who previously could not afford the high-priced product. This further increased the already high consumption of not just this product, but all tobacco products. In 1900, 301 million pounds of tobacco were used in domestic manufacturing in the United States. By 1918, almost 500 million pounds of tobacco were harvested for products. In terms of consumption, 2.5 billion cigarettes were smoked by the American public in 1900. This number climbed up to a high of 640 billion in 1981 (Ravenholt, p. 221). These statistics illustrate the grip the tobacco industry had on the American people. Historically speaking, this exponential growth in production, manufacturing and consumption is one of the most dramatic increases for a single product since the early foundations of the American economy.

Profit Margin Expansion Strategies of Big Tobacco

By 1963, a staggering 4,345 cigarettes (or about 12 cigarettes per day) were smoked annually per adult in the United States (see Chart A1 in the Appendix). Many factors contributed to the prevalence of smoking in the United States. The most important factor that propelled and has sustained the epidemic is easy access to cheap cigarettes. As previously stated, by the early 1900s, almost 3 billion cigarettes were being smoked by United States citizens per year. The leader of the industry, Duke's American Tobacco Company, was capitalizing off the invention of James Bonsack to gain a firm share of the market (Chaloupka, 2007). Because of the exponentially higher rates of production, prices were set remarkably low. Along with low prices, the tobacco companies, in particular Duke's, began an aggressive marketing campaign to attract current and potential new users. The company grew so large and so fast that it was eventually dissolved into three smaller companies (R. J. Reynolds, Liggett & Myers, and Lorillard) in 1911 due to anti-trust laws. However, their tactics influenced the remaining companies who immediately capitalized on a newly open share of the market (Kluger, 1996).

In particular, one of the major selling points of cigarettes at the time was it was perceived to be the most convenient and effective source of nicotine intake. Cigarettes already came pre-rolled and were the most effective method in terms nicotine absorption. When compared to other products, cigarettes are more efficiently absorbed because the nicotine reaches the lungs. The lungs

have a much larger surface area than the human mouth. This results in not only faster absorption, but higher concentrations of the nicotine being absorbed. Additionally, because the blood vessels in the lungs are centrally located in the body, the effects of the chemicals reach the brain faster than in the mouth (DHHS, 200). It was also publicly understood that cigarettes were not as harsh and required less skill to smoke than cigars because inhaling the smoke was much easier than keeping it in the mouth (Giovino, 2002). Shockingly as well, it was commonly thought that smoking cigarettes was a safer substitute than the other previous methods such as chewing it or smoking cigars (Ravenholt, p. 218).

In terms of reaching the public, tobacco companies ensured that their products were distributed to as many retailers as possible. In many cases, the cigarette companies would offer significant discounts to retailers to carry and sell cigarettes (FTC, 2019). Not only were prices low to begin with, but because of discounts, retailers themselves undercut the low prices even more. As a result, the habit of smoking extended across classes in American society. The tobacco companies were able to do this because of the incredible efficiency of mass production. Additionally, many of the tobacco companies gifted soldiers with packs of cigarettes during World War I. Initially justifying this action by stating the cigarettes could benefit soldiers in times of famine, in reality this decision helped the companies establish their customer base (Smith et. al 2009). Following the war, millions of soldiers came home with an addiction to cigarettes and other tobacco products (Burns et al. 1997).

As the 1900s progressed, the tobacco companies made a realization that led to significantly higher revenue and much more loyal consumers. They realized that manipulating the product itself could also attract individuals who were reluctant to start smoking despite the already low prices of the products. First, companies began releasing variations of cigarettes. These products varied in tobacco content. The content of the tobacco in the cigarettes resulted in variations of nicotine content, flavor and mildness. The companies experimented with different preparations of the plant as well as using both domestic, foreign and blended tobaccos in the cigarettes (Giovino, 2002). Examples included using Turkish tobacco leaves which burned much easier than American tobacco or curing the leaves longer than usual in order to lower the nicotine concentration of the products (IOM, 2001). These different combinations of products were extremely beneficial to the bottom line of big tobacco companies present in the United States.

Throughout the 20th century, many tobacco companies capitalized on these successes by launching full-scale advertising campaigns in order to gain larger shares of the growing market. Every year, companies spent millions of dollars of advertising, branding and positioning. Over the century, advertising was focused primarily on campaigns that showcased branding. Such campaigns date back to Duke's American Tobacco Company, which would include picture cards in packs as well as sponsor events (Kluger, 1996). Branding has been a very important source of recognition in the tobacco industry. One of the first major campaigns in the industry was conducted by the R.J. Reynolds Company. The company launched a nationwide initiative for its Camel brand in 1913, declaring that Camel cigarettes contained the "American Blend" (R.J. Reynolds, 2006). This initiative was extremely successful in generating sales for Camel cigarettes. Following the end of World War, other companies followed suit to capitalize on the high demand (Schoenberg, 1933).

In addition, a lot of time and attention in tobacco advertising shifted towards product packaging. Companies spent millions on research and development of what they thought to be profitable packaging. Studies showed that variations in packaging shape and size can influence sales (Kotnowski et al. 2013). Additionally, research showed that companies in the past were more

successful when they sold cigarettes in packaging that was more visually appealing versus plain in image. Furthermore, packaging was extremely important and needed to be developed carefully because unlike most consumer products, cigarette packages were used and carried over days and to many locations This visibility in all sorts of public situations was a consistent form of mobile advertising (Wakefield et al. 2008). For all of these factors, tobacco companies put in a lot of effort in trying to position themselves against competitors through specific colors, fonts, slogans and logos. This research resulted in many brands having logos that became household names in American society throughout the 20th century.

Another vehicle in society that tobacco companies took advantage of through advertising was the public perception of smoking. Many of the original large-scale advertisements proclaimed that smoking cigarettes led to weight loss, prolonged youth and increased attractiveness (Bates et al.). Additionally, throughout the early 1900s, smoking cigarettes was associate with glamour, Hollywood and the elite society (IOM, 2007). Many individuals dreamed to be like the stars and to be associated with show business and the big tobacco companies capitalized on the opportunity to increase revenues:

> We believe that most of the strong, positive images for cigarettes and smoking are created by cinema and television. We have seen the heroes smoking in "Wall Street," "Crocodile Dundee," and "Roger Rabbit." Mickey Rourke, Mel Gibson and Goldie Hawn are forever seen, both on and off the screen, with a lighted cigarette. It is reasonable to assume that films and personalities have more influence on consumers than a static poster of the letters from a B&H pack hung on a washing line under a dark and stormy sky.[1]

The most common method for infiltrating the cinema industry was through advertising by product placement. This method was achieved by paying the movie companies for the ability to place their product in the movie in some capacity. Advertising by directly being viewed through entertainment was a very uncommon tactic for all commercial products (Lackey, 1993). Cigarette companies were the first ones to truly rely on product placement as a major source of consumer exposure. The industry not only realized the potential product placement carried, but also pioneered the intersection between consumerism and entertainment (Sargent et al. 2001). In addition to product placement, the companies would also pay celebrities to be seen in public or in additional advertisements using their cigarettes (Mekemson et al. 2002).

In 1998, it became illegal for tobacco companies to pay for the placement of products in movies. This, like many of the other marketing tactics, have been restricted over the course of the century; however, the biggest selling point for the products is their sheer addictiveness. Cigarettes contain large concentrations of nicotine, which is an extremely addictive chemical. As discussed previously, the companies tried many ways to get people hooked on the products as quickly as possible. Once individuals became consumers of products, they tended to become users for years in the future. The cigarette companies have long defended the advertising of smoking by claiming that, because it is a voluntary activity requiring a conscious cash purchase, smokers choose to smoke. However, concentrations of nicotine absorbed by the body alter receptors in the brain that produce the sense of pleasure and arousal. Following these alterations, a sudden halt in the presence of nicotine creates symptoms of withdrawal that many users alleviate by purchasing and consuming more cigarettes (Roh, 2018). Consequently, the choice to smoke is not one that is as simple as a matter of free will and conscious decision making.

[1] Phillip Morris, 1989

Medical History of Tobacco Usage

Prior to the beginning of the 20th century, knowledge of the health complications connected to tobacco consumption was extremely limited. Individuals within the scientific community had an idea of the side effects of the habit, but ultimately, major research was stalled for a number of reasons. Mainly, people never attributed the health complications of tobacco consumption to tobacco itself. Even though scientists identified damage to the respiratory systems of deceased individuals post-mortem, the lack of knowledge often resulted in a cause of death being attributed to tuberculosis (Ravenholt, p. 218). However, advancements in scientific experimentation and diagnostic technology contributed to significant conclusions related to the association between health complications and tobacco smoking being made. Early studies done in the 1900s did find a correlation between lung cancer and the habit of smoking cigarettes, yet at that time scientists were able to fully attribute causation to this relationship. Scientists also considered asphalt dust, air pollution from industrialization, the influenza pandemic of 1918 and exposure to poison gas during World War I as other contributing factors (Proctor, 2012).

As research advancements progressed throughout the century, it became obvious that the relationship was in fact causal. Evidence for the link between lung cancer and cigarette consumption came from a number of sources. First, a clear causal link was observed through the conducting of large-scale population studies. One of the most important and earliest population studies was completed in 1939 in Germany. This study assessed over one hundred patients at a hospital who were or were not lung cancer patients and found that those who had lung cancer smoked at much greater rate than the non-cancer patients (Proctor, 2012). Further population studies were conducted in Germany, Great Britain, eventually the United States. Two British researchers named Richard Doll and Bradford Hill conducted a large-scale cohort study in 1954 that found that smokers had a much greater risk of developing lung cancer. Furthermore, they determined that smoking at least 35 cigarettes a day increased the likelihood of being diagnosed with terminal lung cancer by over 40 times (Doll et al. 1954).

Additional studies involving cellular pathology and animal experimentation further emphasized the hazardous link. At the same time, scientists began exploring not just the long-term effects of smoking cigarettes but also the chemical composition of the products. More specifically, many of the tobacco companies themselves hired external consultants to perform chemical tests on the products. Among the companies were Phillip Morris, Brown and Williamson and the Lorillard company. The results from these studies found that there were over a dozen carcinogens found in cigarette smoke and that exposure to such chemicals could increase the likelihood of having cancer. These carcinogens included arsenic, chromium, nickel and benzopyrene (Proctor, 2012). With mounting evidence supporting a link between smoking and health complications, organizations within the United States began to take an official stance on the matter. Following their cohort study led by scientists E. Cuyler Hammond and Daniel Horn, the American Cancer Society publicly declared the association (Hammond et al. 1954). Their claim was soon followed by the Public Health Cancer Association issuing a warning to the public about the harmful effects of smoking.

In 1961, leaders from the American Cancer Society, the American Public Health Association, and the National Tuberculosis Association drafted a letter to President John F. Kennedy. In the letter, they inform the president of the results that have been observed in their studies. The leaders additionally illustrated the threat that cigarettes have had on the American public and urged the President to investigate the issue further. President Kennedy responded by forming an advisory committee led by Surgeon General Luther Terry. Terry, using evidence from

a number of studies, including those conducted by the American Cancer Society, was able to make an extremely resounding conclusion in 1964. The conclusion that was determined by him and his committee was that a strong causal link existed between smoking cigarettes and health complications such as cancer. This was a crucial milestone in the research and understanding of the harmful effects of smoking because it was the first time the federal government formally announced the existence of the causal relationship.

The Response of the Tobacco Industry

The medical effects of cigarette smoking becoming more apparent not just to the tobacco companies and government, but to the American public as well. In response, tobacco companies began launching marketing campaigns to counteract the negative medical news. This counteraction was designed to delay further research initiatives and regulatory intervention by the government and similar agencies (Brandt, 2012). The companies were trying to deflect the news by releasing information to the public designed to create scientific uncertainty. From an advertisement standpoint, the companies began featuring doctors and nurses in print and video advertising. The goal with this marketing strategy was to undermine the harmful effects that were being discovered by extensive research (Brandt, 2007). One of the largest pro-tobacco movements that was illustrated by the companies was the implementation of the *A Frank Statement to Cigarette Smokers* advertising initiative in 1954. This was one of the first and most significant marketing campaigns conducted by the tobacco companies to try and preserve their large economic profit margins.

In 1953, six of the largest American Tobacco Companies, which included Brown and Williamson, met with public relations companies in New York City. The goal of these meetings was to attempt to preserve the extremely high growth of cigarette consumption by discrediting the scientific research and painting cigarettes in a positive light (Goodman, 1994). The recommendation was made by the advertising firms to produce scientific evidence that suggested that the studies previously done were false in their causal findings. Such a controversy, speculated the firms, would shift the cultural understanding of cigarettes from being unfavorable to once again being held in a positive regard (University of Bath, 2012). This recommendation led to the creation of the Tobacco Industry Research Committee. This group was created to manufacture inconclusive evidence between harmful health effects and smoking cigarettes. The committee recruited a number of accredited scientists who were already skeptical about the link. The voices of these skeptical scientists were amplified and were broadcasted to present the image to the public of a tobacco industry that was concerned and responsible for the welfare of its consumers (Brandt, 2012).

The first edition of the *A Frank Statement to Cigarette Smokers* was published in over 400 different U.S. newspapers in 1954. The major conclusion made from the paper was that although research implicates cigarettes as the cause of lung cancer, studies have also suggested that there are other causes. With this in mind, the document stated that there is not conclusive agreement amongst medical authorities and that any statistics supporting the link could be applied to risk factors that are not cigarettes. The statement then announced the foundation of the Tobacco Industry Research Committee and explained that its goal is to aid in preserving the health of its consumers. Finally, the advertisement detailed a number of promises from the companies. It first assured the public that not only are the products safe to use as intended, but that research by the committee will be dedicated to creating even safer tobacco products. In conclusion the statements

ended with a promise from all of the tobacco companies involved that they "always have and always will cooperate closely with those whose task it is to safeguard the public health."[2]

The original release and subsequent publishing of this statement illustrated that the tobacco companies doubled down on their strategy to create doubt in the scientific community's research health claims. Additionally, the statement suggested that any potential health complications developed by users were at the fault of the consumer because cigarettes were not conclusively linked to getting sick (Brandt, 2012). The effects of the initiative to publish deceptive advertising were extremely positive for tobacco companies. Overall, theirs ads accomplished their task of projecting a positive image of smoking to current and potential new smokers (Bates et al.). The tobacco companies continued their partnership with the advertising firms from 1954 to 1961. During this time, the number cigarettes sold per year increased by over 32% and the annual per capita consumption of cigarettes increased by over 20%. (Brandt, 2012). The companies continued to release these statements after the partnership had ended in order to deflect further studies and reports such as the Luther Terry's in 1964. It is clear the tobacco companies were well aware of the health risks of their products. However, they instead chose to further their own interests at the expense of American public health and welfare.

FDA Regulations Prompt Legal Action

Since the mid-1800s, the federal government has assumed the responsibility for protecting the public from consuming hazardous goods. Most notably, in 1848, the United States government began using chemical testing to analyze whether agricultural products being manufactured by farmers were safe to eat. This responsibility was delegated to the Department of Agriculture and was later passed along when lawmakers decided that chemical testing was needed to be expanded not just to harvested crops but also to other food products and medications. This realization culminated in the Congressional passing of the Pure, Food and Drugs Act in 1906. This Act made business dealings in false and mislabeled food and drugs illegal. To ensure that commercial goods being sold were adhering to the new regulations, the government created a federal party to monitor food and drug commerce. This Act created the Food and Drug Administration (FDA, 2018). However, it was not until the 1930s that the FDA was truly legitimized as a governing party in the United States. With the passing of the Federal Food, Drug and Cosmetic Act of 1938, the FDA was given full authority to protect the welfare of the public as it pertained to the consumption of foods, medicines, cosmetics and medical devices. Overtime, this original statute of law has been further bolstered by amendments. One in particular was the Kefauver-Harris Amendment of 1962, which required companies to prove not just safe usage of their products but effectiveness as well. In addition, the FDA has been updated overtime to keep up with the constantly evolving economic, political, social and technological climate of the United States. Recently, this was accomplished with the FDA Modernization Act of 1997.

Since its formal recognition in the 1930s, the FDA had made attempts to provide the public with safer alternatives to smoking but did not crack down on the industry with any restrictions or regulations (Szubin, 1998). However, it was clear, based on scientific research, that the nicotine present in cigarettes was extremely addicting and that the health complications caused by smoking were detrimental to the American public. Although there were a few regulations and guidelines that the big tobacco companies needed to follow, the companies often found loopholes around what the government intended to be restrictions. Additionally, the companies were able to adapt

[2] "Daily Doc: The "Frank Statement" of 1954." www.tobacco.org. 2017-11-07.

their marketing strategies rather quickly in circumstances where they could not work around the rules. An example of this was seen in 1969, when Congress enforced an Act that ended television and radio advertising of cigarettes (see Table A1). In response to this restriction, the tobacco companies completely shifted funding to work around the new rules. The funding shift resulted in a 300 percent increase in newspaper advertising spending (14.7 million dollars to 59.3 million dollars) and a doubling of magazine advertising spending (49.5 million dollars to 98.3 million dollars) from 1970 to 1971 (Bayer, p. 13). This move by the big tobacco companies ended up being extremely successful because three years following the passing of the Act, cigarette per-capita consumption rose by 4.5 percent to the highest rate since the Surgeon General report of 1964 (Warner, 1979; see Chart A1).

Prior litigation against the tobacco industry had been relatively futile for those who claimed the tobacco companies were responsible for any bodily harm. As medical knowledge became more available to the public, individuals began to sue the companies concerning a number of issues, such as negligence in both product creation and promotion. However, the companies countered by citing their own reports and challenging the fact that there was yet to be conclusive evidence suggesting the causal link (Brandt, 2012). The primary reason for litigation then shifted to the idea that the tobacco companies should have provided consumers with more of a formal warning of the potential risks. This, however, was very easily fought by the companies because they were already required by Congressional law to disclose pre-written Surgeon General warnings on all packages. This was being adhered to by all members of the tobacco industry; therefore, they were able to defend their actions in court. Regardless of what the plaintiff's state laws were at the time, the companies were able to argue that Congressional Act had priority. Additionally, the tobacco industry, which was worth billions of dollars, was able to overwhelm plaintiffs with high legal costs (Douglas et al. 2006). The legal resources and implemented legislature allowed the tobacco companies to act with very little regulation, which further contributed to the detriment of the American people.

In 1996, the FDA decided to place advertising restrictions on the tobacco companies. The FDA's actions were being conducted with the primary goal of reducing advertisements that targeted minors. Research had long suggested that tobacco companies used entertainment and other media to convince young adults to take up smoking. This was done with the hope of creating addicted users at younger ages, which would create a long running customer relationship (NCCDPHP, 2012). The restrictions were broken down into 7 guidelines that had to be followed. These guidelines included:

1. Ban on billboard advertising within a certain distance of playgrounds or schools.
2. Prohibition of colored print advertising except for in predetermined adult publications and facilities.
3. Prohibition of music in radio advertising and ban on color and pictures in video advertising.
4. On top of the Surgeon General warning, packaging needed to state that the products were for ages 18+ only.
5. Products that mimic cigarettes packaging in physical appearance or motto must be modified.
6. Prohibition of including gifts or putting tobacco products on sale.
7. Ban on tobacco advertising at social and cultural events.[3]

Not surprisingly, the tobacco companies were furious with these sanctions being placed upon them by the FDA. They immediately attempted to push back on these restrictions.

[3] Cohen, 1997

First, the tobacco companies claimed that their marketing strategies were a form of commercial speech and that placing sanctions on their methods was a violation of their First Amendment rights detailed in the Constitution (Cohen, 1990). However, the FDA used Supreme Court precedent to justify their actions. This justification came from the ruling in the case *Central Hudson Gas and Electric Corp. vs. Public Service Commission of New York* (Table A2). This case, which was heard in 1980, concerned the matter of restricting commercial speech. The outcome of this case resulted in a 4-prong test to determining whether the restrictions placed on a company's commercial speech by a federal agency violated the Constitution. The test, known as the *Central Hudson Framework*, consists of four questions regarding whether an agency's restrictions are constitutional. The questions are as follows:

1. Is the commercial speech at issue protected by the first amendment?
2. Is the government interest in restricting it substantial?
3. Does the restriction directly advance the government interest asserted?
4. Is the restriction more extensive than necessary to serve the government interest?[4]

To answer the first question, cigarette advertising in itself is not protected by the first amendment. Because it is not explicitly featured in the Constitution, it could theoretically be restricted. Second, the FDA cited their interest as protecting the health, safety and welfare of the citizens:

> The purpose of the advertising regulations "is to decrease young people's use of tobacco products by ensuring that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people." (Cohen, 1997)

This interest is absolutely substantial. Third, the FDA's restrictions would definitely directly advance the government's interest. Lastly, it would be hard to argue against the notion that the restrictions were too extreme (Cohen, 1997). Therefore, the FDA believed they were acting reasonably with these seven major regulations on the tobacco industry. The tobacco companies recognized this too. However, these restrictions would significantly damage profits and result in business being placed in jeopardy. The companies needed to come up with a new way to counter these rule changes being proposed by the FDA.

The tobacco companies then raised the issue of whether the FDA had the right to get involved in the matter at all. The tobacco companies' main argument was the fact that for the entire existence of the FDA, this was the first time the FDA had directly regulated the industry. The industry had followed the legislation given to them by Congress and now claimed it was not fair to be required to take regulations from a separate governmental power. As a result, one company in particular, Brown and Williamson, took the FDA to court on the matter (Greenhouse, 2000). Both sides presented their case to the United States District Court for the Middle District of North Carolina. The District Court ruled in favor of the FDA. Brown and Williamson appealed the decision and consequently the dispute was heard before the Court of Appeals for the Fourth Circuit. The decision from the Circuit Court resulted in a victory for Brown and Williamson. Because of the split decision between the two federal courts, the case was moved up to be heard before the Supreme Court. Subsequently, the hearings for *FDA vs. Brown and Williamson Tobacco Company* began a few years later, in December of 1999.

FDA vs. Brown and Williamson Tobacco Corporation

In presenting their case for having the authority to control big tobacco, the FDA referenced both legislation and court precedent. The first and most compelling argument for the FDA was the reference to the Federal Food, Drug and Cosmetic Act of 1938 (see Table A1). In Chapter Nine of

[4] Cohen, 1990

the Act, it is stated that one particular substance the FDA had control over was tobacco. Officials representing the FDA claimed that this legal language, coupled with recent studies stating the harmful effects of cigarettes and in particular nicotine, was more than enough evidence to swing the court in their favor.

In response to this argument by the FDA, representatives of the big tobacco industries were quick to point out that this was the first time since the Food, Drug and Cosmetic Act was passed that the FDA had gotten involved in matters concerning tobacco. During this extremely long time period of no involvement from the FDA, it was claimed that a new party had been clearly established to control the tobacco industry. This new party was the collective legislative branch and, in particular, Congress. Since the passing of the Food, Drug and Cosmetic Act, Congress had passed major reforms and legislation related to protecting the American people from dangerous tobacco products. The first of these acts was passed in 1965. This Act, which is known as the Cigarette Labeling and Advertising Act, resulted in a requirement for cigarette packages to contain the phrase: "Caution: Cigarette smoking may be hazardous to your health." This Act led to the United States becoming the first country to have warning labels on tobacco products.

Five years later, Congress decided that having just a warning on the packages was not enough control on the tobacco industry. Cigarette and tobacco consumption were still alarmingly high. As a result, Congress passed the Public Health Cigarette Smoking Act of 1969. The last major act cited by Brown and Williamson was the Comprehensive Smoking and Education Act of 1984 (see Table A1). These are three of many congressional initiatives that were referenced by the side representing Brown and Williamson. Because Congress had clearly stepped in countless times to control the tobacco industry while the FDA remained uninvolved on the issue, the big-tobacco companies claimed that the FDA had no right to all of a sudden step in. The power to regulate the tobacco industry, according to the big-tobacco companies, had shifted from the executive branch to the legislative branch.

This idea of branches of government is derived from the concept of separation of powers. Separation of powers was a main feature of the original United States Constitution. It outlined the foundation of the structure of the newly formed American democracy. The government would be divided into three equal entities, or branches. The first one is known as the legislative branch. The main principle of this branch is to create, vote, and effectively pass laws and amendments to help maintain the political order in society. Within this branch is Congress, which is made up of both the Senate and the House of Representatives. The second division is the executive branch. This sector is led primarily by the elected President and his federally appointed cabinet and departments. The responsibility of the executive branch is for the President to lead the nation and command the armed forces and the appointed federal agencies to enforce the passed laws by the legislative branch. Lastly, the judicial branch, which is made up of the Supreme, civil and criminal courts, is responsible for interpreting the Constitution and subsequent laws passed.

Although the original idea of the separation of powers was to split duties between separate branches of government, there are unavoidable situations in which significant overlap arises between the three over particular matters in protocols. When these situations arise, one branch will ultimately have more power over one or both of the other invested branches. The scenarios where an overlap or overruling of a branch by another were distributed across the three branches. This overlap ended up resulting in a system of checks and balances that allowed the government to function in an efficient manner. In the context of this case, the big tobacco companies were arguing that the FDA, a federal agency of the executive branch, was abusing its power. In doing so, they were asserting unconstitutional authority over Congress who, in the claim made by the tobacco

companies, had the responsibility to regulate them as the legislative branch. However, in terms of the shift in power, because there was no legal literature that definitively stated the FDA lost control of its duties, the FDA claimed there was still justification for getting involved. Therefore, this argument made by the big tobacco companies left an immense amount of ambiguity in the case that would need to be resolved by the Supreme Court.

For decades, the FDA had not gotten involved in tobacco-related matters and had justified their lack of involvement on the grounds that the tobacco companies never claimed their products were health-related. The FDA was only now just getting involved in the late 1990s because of the mounting evidence that suggested significant dangers to the body from smoking (Szubin, 1998). Additionally, it was seen in the prior decades that Congress was actually being manipulated by big tobacco through significant lobbying. Tobacco companies knew their significant impact on the American economy in the 1950s, as it was an extremely wealthy industry that brought significant revenue to many states. When the Surgeon General report of 1964 was released, the Federal Trade Commission attempted to step in and modify packaging on cigarettes. However, the FDA fought to instead have legislation be implemented by Congress and won (Mukherjee, 2010). This regulation was in the form of the Federal Cigarette Labeling and Advertising Act of 1965. The Act was originally going to require tobacco companies to print the causal link between smoking and cancer on each package. This draft was never passed, as the tobacco companies lobbied to Congress to change the wording on the packaging. Congress, knowing what a significant decline in tobacco revenues could do to the nation, decided to modify the wording to only mention that cigarettes "may be dangerous to your health" (Brandt, 2007).

Because of the involvement from the legislative branch, the lawyers representing Brown and Williamson were claiming that Congress now had the power to regulate them. At this point, the FDA referenced a Supreme Court ruling from 1968. The Supreme Court case in discussion was *United States vs. Southwestern Cable Company* (Table A2). This case featured the dispute between the Federal Communications Commission (FCC) and Southwestern Cable Company. The FCC is responsible for regulating interstate communications through all technological media. These media include the radio, television, satellite, wire and cable communications. In 1968, the FCC launched an initiative to control antenna television usage that Southwestern Cable Company disagreed with. In particular, Southwestern Cable Company believed that the FCC was not allowed to enforce this initiative because it they saw the initiative as being out of the scope of jurisdiction for the FCC. The case was heard before the Court of Appeals before being taken to the Supreme Court. The Court ultimately ruled in favor of the FCC. More specifically, the Court ruled that the original statute that established the FCC, the Communications Act of 1934, gave the Commission the right to act. This led to the precedent that was cited by the FDA. The Food and Drug Administration recognized that Congress had been regulating the tobacco industry for the past decades prior; however, because of the ruling in *U.S. vs. Southwestern Cable Co,* the FDA argued that the original statute of the 1938 Federal Food, Drug and Cosmetic Act gave them the right to step in.

In response to this testimony referencing the ruling and precedent established in *U.S. vs. Southwestern Cable Co,* the representatives of big tobacco introduced the Chevron Deference. This is a doctrine that was established in the Supreme Court case *Chevron U.S.A. Inc. vs. Natural Resources Defense Council Inc* (Table A2). This case, which was heard before the court in 1984, was over the issue of whether the Environmental Protection Agency had a right to regulate companies further than what Congress had originally intended. Congress had passed the Clean Air Act to regulate the extent to which companies in the United States could pollute the air. The ruling

in this case created the doctrine that has been used thousands of times to settle disputes in court. The Chevron Deference states that an executive branch agency has authority over a particular matter only if the intent of Congress regarding the issue is determined to be ambiguous. In the case of *FDA vs. Brown and Williamson*, the tobacco companies argued that Congress had established authority over regulating tobacco. This authority was clear and visible to all parties involved, so therefore, they claimed that the FDA intervention was impermissible (Morris, 2001). This testimony was calculated to completely overrule the precedent established by *U.S. vs. Southwestern Cable Company*. It was at this point in the trial that closing arguments were made and the decision was turned over to the Supreme Court justices.

Ruling and Impact

Almost four months after the hearings began, it was time for a decision to be made. With concluding arguments being made from both sides, it was clear that the Supreme Court justices had a myriad of political Acts and precedents to sift through in making a ruling. Ultimately, the Supreme Court ruled on March 21, 2000 in favor of the tobacco companies. In summary, it was determined that because the FDA had failed to intervene within the tobacco industry since the Federal Food, Drug and Cosmetic Act in 1938 and during this time Congress had passed multiple acts regulating the industry, the FDA had lost its authority to be the regulator of the companies (Morris, 2001). The ruling was 5-4 in favor of the tobacco corporations. The five justices that ruled in favor of big tobacco were Chief Justice William Rehnquist, Antonin Scalia, Anthony Kennedy, Sandra Day O'Connor and Clarence Thomas. The four justices that ruled in favor of the FDA were Stephen Breyer, John Stevens, David Souter and Ruth Bader Ginsburg. It is interesting to note that, historically speaking, the five justices who ruled in favor of the industry lie on the conservative side of the political spectrum while the four who were pro-FDA intervention were on the liberal side of the spectrum (Martin et al. 2007). Government intervention in business and industry has been a highly discussed issue, with the conservatives promoting a laissez-faire ideology. This means that they favored as little government intervention as possible in business, which could explain why the five conservative justices ruled the way that they did.

Regardless of the political ideology that may have motivated the decision, it did not change the fact that the Court ruled that Congress was the authoritative figure over the tobacco industry. In the past, Congress had passed acts to monitor the companies. Unfortunately, however, these acts were outdated, and Congress had no intention of intervening in the near future. Additionally, as previously discussed, tobacco companies were very smart and easily modified their tactics to stay ahead of government regulation. A strong example of this behavior was their response to the Public Health Cigarette Smoking Act of 1969. Almost immediately after the Act was passed, many of the tobacco companies pulled all their money out of technological media advertising and more than doubled their print advertising. Although they may have lost their consumer channels via television, they dramatically increased their reach via published advertisements. The tobacco industry had an established authority and guidelines to abide by, but the rules they needed to follow were extremely lenient. The only group that seemed to recognize the problem at hand was the Food and Drug Administration. The FDA had tried to intervene in the name of the welfare of the American people in 1996 but were ultimately struck down by the Supreme Court due to established and disorganized precedents.

Once the ruling was handed down from the Supreme Court, the FDA withdrew its proposed regulations. Around the time that this case was being handled at the level of the federal government, many U.S. states signed agreements with the some of the largest tobacco companies

in the United States. Known as the Master Settlement Agreement, it appeared to be a tremendous step in controlling the tobacco industry and lowering the incidence of tobacco-related illnesses (Hovland et al. 2015). A major point of the agreement was that the tobacco companies needed to settle their lawsuits that were being litigated at the state level with consumers all over the country. The payouts totaled over 200 billion dollars and went to the consumers who had sued the companies. Prior to the agreement, many citizens attempted to hold the tobacco companies accountable for their health complications by suing the corporations. However, the tobacco companies won almost every case tried against them by overwhelming the plaintiffs with legal expenses: "the way we [RJ Reynolds tobacco company] won these cases was not by spending all of our money, but by making that other son of a bitch spend all [of] his." (Douglas et al. 2006) Additionally, revenues of tobacco sales went back to the states to fund cessation and health benefit programs. Along with the payouts, the agreement allowed the states to place restrictions on tobacco commerce that were similar to those that the FDA had been trying to place in 1996 (Hovland et al. 2015).

With the individual states having the authority to regulate in-state tobacco advertising, it would have seemed like, for the most part, that the big tobacco industry would now be held in check. However, the tobacco companies fought back in 2001. Massachusetts attempted to enact restrictions on advertising towards minors in terms of proximity to schools and playgrounds. One of the major companies who agreed to the Master Settlement Agreement, the Lorillard Tobacco Company, argued that despite the settlement agreement, the restrictions were different from the federal laws they had been abiding by for decades.[5] They were referencing the restrictions handed out by Congress who the Supreme Court had determined had the authority to regulate the industry. This dispute with the State of Massachusetts was taken to the Supreme Court and became known as *Lorillard vs. Reilly* (Table A2). The State of Massachusetts cited the recently implemented Master Settlement Agreement as a justification for their actions. Additionally, this case directly brought the Tenth Amendment into question. This amendment concerned the principle of Federalism in that any authority not delegated to the federal government by the Constitution is authority reserved to the individual states. However, there was no precedent for matters in which federal legislation gave overlapping power to both the states and Congress.

The Court ruled in another controversial 5-4 decision that Congress had sole control over cigarette advertising as detailed by the Federal Cigarette Labeling and Advertising Act and subsequent Acts (Hovland et al. 2015). Consequently, *Lorillard vs. Reilly* resulted in the tobacco companies regaining their control over the nation that they had possessed for decades. Once again, differing claims between levels of government contributed to the further advancement of profits for tobacco companies. The impact of this confusion was tremendous. The Congressional Acts had successfully limited media advertising; however, no updates had been made to control other forms of promotion that, at this point, the companies had totally shifted to. Without any significant regulations on how they could advertise, big tobacco companies poured resources into getting their products in as much of the public eye as they were able to under current Congressional regulation.

The regulations were weak compared the capabilities of the companies. From 2000-2008, total cigarette marketing purchasing was over 10 billion dollars annually (see Table A3). This spending was allocated across many different types of categories. Most notably, companies spent money on sponsorships, point of sale exposure, public entertainment exposure, price discounts and promotional allowances (FTC, 2011). The forms of marketing that were limited by Congress only accounted for 7.3% of total expenditures in 2000 and only 1.9% in 2008. With the exception of

[5] https://www.oyez.org/cases/2000/00-596

the price discounts, all of the top avenues for marketing expenditures and promotional allowances would have been controlled significantly by the FDA's proposed regulations that were denied by the Supreme Court. During this same time period in which no further regulation was placed upon the companies, cigarette consumption per capita was still high. In 2000, annual cigarette consumption per capita was 2,076 and in 2008, it was 1,507 (Wang et al. 2016). This also fails to take into account all forms of tobacco consumption and only captures the per capita usage of individuals 18 and older. In reality, tobacco usage for minors still remains a crucial issue today. In 2008, roughly 12% of 12th graders in the United States used cigarettes on a daily basis (see Chart A2). Tobacco consumption by minors had been targeted by the 1996 FDA proposal that was struck down over a decade prior. The fallout from the controversial rulings left many legislators in Congress wanting to grant the FDA authority over the tobacco industry and yet, that did not occur until 2009, almost a decade after the *FDA vs. Brown and Williamson Tobacco Corp.* ruling.

The Family Smoking Prevention and Tobacco Act

In June of 2009, the newly elected Congress and Senate passed the Family Smoking Prevention and Tobacco Act (FSPT Act). This Act, which was signed by President Barack Obama, was the turning point in the fight against regulating the tobacco industry because the FDA now was given the authority to regulate the tobacco industry. By restoring power back to the FDA, the federal government was honoring the authority of the original 1938 statute. The FDA had argued this a decade prior by stating that they possessed the authority in controlling the tobacco industry because of the Federal Food, Drug and Cosmetic Act. Furthermore, the FDA supplemented this argument with precedent from *U.S. vs. Southwestern Cable Company* that was overruled by the Supreme Court in 2000. The signing of this FSPT Act in 2009 superseded the 2000 Supreme Court ruling in *FDA vs. Brown and Williamson Tobacco Corp.*; however, the greatest impact was the fact that the FDA could enact the changes needed to improve the welfare of the American people.

The single most critical part of the FSPT Act was the authority given to the FDA to restrict tobacco marketing and sales to minors. The FDA banned sales to minors, vending machine sales, promotional giveaways and tobacco sponsorships in sports and entertainment. The FDA also required the tobacco companies to make the labels larger and more visible. Additionally, the labels now had to include explicit side effects of using tobacco products. Examples of this included statements that a product causes mouth cancer, lung cancer or gum disease. In terms of marketing new products or using new strategies, the tobacco companies must file an application and obtain approval from the FDA before launching the initiative. In addition to needing approval for new products being sold, tobacco companies must provide the FDA with all of the ingredients in each product. As for helping those addicted who were fighting health-related complications from smoking, the FDA also moved to increase funding for cigarette cessation programs. The FSPT Act was a huge victory in controlling the industry and was heralded as "a tremendous opportunity to finally hold tobacco companies accountable and restrict efforts to addict more children and adults." (Abrams, 2009) Additionally, the federal government, on the recommendation of the 2000 Surgeon General Report, *Reducing Tobacco Usage*, implemented the largest excise tax on cigarette purchasing in history. This increase brought the combined federal and state taxes to at least $2.20 per pack in each state. This was an increase in over 300% from 1995 to its implementation in 2009 (CDC, 2009).

The impacts from these imposed taxes and regulations have been crucial in improving the welfare of the American public. One of the goals of raising the cigarette tax was to discourage minors from purchasing. Although revenues for cigarette products have increased from 7.64 billion

to 12.46 billion dollars since the Family Smoking Prevention and Tobacco Prevention Act, total sales and consumption have decreased considerably. Increases in revenue have only occurred because of the much higher taxes that have been implemented. As of 2016, tobacco expenditures have been the lowest since 1997 (FTC, 2016). The impact on public health, in particular on the welfare of minors, has been resoundingly positive (see Chart A2). The daily cigarette consumption prevalence by 12th graders dropped from 12% in 2008 to 3.6% in 2019 and is projected decline even further going forward. As for U.S. adults, cigarette smoking was at an all-time low of 13.7% in 2018. Additionally, according to the CDC, the three largest metrics for measuring rates of cigarette cessation saw large increases. These metrics include past year quit attempts, recent successful cessation, and the quit ratio (Creamer et al 2019). What can clearly be illustrated is having the FDA in control of regulating the tobacco industry has been the most successful government decision in combatting this public health crisis. Although it would have been better if the FDA had been able to do this in 1996 and not be denied by the Supreme Court, it is still can considered a victory that the nation is moving in the right direction in terms of sustaining the general welfare of the population.

Conclusion: E-cigarette Epidemic Presents a Chance to Act Differently

The FDA's actions following the passing of the Family Smoking and Tobacco Prevention Act of 2009 have been essential in curtailing the tobacco industry and ensuring that individuals are aware of the inherent risks of smoking. Not only did adult cigarette consumption reach an all-time low as of 2018, but cessation rates have annually increased and cigarette smoking amongst minors has decreased to the lowest daily use ever (see Chart A2). Although these are all tremendous strides towards protecting the welfare of the American people, the FDA still has work in controlling the industry. More recently, a new type of threat to the health of the people has come up. This threat is nicotine intake via electronic cigarettes (or e-cigarettes). Since 2011, e-cigarette usage has increased dramatically across the nation while cigarette consumption has decreased (Singh et al. 2016). More alarming is the rise in e-cigarette usage by minors. In 2018, 20.8% of high school students and 4.9% of middle school students used e-cigarettes. These percentages were extremely significant increases from 2017. For high school students, e-cigarette usage increased by 77.8% (from 11.7% to 20.8%) and, for middle school students, usage increased by 48.5% (from 3.3% to 4.9%) (Gentzke et al. 2019). These increasing rates are an extreme cause for concern for a number of reasons. First off, the long-term effects of these products are unknown. E-cigarettes have only become popular over the last decade. Consequently, not enough time has passed to be able to study the health complications that could potentially arise as a result of daily consumption. Many of the first studies linking cancers to cigarette smoking were published in the 1950s, which was decades after the mass production and consumption of hand-rolled cigarettes began. The fact that no one has any information on the effects of using e-cigarettes past 10 years can be very costly if there happens to be significant health complications caused by long-term usage. Additionally, these products, while not actually containing tobacco, contain large quantities of nicotine. The nicotine can result in addictive effects comparable to that of tobacco usage and lead to prolonged usage.

The Family Smoking and Tobacco Prevention Act covered smokeless tobacco but not non-tobacco nicotine products, such as e-cigarettes. However, in May of 2016, the FDA used its authority gained from this Act to classify e-cigarettes as tobacco products. By doing so, they claimed the ability to regulate the marketing, labelling and production of all products and liquids associated with e-cigarettes (FDA, 2016). Three months later, the FDA extended its regulatory

power to include e-cigarettes. This meant that they would now be responsible for controlling marketing, product features and appeal to minors. Additionally, the FDA instituted the requirement of placing warning labels on products and banning the sale of products to individuals under the age of 18 (FDA, 2017). Although actions by the FDA have been taken, they are not doing enough. Authority was fully assumed by the agency in 2016; however, the rate of e-cigarette consumption was at its highest in 2018. Additionally, the rate of increase for the consumption of e-cigarettes has skyrocketed from 2017. This means that although steps have been taken to protect the public from this extremely addictive and potentially harmful product more needs to be done. Furthermore, e-cigarette and tobacco companies that feature e-cigarette divisions have begun to litigate the efforts of the FDA to hinder their business. No formal law gives the FDA control of the e-cigarette business. The Family Smoking and Tobacco Prevention Act extends to smokeless tobacco but not e-cigarettes. Consequently, tobacco companies like the Altria group have begun to draft legislation for Capital Hill that would protect their products from regulation (Lipton, 2016). This situation is becoming very similar to what had happened in 1996 when the FDA attempted to regulate the tobacco industry's marketing of cigarettes. Now, one can only assume and, for the sake of the of the welfare of the American people, hope that the federal government will act in a manner that will result in the efficient containment of activities relating to this emerging health hazard.

Works Cited

Abrams, Jim. "No smoking: Historic vote could bring new limits". Yahoo News. Associated Press. Archived from the original on 14 June 2009.

ALA (American Lung Association). 2004. Trends in Tobacco Use. New York: American Lung Association.

Alchin, Linda. "Trade in the Colonies." Land of the Brave, February 2017. https://www.landofthebrave.info/trade-in-the-colonies.htm.

Bates, Clive, and Andy Rowell. "Tobacco Explained" (PDF). World Health Organization.

Bayer, R., & Feldman, E. A. (2004). Unfiltered: conflicts over tobacco policy and public health. Cambridge, MA: Harvard Univ. Press.

Brandt AM. The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America. Basic Books, New York, 2007.

Brandt AM. Inventing conflicts of interest: A history of tobacco industry tactics. Am. J. Public Health 2012; 102: 63–71.

Burns, Eric. The Smoke of the Gods: A Social History of Tobacco. Philadelphia: Temple University Press, 2007.

Burns DM, Lee L, Shen LZ, Gilpin E, Tolley HD, Vaughn J, Shanks TG. 1997. Cigarette smoking behavior in the United States. Changes in Cigarette Related Disease Risks and Their Implication for Prevention and Control. Smoking and Tobacco Control Monograph No. 8. Bethesda, MD: DHHS, National Institutes of Health, National Cancer Institute. Pp. 13-112.

Creamer MR, Wang TW, Babb S, et al. Tobacco Product Use and Cessation Indicators Among Adults – United States, 2018. Morbidity and Mortality Weekly Report 2019, 68(45);1013-1019

Chaloupka FJ. Cigarettes: old firms facing new challenges. In: Tremblay VJ, Tremblay CH, editors. Industry and Firm Studies. 4th ed. Armonk (NY): ME Sharpe; 2007. pp. 80–118.

Chaloupka FJ, Cummings KM, Morley CP, Horan JK. 2002. Tax, price and cigarette smoking: evidence from the tobacco documents and implications for tobacco company marketing strategies. *Tobacco Control* 11(Suppl 1):I62-I72.

Cohen, Henry. *Constitutionality of Banning Cigarette Advertising.* S.l : s.n., 1990.

Cohen, Henry. *Tobacco Advertising: Whether the FDA's Restrictions Violate Freedom of Speech.* S.l : s.n., 1997.

"Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products". Federal Register. US Food and Drug Administration. 81 (90): 28974–29106. 10 May 2016.

DHHS. 2000. Reducing Tobacco Use: A Report of the Surgeon General. Atlanta, GA DHHS.

Doll R, Hill AB. The mortality of doctors in relation to their smoking habits. BMJ 1954;1:1451–5.

Douglas, C. E., Davis, R. M., & Beasley, J. K. (2006). Epidemiology of the third wave of tobacco litigation in the United States, 1994-2005. Tobacco Control, 15, 9–16. doi: 10.1136/tc.2006.016725

"FDA's New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products". United States Food and Drug Administration. 17 August 2017.

Federal and State Cigarette Excise Taxes --- United States, 1995--2009. (n.d.). Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5819a2.htm

Federal Trade Commission. Federal Trade Commission Cigarette Report for 2007 and 2008. Washington: U.S. Federal Trade Commission; 2011.
Federal Trade Commission. Federal Trade Commission Cigarette Report for 2016. Washington: Federal Trade Commission, 2019.
Federal Trade Commission. Federal Trade Commission Cigarette Report for 2017. Washington: Federal Trade Commission, 2019.
Gentzke AS, Creamer M, Cullen KA, et al. Vital signs: tobacco product use among middle and high school students—United States, 2011–2018. MMWR Morb Mortal Wkly Rep 2019; 68:157–64.
Giovino, GA. 2002. Epidemiology of tobacco use in the United States. *Oncogene* 21(48): 7326-7340.
Goodman, Michael J. (1994-09-18). "Tobacco's Pr Campaign : The Cigarette Papers". Los Angeles Times. ISSN 0458-3035
Greenhouse, Linda. 2000. "High Court Holds F.D.A. Can't Impose Rules on Tobacco". *The New York Times.*
Hammond EC, Horn D. The relationship between human smoking habits and death rates: a follow-up study of 187,766 men. JAMA 1954;155:1316–28.
Hovland, R., Wolburg, J. M., & Haley, E. (2015). Readings in advertising, society, and consumer culture. London: Routledge.
IOM. 2001. Clearing the Smoke: *Assessing the Science Base for Tobacco Harm Reduction*. Washington, DC: National Academy Press.
Institute of Medicine. 2007. *Ending the Tobacco Problem: A Blueprint for the Nation.* Washington, DC: The National Academies Press. doi: 10.17226/11795.
Johnston, L. D., Miech, R. A., O'Malley, P. M., Bachman, J. G., Schulenberg, J. E., & Patrick, M. E. (2019). Monitoring the Future national survey results on drug use 1975-2018: Overview, key findings on adolescent drug use. Ann Arbor: Institute for Social Research, University of Michigan.
K. Kotnowski, D. Hammond. The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. Addiction, 108 (9) (2013), pp. 1658-1668, 10.1111/add.12183
Kluger R. Ashes to Ashes: America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris. New York: Alfred A Knopf; 1996.
Lackey WB. Can Lois Lane Smoke Marlboros: An examination of the constitutionality of regulating product placement in movies. U. Chi. Legal F. 1993; 1993: 275–417.
Lipton, Eric. (2 September 2016). "A Lobbyist Wrote the Bill. Will the Tobacco Industry Win Its E-Cigarette Fight?". The New York Times.
Martin, Andrew D.; Quinn, Kevin M. (2007). "Assessing Preference Change on the US Supreme Court". *The Journal of Law, Economics, & Organization*. 23 (2): 365–385.
Mekemson C, Glantz SA. How the tobacco industry built its relationship with Hollywood. Tob. Control 2002; 11 (S1): i81–i91.
Morris, Rodney A. "SSSmokinnn': The Supreme Court Burns the FDA's Authority to Regulate Tobacco in FDA V. Brown & Williamson Tobacco Corp.(Survey of Health Care Law)." *Creighton Law Review* 34.4 (2001): n. pag. Print.
Mukherjee, S. (2010). The emperor of all maladies: a biography of cancer. New York: Simon & Schuster, 2010.
National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking

and Health. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta (GA): Centers for Disease Control and Prevention (US); 2012. 5, The Tobacco Industry's Influences on the Use of Tobacco Among Youth.

Philip Morris cigarette marketing – a new perspective. Kelly Weedon Shute Advertising; November 1989. Access date: January 26, 2020. Bates No. 2501057693-7719.

Porter, Patrick P. "Origins of the American Tobacco Company" The Business History Review, Vol. 43, No. 1.(1969).

Proctor, R. N. (2012). The history of the discovery of the cigarette–lung cancer link: evidentiary traditions, corporate denial, global toll: Table 1. *Tobacco Control*, *21*(2), 87–91. doi: 10.1136/tobaccocontrol-2011-050338

Ravenholt, R. T. "Tobacco's Global Death March." Population and Development Review 16, no. 2 (1990): 213-40. Accessed January 13, 2020. doi:10.2307/1971589.

R.J. Reynolds. 2006. R.J. Reynolds Tobacco Company History. Web Page. Available at: http://www.brownandwilliamson.com/company/profileHistory.aspx

Roh S. (2018). Scientific Evidence for the Addictiveness of Tobacco and Smoking Cessation in Tobacco Litigation. Journal of preventive medicine and public health = Yebang Uihakhoe chi, 51(1), 1–5. doi:10.3961/jpmph.16.088

Sargent JD, Tickle JJ, Beach ML, Dalton MA, Ahrens MB, Heatherton TF. Brand appearances in contemporary cinema films and contribution to global marketing of cigarettes. Lancet 2001; 357: 29–32.

Schoenberg EH. 1933. The demand curve for cigarettes. The Journal of Business of the University of Chicago 6(1):15-35.

Singh T, Arrazola RA, Corey CG, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2015. MMWR Morb Mortal Wkly Rep 2016; 65:361–367. DOI: http://dx.doi.org/10.15585/mmwr.mm6514a1

Smith, E. A., & Malone, R. E. (2009). "Everywhere the soldier will be": wartime tobacco promotion in the US military. American journal of public health, 99(9), 1595–1602. doi:10.2105/AJPH.2008.152983

Szubin, Adam J. "Leveling the Playing Field: The FDA's Regulation of Nicotine Dependence Products." *Harvard Law School*, January 30, 1998.

U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

United States Code: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 Suppl. 5 . 1934.

University of Bath (October 17, 2012). "Hill & Knowlton". www.TobaccoTactics.org.

Wakefield, M. A., Germain, D., & Durkin, S. J. (2008). How does increasingly plainer cigarette \ packaging influence adult smokers' perceptions about brand image? An experimental study. Tobacco control, 17(6), 416–421. doi:10.1136/tc.2008.026732

Wang, T. W., Kenemer, B., Tynan, M. A., Singh, T., & King, B. (2016). Consumption of Combustible and Smokeless Tobacco — United States, 2000–2015. MMWR. Morbidity and Mortality Weekly Report, 65(48), 1357–1363. doi: 10.15585/mmwr.mm6548a1

Warner, Kenneth E. "Clearing the Airwaves: The Cigarette Ad Ban Revisited." Policy Analysis, vol. 5, no. 4, 1979, pp. 435–450. JSTOR, www.jstor.org/stable/42783355. Accessed 27 Jan. 2020.

Xu X, Bishop EE, Kennedy SM, Simpson SA, Pechacek TF. Annual Healthcare Spending

Attributable to Cigarette Smoking: An Update.. American Journal of Preventive Medicine 2014; 48 (3): 326–333.

Appendix

Table A1: Significant Legislature Referenced in Text

Act	Description
Pure, Food and Drugs Act (1906)	- Created the FDA
Federal Food, Drug and Cosmetic Act (1938)	- Congress gave the U.S. FDA the authority to oversee the safety of food, drugs, medical devices and cosmetics - In Chapter Nine of the Act, it is stated that one particular substance the FDA had control over was tobacco
Cigarette Labeling and Advertising Act (1965)	- Cigarette packages must contain the phrase: "Caution: Cigarette smoking may be hazardous to your health"
Public Health Cigarette Smoking Act (1969)	- This Act stated that tobacco companies had to include the Surgeon General warning label on cigarette packages. - "Warning: The Surgeon General Has Determined that Cigarette Smoking Is Dangerous to Your Health" - Cigarette advertisements were officially banned from American television.
Comprehensive Smoking and Education Act (1984)	- Established a national program to increase availability of information on dangers of cigarettes - Tobacco product labels had to include specific health warnings such as: emphysema, heart disease, cancer and pregnancy complications - Example: "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy."
Family Smoking and Tobacco Prevention Act (2009)	- Congress gave the FDA full authority in controlling the tobacco industry

Table A2: Significant Supreme Court Rulings Referenced in Text

Act	Significant Precedent
U.S. vs. Southwestern Cable Co. (1968)	- If a department has original statute establishing authority over a jurisdiction, then the department has ultimate control
Central Hudson Gas and Electric Corporation vs. Public Service Commission of New York (1980)	- Central Hudson Framework was established which states that if a department's measures pass an array of criteria, then department can restrict commercial speech
Chevron U.S.A. Inc vs. Natural Resources Defense Council (1984)	- Established the precedent that if authority for a matter is clearly established by an entity other than that of the original statute, the original party loses control
FDA vs. Brown and Williamson Tobacco Corp. (2000)	- Supreme Court ruled that the FDA did not have the author and therefore right to restrict the tobacco advertising and industries on a larger scale
Lorillard vs. Reilly (2001)	- In situations where federal and state law contradict one another, federal law overrules state law

Chart A1: Adult Per Capita Consumption of Cigarettes (1900-2002)

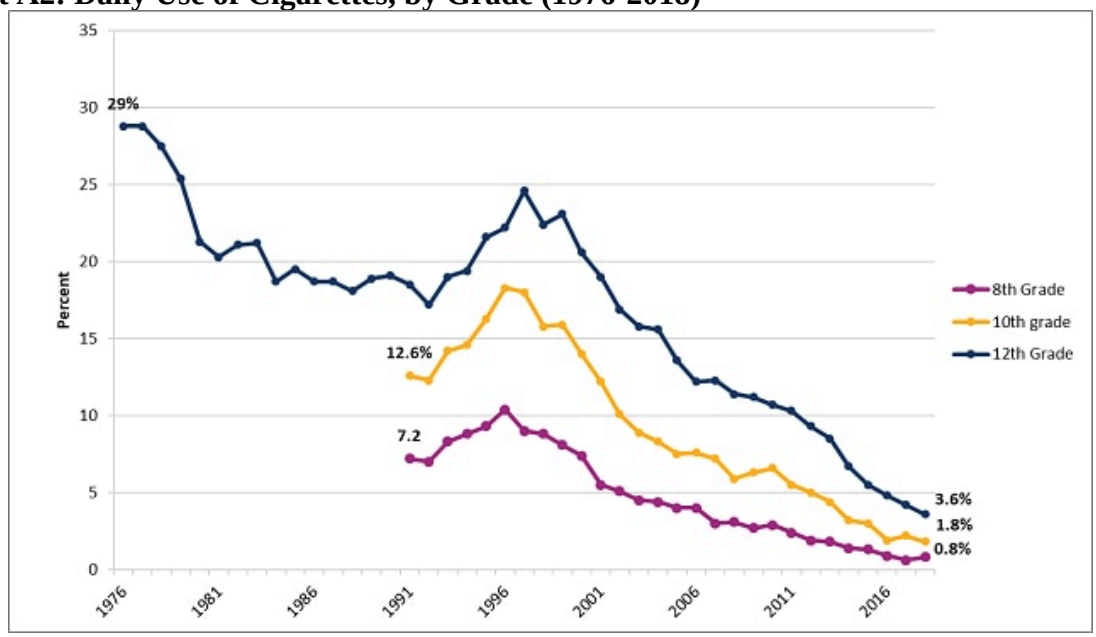
Source: "1 Epidemiology of Tobacco Use: History and Current Trends." Institute of Medicine. 2007. Ending the Tobacco Problem: A Blueprint for the Nation. Washington, DC: The National Academies Press. doi: 10.17226/11795.

Table A3: Cigarette company marketing expenditures, in millions of dollars, 2000–2008

Year	Advertising ($)	Promotion and other ($)	Total ($)	Advertising as % of total
2000	702.9	8,889.8	9,592.6	7.3%
2001	497.1	10,719.1	11,216.2	4.4%
2002	417.5	12,048.9	12,466.4	3.3%
2003	362.8	14,783.2	15,146.0	2.4%
2004	281.4	13,868.5	14,149.9	2.0%
2005	238.4	128,792.6	13,111.0	1.8%
2006	293.9	12,195.8	12,489.7	2.4%
2007	249.1	10,615.7	10,864.8	2.3%
2008	191.4	9,751.0	9,943.1	1.9%

Source: Federal Trade Commission. Federal Trade Commission Cigarette Report for 2007 and 2008. Washington: U.S. Federal Trade Commission; 2011.

Chart A2: Daily Use of Cigarettes, by Grade (1976-2018)



Source: Source: Johnston, L. D., Miech, R. A., O'Malley, P. M., Bachman, J. G., Schulenberg, J. E., & Patrick, M. E. (2019). Monitoring the Future national survey results on drug use 1975-2018: Overview, key findings on adolescent drug use. Ann Arbor: Institute for Social Research, University of Michigan.