

## Ethical Evaluation of Family Smoking Prevention and Tobacco Control Act Using Nancy Kass Framework

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### Abstract

*Purpose:* This paper aims to evaluate the Family Smoking Prevention and Tobacco Control Act through the lens of Nancy Kass' ethical framework. The focus is on assessing the public health objectives, effectiveness, and ethical implications of the Act, particularly in reducing smoking rates and protecting public health.

*Design/methodology/approach:* The study employs a qualitative analysis, applying Nancy Kass' ethical framework to evaluate the Family Smoking Prevention and Tobacco Control Act. The framework's six-step approach is used to assess the public health goals, effectiveness, burdens, and ethical justifications of the Act.

*Findings:* The evaluation reveals that the Family Smoking Prevention and Tobacco Control Act has been partially effective in achieving its goals, particularly in regulating tobacco products and reducing youth smoking rates. However, there are significant gaps in its implementation, particularly concerning the regulation of e-cigarettes. The ethical analysis shows that while the Act imposes certain burdens on tobacco companies and consumers, these are justified by the potential public health benefits.

*Research limitations/implications:* The analysis is limited to the application of the Kass framework and does not incorporate empirical data on the long-term health outcomes of the Act. Future research could include quantitative assessments of the Act's impact on public health.

*Practical implications:* The findings suggest that stricter enforcement and comprehensive regulation, especially of newer tobacco products like e-cigarettes, are necessary to fully realize the Act's public health goals. Policymakers should consider the ethical balance between individual rights and community health benefits. The Act represents a significant step in promoting public health by reducing tobacco-related harm. However, its partial implementation underscores the need for continued efforts to address emerging challenges in tobacco regulation.

**Keywords:** Public Health Ethics, Tobacco Control, Family Smoking Prevention Act, Nancy Kass Framework, Smoking Reduction, FDA Regulation, Health Policy.

*Article Classification:* Research article. This classification reflects the in-depth analysis and application of a specific ethical framework to evaluate a public health policy.

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### **Introduction**

When it comes to virtue ethics, a person-centered approach is preferred over an action-centered approach: it considers the virtue or character trait of who is carrying out an action rather than the ethical obligations and standards or the effects of specific actions. According to the American Public Health Association, Public health can be defined as "the art and science of avoiding disease, extending life, and improving health through the coordinated efforts of society" (WHO). The Ethical Practice Principle highlights the key ethical principles that are essential in the public health sector, and that is vital to ensure the health of the individuals is well recognized (Kaufman et al., 2015).

According to the World Health Organization, public health ethics is a systematic strategy for defining, prioritizing, and justifying various courses of public health action based on ethical principles, the values and beliefs of stakeholders, as well as scientific and other data. Each field of practice is marked with the underlying ethical position that it adheres to. As illustrated by the many ethical standards relevant in the health sector, there is a link between certain ethical principles and the law in some instances. According to Rothstein, (2002), when it comes to public health, ethical norms are intended to safeguard both the many stakeholders engaged in the supply of healthcare and the consumers (patients) of the services provided by the healthcare system. A considerable correlation exists between the principles and certain existent laws, both favorably and negatively. (Cummings et al., 2020).

Effective public health efforts must be carried out fairly, through fair methods, to reduce existing inequities and define which health burdens are appropriate for a community to be successful (Kass, 2001). This public health program's ethical implication is evaluated using the Kass Framework, which consists of six issues to consider when doing so (Kass, 2001).

Upon rigorous examination of the principles and the applicable legislation, it is shown that some of them are in direct violation of the principles, whilst others enhance or reinforce them. As a result of the interaction, it is necessary to create a balance between the competing interests to protect individual rights while also ensuring the overall health of the community. (Cummings et al., 2020). Ethical issues in the field of public health come from a libertarian viewpoint as well, because public health as a whole takes a collectivist approach to safeguard and gain the most benefit for the largest number of people. The health of others takes precedence over the rights of individuals when certain actions of the individual are restricted for the sake of the community (Kaufman et al., 2015). This may entail coercion/persuasion through the use of an incentive or a penalty, which may influence autonomy and decision architecture.

This is especially troublesome when the definition of "good" given by the Department of Public Health differs from the meaning given by the individual. Consideration should be given to ethics in public health (Kaufman et al., 2015). Public health laws are set up to enhance the health of public citizens. These policies are different in various states, country to country, and even from time to time, relying on the population's needs. Public health policies provide directing principles on which the government should offer preventive and healthcare services. Nonetheless, they all have a shared objective of enhancing the public's well-being. At some point, some laws are established in response to crises and emergencies. The Smoking Prevention and Tobacco Control Act is an example of such a policy in action. According to Nancy Kass' Framework, the public health ethics of the United States 'Family Smoking Prevention and Tobacco Control Act' will be reviewed (Kass, 2001). It will first examine the history of the United States the Family Tobacco Control Act, then examine the utility of Nancy Kass' framework, and then address every issue posed by the Kass Framework to argue the ethics of public health promotion and intervention. Analyzing the Family Smoking Prevention and Tobacco Control Act is essential due to its profound impact on public health, particularly in reducing smoking rates and preventing tobacco use among youth.

The effectiveness of the Act's policies and regulations must be evaluated to ensure they achieve these goals without unfairly burdening certain populations. Nancy Kass's ethical framework is a valuable tool for this analysis, as it is specifically designed for public health interventions. It offers a systematic approach to assessing the ethical dimensions of public health policies, ensuring that they are both effective and just. Nancy Kass's framework for ethical analysis in public health consists of six key questions:

- What are the public health goals of the program?
- How effective is the program in achieving its stated goals?
- What are the known or potential burdens of the program?
- Can burdens be minimized? Are there alternative approaches?
- Is the program implemented fairly?
- How can the benefits and burdens of the program be fairly balanced?

#### **What are the public health goals of the proposed program?**

To adhere to Kass' framework, it is necessary to examine and address the objectives of the Family Smoking Prevention and Tobacco Control Act. The core objective of the law is regulating the distribution, marketing, as well as manufacturing of tobacco products. It is essential to list the products, reveal the contents or the ingredients of marketing statistics and tobacco products. According to Lee, Baker, Ranney & Goldstein, (2015), there is a need to disclose the product and smoke ingredients by the manufacturers. Besides, they should also make known the additives, and the byproducts. The Family Smoking Prevention and Tobacco Control Act was signed into law by President Barack Obama in 2009, making it the first law in the world to do so. Consequently, the Department of Food and Drug Administration was granted the jurisdiction to control tobacco product manufacturing, distribution, and promotion as a direct result of the passage of this Act. To achieve these goals the policy through FDA launched "The Real Cost." This is a tobacco prevention program aimed at kids aged 11-18. This program has prevented over three hundred thousand teens from smoking from 2014 to 2016. Moreover, it helped save roughly \$31 billion in smoking-connected expenses. The policy has developed TCORS—Tobacco Centers of Regulatory Science; this corporation has helped research several aspects of tobacco usage to inform the product regulation. Ultimately, non-smokers support the law more than smokers (Rose et al., 2015). The law is now almost twelve years old, and when FDA was last ranked, the government gave it an 'F' since it has not fully implemented all the ACT regulations and had failed to address the rise of harmful but flashy e-cigarettes. Due to the FDA's failure to perform well, tobacco manufacturing companies have established innovative strategies by making candy and fruit-flavored cigarettes alongside e-cigarettes designs, making youths conceal easily.

#### **How effective is the program in achieving its stated goals?**

After that, the next step in Kass' framework is to assess how effective The Federal Family Smoking Prevention and Tobacco Control Act has been in reducing smoking rates. The policy conveys the sense that it should be effective since it is evidence-based. There are areas of success for the act in the process of regulating the usage of tobacco products. The act has succeeded in bringing these products under the authority of the FDA. Such products include e-cigarettes, pipe tobacco, cigars, and hookah. The law has also made it possible to establish a Center for Tobacco Products responsible for handling regulations for the products. Likewise, the law has made it possible for the states to develop retail enforcement programs accountable for inspection. Another achievement is the facilitation of the launching of "The Real Cost," which is a representation of a tobacco use prevention campaign. The campaign aims at the youths from 11 and 18 years (Food and Drug Administration, 2016). According to Food and Drug Administration, (2016), the act has also protected roughly \$31 billion in the charges connected to smoking and virtually 350,000

youths from tobacco between 2014 and 2016. Also, the law has enabled the establishment of the Tobacco Centers of Regulatory Science (TCORS). The centers have focused on research on many issues related to tobacco use in an attempt to inform the regulation of tobacco. Similarly, the FDA has granted the authority to control the sale, distribution, and marketing practices associated with the sale and distribution of tobacco products.

This strategy raises ethical concerns because, notwithstanding the evidence supplied in support of its effective implementation, the evidence suppressed raises ethical concerns. The act has also been associated with different ethical implications. Firstly, it requires the inclusion of graphic warning labels in the packs within the US territory. There are claims that the issue infringes on free commercial speech. Secondly, the FDA has an industry in which many privileges as paternalistic. Likewise, there is a likelihood of a regressive impact on the massive control of these products. The regulated products tend to become expensive to many of the users, exceptionally the less fortunate. Human utilization of tobacco has a long history of more than 500 years (Analysis of the Family Smoking Prevention and Tobacco Control Act Public Law 111-31 Food Marketing Institute, 2009). Until late many years, tobacco utilization, particularly smoking, was unregulated on the planet. In the United States, because the public authority needed appropriate proof that affirmed the connection between tobacco utilization and sickness, cigarette control estimates just arose after the 1960s. Notwithstanding deficient verifications of the risk of tobacco, nicotine dependence was affirmed in the last part of the 1990s as it were. These days, following 60 years of steady endeavors by associations and organizations, governments have put a complex of policies against tobacco approaches like overwhelming admonition signs, prohibiting promoting, tax assessment, executing clean air act and age limits (Food and Drug Administration, HHS, 2010). Because of the advancement made by these actions, smoking pervasiveness in the worldwide setting has been diminished significantly, particularly in top-level salary nations. Therefore, associations and governments currently move their inclinations into the endgame methodology, which plans to wipe out cigarette use by a specific time later on. Be that as it may, the discussion on moral issues around tobacco control additionally draws a generous measure of consideration. Favorable to smoking populace contends that it isn't moral to eliminate tobacco use considering under the structure of common liberties.

#### **What are the known or potential burdens of the program?**

Kass Framework states that the Third Step covers the burdens imposed as a result of the Family Smoking Prevention and Tobacco Control Act. Generally, public health burdens may be categorized into three groups: those regarding privacy and confidentiality, those affecting liberty and self-determination, and lastly, those concerning fairness and justice. (Kass, 2001). Participants in contact tracing do not have the option to choose whether or not to give personal identifying information (Kass, 2001), which inevitably infringes on their liberty and autonomy (Kass, 2001). According to Kass (2001), due to the publishing of results, the person faces the threat of losing his or her employment or revenue as a technique of protecting the public health for the majority of people, without taking into consideration the repercussions for his or her safety and well-being. It is possible that surveillance and tracking are wrong according to virtue ethics (Kass, 2001) even if there is no such consequence. This is due to the violation of individual privacy that occurs despite the value of the technology. Even more so, Kass (2001) claims this is true if tobacco surveillance and tracing are not done equitably, like by monitoring specific groups, or when different jurisdictions have different rules. This can have an impact on the people who are being kept track of.

A person's privacy may be jeopardized by the Tobacco Control Act, which establishes certain limitations on the marketing of tobacco products to children and provides the Food and Drug Administration the abili



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ty to take more action in the future to safeguard public health. Maintaining an individual's private information can also be a matter of ethical concern.

Internationally, the United States, and thus its strategy on international trade, which requires international collaboration, already carries the ethical obligations of justice, which are imposed by international treaties. The tobacco business employs its vast resources to derail or weaken legislation and accords in a variety of countries and areas. History has it that governments have provided support to industries by the imposition of production caps, which have resulted in limited supply and high pricing. When the Tobacco Quota Buyout was implemented in 2005, these limits were lifted, allowing the tobacco to be cultivated freely and in any amount throughout the United States (Jarman et al., 2017). American cigarette makers like Reynolds America (RAI) and Altria Group (MO) are no longer able to depend on the residual tariffs to safeguard their companies from international competition because of public opinion against tobacco usage and excise taxes reaching up to an extra \$5.85 per pack. Although sales in the United States have been dropping, they have been able to reap profits in other countries and convince a huge number of American farmers to switch to growing the crop in recent years. Interestingly, whereas an acre of maize yields a profit of around \$100, an acre of tobacco yields a profit of \$1,000 to \$1,500. It was predicted that more than four million people throughout the globe will die as a result of smoking in 2005, and that number would climb to 10 million by 2030. (Jarman et al., 2017).

The development, manufacturing, and distribution of tobacco pose a threat to justice in individual states. Through the restriction of imports and the encouragement of exports, governments have been able to manipulate the tobacco trade in a variety of ways. As previously demonstrated, they do so to attain a diverse range of economic, political, and diplomatic interests. International agreements have argued for the protection of health and the prevention of harm. Health is often regarded as a fundamental human right and desire shared by all people everywhere. The International Covenant on Economic, Social, and Cultural Rights specifies that governments have a responsibility to ensure that people's health and well-being are not threatened. As a result of increased awareness and information, we have only witnessed a decrease in the youth and middle-aged populations. This knowledge has manifested itself in a variety of ways, including commercials, the internet, and even the death of close relatives.

Justice can be jeopardized by communicating to and offering services to those who are difficult to reach, such as members of underrepresented groups, who are an existential danger to national equity. Tobacco and poverty are inextricably linked (Thomas and Gostin, 2013). Tobacco usage accounts for up to 10% of total family spending, which means that the poorest households have less money to spend on essentials like food, education, and health care. Tobacco use has well-known negative health effects, but it also causes hunger, raises health-care costs, and shortens life expectancy. In addition to raising the illiteracy rate, tobacco use diverts resources that could be going toward education. Scholars in both fields have generally ignored the link between tobacco use and rising levels of poverty.

#### **Can burdens be minimized? Are there alternative approaches?**

The fourth phase of Kass' Framework explores ideas for reducing the burdens of the Family Smoking Prevention and Tobacco Control Act. The law has made tremendous progress in terms of restricting the use of tobacco and tobacco-related items. However, there is still more work to be done in this area. Besides, "The FDA has failed in exercising its mandate in the regulation by not taking the appropriate steps and protecting the public. It has also failed to remove menthol and flavors associated with the products" (Rose et al., 2015). The youths are highly attracted by the use of flavors in tobacco and its consequences. The use of menthol in tobacco has attracted vast numbers of youths who end up addicted,

making it difficult to end their smoking habit. Although the FDA has placed strict regulations, it has failed to do so on e-cigarettes and cigars. Besides, the milestone the FDA has achieved exceeds the undone and the areas of weakness. The FDA has successfully regulated the industry, making the law efficient (Sharpless & Zeller, 2019). Also, the law has enabled the establishment of the Tobacco Centers of Regulatory Science (TCORS). The centers have focused on research on many issues related to tobacco use in an attempt to inform the regulation of tobacco. Furthermore, the FDA has granted authority to control the sale, distribution, and marketing activities of tobacco products following federal law (Rose et al., 2015). The rules incorporate banning the sampling products and the use of vending machines. Another area of restriction is tobacco selling in retail and face-to-face interactions between retailers and customers. Another control area is expanding the existing limits on the branding of non-tobacco products and the other brand sponsorships involving tobacco (Rose et al., 2015). However, many people oppose the law claiming that it goes against their rights.

#### **Is the program implemented fairly?**

The fifth step in Kass' framework inquires as to whether or not the implementation is fair. However, even if the term "fair" is subjective, it can be interpreted as the distribution of benefits being equal to the distribution of burdens (Kass, 2001). When only specific groups of the population are prioritized for being deemed vulnerable, stereotypes and stigmas can be maintained. This is especially true in just distribution (Kass, 2001). This policy targeted consumers, manufacturers, and distributors of tobacco products. Before this policy, manufacturers added fruits and flavors when manufacturing the cigarettes to please and attract more users, which would increase their sales. Candy flavored cigarettes could easily please first-time smokers, particularly children. Consequently, this attraction further leads to more children and adults' addiction to the product. The policy banned the usage of additives since they could increase dependency on the harmful product. Additionally, some manufacturers laced their products with harmful and addictive substances. Therefore, the policy needs the manufacturers to indicate all the ingredients utilized to make the commodities. This enhanced consumer awareness of the product they inhaled. The policy further obligates the manufacturers to put a visible warning concerning the tobacco's side effects on the package.

#### **How can the benefits and burdens of a program be fairly balanced?**

Finally, Kass' approach takes care of the burden-to-benefit ratio. The majority of the ethical risks and burdens presented by this policy are arbitrary when weighed against the threat and burden of death posed by failing to comply. Given the risk-averse mentality of the vast majority of humans, this would appear to be a positive balance. It is more important to be in perfect health and to remain alive following a public health emergency than it is to incur minor liabilities in terms of privacy, liberty, and justice even if the probabilities were not taken into consideration. In an emergency, there is no time for argument because of the gravity and immediacy of the event. Therefore, responding quickly and in line with the Mills Harm Principle maximizes benefit. The longer it takes for officials to respond, the less the advantage exceeds the burden, because the threat has grown in severity, necessitating more severe infringements to be committed. Some restrictions on personal liberty, on the other hand, are unavoidable, just as there will always be those who disagree with any plan. Neither of them, however, is sufficient justification to prevent a public health project from being implemented unless they come from a significant number of people (Kass, 2001).

#### **Conclusion**

Ultimately, to benefit the greatest number of people, public health authorities have an ethical duty to seek truth and equality. The ethical evaluation of public health interventions might be aided by using the Kass framework. In the last fifty years, the Tobacco Control Act of 2009 is the most significant legislation concerning the tobacco industry. This policy targeted consumers, manufacturers, and distributors of tobacco products. Marketers and advertisers of the commodity are also needed to abide by this policy. They are not permitted to give away promotional materials and sample cigarettes to youths and other users. As the document stands, the law is used fairly and ethically. The regulation leads to improved public health as it reduces the exposure to different health conditions due to smoke. Regarding the unintended/unforeseen consequences, the issue can give rise to illicit markets that sell the regulated products in so much control. That the policy is implemented fairly and that the benefits outweigh the ethical burdens. Beyond politics, advocates of public health must navigate ethical swamps and looming legal threats. Given the enormous public health benefits and economic productivity of a tobacco-free society, political and legal battles are well worth the cost. The impact of tobacco in increasing poverty has been largely disregarded by researchers in both sectors, and it is in this area that future research should be concentrated.

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