



SRNT

OXFORD

Original investigation

# Assumption of Risk and the Role of Health Warnings Labels in the United States

K. Michael Cummings MPH, PhD<sup>1</sup>, Jonathan Gdanski JD<sup>2</sup>, Nichole Veatch BA<sup>3</sup>, Ernesto Marcelo Sebríe MD, MPH<sup>4</sup>

<sup>1</sup>Hollings Cancer Center and Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, SC; <sup>2</sup>Schlesinger Law Offices, PA, Fort Lauderdale, FL; <sup>3</sup>US Research; <sup>4</sup>International Research, Campaign for Tobacco-Free Kids, Washington, DC

Corresponding Author: K. Michael Cummings, MPH, PhD, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, 67 President Street, MSC 861, Charleston, SC 29425, USA. Telephone: 843-876-2429; E-mail: [cummingk@musc.edu](mailto:cummingk@musc.edu)

## Abstract

**Introduction:** This article provides historical context for understanding how the cigarette industry have manipulated language used in health warning labels (HWLs) to protect them in litigation.

**Methods:** Review of previously secret internal business records from 1964 discussing the role HWLs on cigarettes. Review of the legal challenges made by cigarette manufacturers surrounding HWLs as mandated in the 2009 Family Smoking Prevention and Tobacco Control Act and the language in corrective statements ordered by US Department of Justice.

**Results:** Within days after the Surgeon General's Advisory Committee issued its 1964 Report the cigarette companies plotted how they could use HWLs on cigarettes as a defense in future litigation. Industry lawyers discussed drafting legislation that would preempt other government agencies from requiring HWLs on cigarette containers and in cigarette advertising with language mirroring the key findings of the Surgeon General's Advisory Committee report. In July 1965, Congress did pass legislation which mandated a single watered-down cigarette pack HWL which excluded cigarette advertising, just as industry lawyers had recommended. Subsequent HWL laws passed by Congress in 1969 and 1984 along with the more recent history of manufacturers opposing updated graphic HWLs and corrective statements reflects a consistent and continuing effort by cigarette companies to insulate themselves from taking responsibility for harms caused by smoking.

**Conclusion:** Beginning in the mid-1960s and continuing even through today, lawyers working on behalf of cigarettes companies have worked to manipulate the language of consumer warnings to focus responsibility for the harms caused by smoking on smokers.

**Implications:** In tobacco litigation, juries should be informed about the industry's coordinated effort to draft legislation and water down the original caution statements proposed on cigarette containers and in advertising even though Congress ultimately is responsible for the law that was enacted. In addition, even though the 1992 Supreme Court decision in the Cipollone case preempted post-1969 failure to warn claims against cigarette makers, this protection does not apply on pre-1969 warning claims where the evidence shows that cigarette companies understood they were selling a defective product that when used as intended would harm their customers. Thus, those initiating smoking before 1969 and subsequently harmed by cigarettes can hold cigarette makers responsible for their failure to warn them about health risks.

## Introduction

One of the primary conclusions of the 1964 Surgeon General's Advisory Committee (SGAC) was the finding that cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.<sup>1</sup> One of the earliest and best known remedial actions taken by the government was requiring a health warning label (HWL) printed on one side of cigarette packs.<sup>2</sup> The Federal Cigarette Labeling and Advertising Act of 1965 (Public Law 89-92) was passed by US Congress on July 1, 1965 and signed into law on July 27, 1965.<sup>2</sup> The law, which became effective, January 1, 1966, required all cigarette packaging to carry the following statement "Caution: Cigarette Smoking May be Hazardous to Your Health." Subsequent labeling laws were enacted by Congress in 1969 and 1984 to further strengthen the HWL on packs and to require them also on print and billboard cigarette advertising.<sup>2</sup> Although some might debate how impactful the existing HWLs have been in discouraging smoking, most people would say that Congress did the right thing in requiring them. Although several books have provided detailed accounts of how the Federal Trade Commission's (FTC) efforts to get meaningful HWLs on cigarettes and advertising were undermined by industry through its political clout, the full story of how HWLs actually came about in the mid-1960s is not as well known.<sup>3-5</sup> This article provides historical context for understanding how the cigarette industry manipulated language used in HWLs and more recently in court-mandated corrective statements. Previously secret internal business records are described which reveal that while the cigarette companies publically refuted the need for HWLs on cigarettes, industry lawyers were at the same time discussing how HWLs might actually be helpful to them in litigation by shifting responsibility for the harms caused by cigarettes from themselves to smokers.

## Methods

The data for this article come from four main sources: (1) the 1989 Surgeon General's Report on smoking and health and information on the history of HWLs,<sup>2</sup> (2) information pertaining to HWLs on cigarette packages as required by the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA),<sup>6-8</sup> (3) previously secret and confidential tobacco industry documents (eg, memoranda) that describe cigarette manufacturers efforts to craft legislation on cigarette pack warnings,<sup>9-15</sup> and (4) a review of the legal challenges by cigarette manufacturers that shaped the final text of corrective statements as originally ordered by a Federal Court in 2006.<sup>16-20</sup> Tobacco industry documents were found on the Truth Tobacco Industry Documents Web site using a snowballing search approach for any industry documents dealing with "minutes of meetings" of industry executives in the days and weeks immediately following the release of the 1964 Surgeon General's Report on January 11, 1964. Initially this search yielded 162 records with many duplicates copies found. Within this group of documents we focused on documents reporting minutes of meetings of an ad hoc committee of industry lawyers and executives that took place between January 12 and 23, 1964. These meeting minutes describe how the industry might respond to anticipated forthcoming FTC rules requiring HWLs on cigarette packs and in cigarette advertising. Follow-up searches were narrowed using the names of the lawyer who authored the meeting minutes (ie, Fred Haas, a lawyer working at Liggett & Myers).

## Results

**Table 1** provides a chronology of events affecting HWLs on cigarette packaging (ie, packs, cartons) and on tobacco advertising beginning in 1964 through the passage of the 1984 law that mandated the current four rotating health warnings in use today and the 2009 FSPTCA which gave the US Food and Drug Administration (FDA) authority to update HWLs. According to the 1989 Surgeon General's Report, the US FTC was the driving force behind the original warning label policy effort.<sup>2,21,37,38</sup> The FTC's role in pushing for HWLs on cigarettes packaging and advertising is further supported by the internal business records of the cigarette companies.<sup>9-15</sup>

### How the First HWL Came About

On January 22, 1964, 11 days after the SGAC released its report, the FTC issued a proposed rule on health warnings on cigarette packages and advertisements.<sup>2,21</sup> The FTC's original proposed rule would have required cigarette containers and advertisements to carry the following two health warning statements: (1) Caution: Cigarette smoking is a health hazard: The SGAC on Smoking and Health has found that "cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate," and (2) Caution: Cigarette smoking is dangerous to health. It may cause death from cancer and other diseases. The FTC proposed rule was followed by a 6-month period of public comments and hearings. After the review and public comment period, the final FTC rule was released on June 22, 1964, and required all cigarette containers and advertisements to disclose "cigarette smoking is dangerous to health and may cause death from cancer and other diseases."<sup>22,37,38</sup> The FTC rule requiring the warning statement on cigarette packaging was to take effect on January 1, 1965, with extension to cigarette advertising by no later than July 1, 1965. However, implementations of the FTC product labeling rules were delayed at the request of Congress, which at the time was considering various bills that would address product labeling and advertising.<sup>2,23-25</sup>

### FTC Proposed Rule Stopped

On July 1, 1965, the US Congress passed the Federal Cigarette Labeling and Advertising Act, mandating its own cigarette HWLs and preempting the FTC or any other government agency from taking additional action on product labeling and advertising until July 1, 1969, at which time the issue would be revisited.<sup>26,27</sup> Congress also required the FTC to issue an annual report on cigarette advertising and the effectiveness of the HWL adopted by Congress. Congressman Horace Kornegay (D-NC), who latter would serve as vice president and counsel (January 1969–June 1970), president (June 1970–February 1981), and finally chairman (February 1982–December 1986) of the Tobacco Institute (ie, a trade association created in 1958 jointly funded by cigarette manufacturers), was one of the congressional leaders who negotiated the final language of the 1965 Labeling Act.<sup>28</sup> The Act was signed into law by President Johnson on July 27, 1965, with a required HWL: "Caution: Cigarette Smoking May be Hazardous to Your Health" to appear only on one side of cigarette containers (not advertisements) starting January 1, 1966.<sup>2</sup> Unlike the proposed HWLs proposed by the FTC, the HWL mandated by Congress does not include a reference to cancer or other diseases. On July 28, 1965, the FTC vacated its proposed rule on cigarette product labeling and advertising.<sup>2,29</sup>

**Table 1.** Chronology of Events Impacting Cigarette Warning Labels in the United States

Date	Source	Findings
January 11, 1964	Surgeon General's Advisory Committee Report issued <sup>1</sup>	Cigarette smoking is a hazard of sufficient importance in the United States to warrant appropriate remedial action
January 12, 1964	Meeting of the Tobacco Institute Executive Committee <sup>9-12</sup>	The cigarette industry must maintain a united front. Special Lawyer Committee should clear any public statements about the SGAC Report. The cigarette industry can no longer put much stock in the semantics of causative factors in litigation defense since the SGAC Report provides an explicit definition of cause. Rules about product labeling and advertising will be forthcoming and discussed at the upcoming January 17, 1964 Tobacco Institute Executive Committee meeting
January 17, 1964	Meeting of the Tobacco Institute Executive Committee <sup>13</sup>	FTC will be issuing proposed rules on product labeling and advertising. Congressional action on product labeling and advertising is preferable if it preempts FTC and state and local actions. An ad hoc committee is assigned the task of drafting a bill for Congressional action that will preempt the field and exclude advertising copy
January 20, 1964	Meeting of the Cigarette Industry Special Lawyer Committee <sup>13,14</sup>	Initial drafts of the Congressional bills drafted by the ad hoc committee reviewed and discussed. A pack warning would potentially enhance the industry's legal defense of assumption of risk
January 22, 1964	Federal Trade Commission <sup>20,21</sup>	The FTC proposes rules that would require cigarette containers to carry two warnings: (1) Caution: Cigarette Smoking is a Health Hazard. The Surgeon General's Advisory Committee on Smoking and Health has found that cigarette smoking contributes substantially to mortality from certain diseases and to the overall death rate. (2) Caution: Cigarette smoking is dangerous to health. It may cause death from cancer and other diseases
January 23, 1964	Meeting of the Cigarette Industry Special Lawyer Committee <sup>13,15</sup>	The proposed FTC rules should be opposed, especially the unfortunate referencing of mortality and death rates. Every effort should be made to tone down the caution notices proposed
June 6, 1964	Federal Trade Commission <sup>2</sup>	After 6-months of public comment FTC issues its final proposed rule requiring all advertisements and cigarette containers to disclose cigarette smoking is dangerous to health and may cause death from cancer and other diseases. The rule would require pack warnings to appear on January 1, 1965, and on cigarette advertising by no later than July 1, 1965
December, 1964	News reports <sup>22-26</sup>	Various news reports indicate that the FTC final product labeling rule scheduled to take effect on January 1, 1965 will be delayed until July 1, 1965 at the request of Congress that is consider various bills that would health warnings in advertising and on cigarette containers
July 1, 1965	Congress <sup>27,28</sup>	Congress passes the Federal Cigarette Labeling Act of 1965 which requires a single warning statement to appear on one side of cigarette containers: Caution: Cigarette smoking may be hazardous to your Health. The law preempts the FTC and state and localities from requiring different warning messages on cigarette packs and on advertising. The issue of product labeling and advertising will be revisited 3 years later July 1, 1969. The pack warnings will take effect January 1, 1966. The Act requires the FTC to produce an annual report on cigarette advertising beginning in June 1967
July 27, 1965	President of the United States <sup>2</sup>	President Lyndon Johnson signs the Federal Cigarette Labeling Act of 1965
July 28, 1965	Federal Trade Commission <sup>29</sup>	The FTC vacates its proposed rule on product labeling and advertising
June 30, 1967	Federal Trade Commission <sup>30</sup>	In its first report to US Congress on the effectiveness of the cigarette pack warning and impact of cigarette advertising the FTC concludes the current pack warning was ineffective and needed to be strengthened to read: Warning: Cigarette smoking is dangerous to health and may cause death from cancer and other diseases
May 20, 1969	Federal Trade Commission <sup>31</sup>	The FTC announces a proposed rule that would require all cigarette advertisements to disclose clearly and prominently that cigarette smoking is dangerous to health and may cause death from cancer coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases
April 1, 1970	US Congress <sup>2</sup>	Following congressional hearings on product labeling and advertising, US Congress passes the Public Health Cigarette Labeling Act of 1969 required a new warning on one side of cigarette containers (effective November 1, 1970): Warning: The Surgeon General has determined that cigarette smoking is dangerous to your health. Congress also makes extended and expanded the preemption barring any other agencies from requiring warnings on cigarette containers and barring the FTC's warnings on packs and on advertising through June 1971
March 30, 1972	Federal Trade Commission <sup>2</sup>	After the Congressionally mandated moratorium barring the FTC from issuing required warnings be included in cigarette advertising the FTC negotiated a consent decree with the cigarette industry to require the same warning found on cigarette packs to be clearly and conspicuously placed in cigarette advertising

Table 1. Continued

Date	Source	Findings
May 1981	Federal Trade Commission <sup>32</sup>	The FTC issues a report on public understanding of the health risks of smoking and the adequacy of the warnings on cigarette packages and advertising. Among its conclusion is that the public was not well informed about the specific risks of smoking, that the current warning did not effectively communicate specific risks of smoking and that the public had been over exposed to the current warning message. The report recommended a series of rotating warning messages that would be more prominently displayed using a circle and arrow format
October 12, 1984	US Congress <sup>2</sup>	Congress passes the Comprehensive Smoking Education Act of 1984. The law mandated four rotating health warnings but in the same style as the previous warnings. The law also continued the prohibition of state and local action on health cigarette health warnings. The law is to take effect October 12, 1985
June 22, 2009	US Congress <sup>7</sup>	Family Smoking Prevention and Tobacco Control Act enacted, amending FCLAA to require nine rotating text warnings. The law required the FDA to issue regulations requiring graphics depicting the negative health consequences of smoking to accompany the text warnings within 24 months of passage of the Act. The warnings would be required to cover 50% of the top front and back principal display areas of cigarette packs, and 20% of the area of advertisements
June 21, 2011	US FDA <sup>8</sup>	FDA Issues Graphic Warning Label Final Rule; Tobacco industry subsequently sues to block the new labels
August 24, 2012	US Court of Appeals for the DC Circuit <sup>33</sup>	Appeals Court strikes down specific warnings in the FDA GWL Final Rule
March 15, 2013	US Attorney General <sup>34</sup>	Government declines further appeal; announces that FDA will develop new GWLs
October 4 2016	CTFK and other health groups <sup>35</sup>	Health Groups file lawsuit against FDA for GWL delay
March 5, 2019	CTFK and other health groups <sup>36</sup>	A federal court in Boston ruled that FDA must issue a final rule requiring graphic health warnings for cigarettes by March 15, 2020, reducing by over a year FDA's proposed time line, which had a final rule being issued no sooner than May 2021

CTFK = Campaign for Tobacco-Free Kids; DC = District of Columbia; GWL = graphic warning label; FCLAA = Federal Cigarette Labeling and Advertising Act; FDA = US Food and Drug Administration; FTC = Federal Trade Commission; SGAC = Surgeon General's Advisory Committee.

### The Cigarette Industry Discusses HWLs

The Cigarette Labeling and Advertising Act of 1965 was the outcome of congressional hearings and debate that took place in 1964 and 1965.<sup>2</sup> In their public comments about HWLs cigarette companies opposed them claiming that it was unproven that smoking was dangerous to human health.<sup>3-5,39</sup> However, the minutes of meetings of industry executives immediately following the release of the 1964 report by the SGAC shows that company lawyers felt there might be a litigation benefit to having a HWL on cigarette packs.<sup>9,13</sup> Fred Haas, who in 1964 was general counsel for Liggett & Myers Tobacco Company and a member of the industry's special lawyers committee, wrote about a meeting of the Tobacco Institute Executive Committee held Sunday, January 12, 1964, 1 day after the release of report by the SGAC.<sup>9-11</sup> Mr Haas noted that those in attendance at the meeting felt it was of prime importance that all the companies maintain a united front when speaking to the public about the SGAC report.<sup>9</sup> He also noted agreement among industry executives that the special lawyer committee first clear any statements made about the SGAC report. In commenting upon the litigation implications of the SGAC report Mr Haas noted that the report had provided an explicit definition of cause in relationship to smoking and disease and that the industry could no longer put much stock in the semantics of "causative factors" in its future litigation defenses.<sup>9</sup> Mr Haas further suggested that smoker's assumption of risk appears to him to be the cigarette industry's best and only substantial legal defense, other than those of a technical nature.<sup>9</sup> The meeting minutes reflect that legislation concerning product labeling and advertising were likely to be forthcoming from the FTC and would be discussed at a later

meeting of the Tobacco Institute Executive Committee to be held January 17, 1964.<sup>9,12</sup>

In a follow-up memo discussing the January 17th Tobacco Institute Executive Committee meeting, the attendees were told that FTC would be issuing rules on product labeling shortly and that it was inevitable that HWLs would be required on cigarette packs.<sup>13</sup> The meeting minutes report that Morgan Cramer, president of P. Lorillard Tobacco Company, reminded those in attendance that that congressional action on product HWLs would be preferable if it "preempted the field and rendered unlikely the possibility of numerous state laws being enacted."<sup>13</sup> Preemption becomes a key industry strategy around HWLs and other tobacco control policies going forward. The meeting minutes goes on to indicate that the ad hoc committee was directed to prepare a form of bill for congressional action, which would preempt the field and preclude a caution in advertising copy.<sup>13</sup> It was mentioned that such a bill was already in the process of drafting and would be examined by various cigarette company executives.<sup>13</sup>

In a follow-up meeting of Industry's special lawyers committee held on January 20, 1964, Mr Haas reports that initial drafts of congressional bills prepared by the ad hoc committee are reviewed and discussed.<sup>13,14</sup> Mr Haas comments that management should be advised that even if there is a caution notice required on each cigarette package, the decision as to whether smokers had been adequately warned would still be a jury question.<sup>13</sup> However, he went on to say, that it was felt that the companies legal defense of assumption of risk as a result of the SGAC report would be enhanced by a HWL.<sup>13</sup>

Three days later on January 23, 1964, the special lawyer committee meets again in order to review the proposed FTC rules issued the day before.<sup>13-15</sup> The minutes from this meeting commented that the FTC proposed rule, which made reference to “mortality and death rates” was unfortunate and that every effort should be made to tone down the caution notices proposed.<sup>13</sup> Other arguments in opposition to the FTC proposed rules were also discussed including challenging the FTC’s jurisdiction to require HWLs on cigarette packaging and in advertising.<sup>13</sup>

### The Need for New HWLs

In its first report to US Congress on the effectiveness of the 1966 HWL and impact of cigarette advertising the FTC concluded the current pack warning was ineffective and needed to be strengthened to read: “Warning: Cigarette smoking is dangerous to health and may cause death from cancer and other diseases.”<sup>30</sup> On May 20, 1969, the FTC announced a proposed rule that would require all cigarette advertisements disclose clearly and prominently that cigarette smoking is dangerous to health and may cause death from cancer, coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases.<sup>31</sup> Before the rule could go into effect, Congress passed the Public Health Cigarette Labeling Act of 1969 which required a new HWL on cigarette containers (effective November 1, 1970): “Warning: The Surgeon General has determined that cigarette smoking is dangerous to your health.”<sup>2</sup> The attribution of the warning to the Surgeon General was important to the tobacco industry for two reasons. First, it allowed the cigarette companies to continue its public position that they do not accept the view that cigarettes are a proven hazard to health (rather, it is the Surgeon General’s position), even though company internal business records revealed that they knew and accepted the fact that smoking was a cause of cancer and other diseases.<sup>3-5,39-44</sup> Second, it further strengthened their argument made in litigation that smokers were being warned about the dangers of smoking (in this case by the Surgeon General), thereby releasing the companies from the obligation to inform consumers about the health risks associated with using their cigarettes.<sup>45</sup> Congress also extended and expanded the preemption barring the FTC or any other government agencies except for Congress to define the scope and location of HWLs on cigarette packaging. The new Act also banned advertising on television and radio effective January 2, 1972.<sup>2</sup> The FTC preemption on HWLs appearing in advertising was extended through June 1971.<sup>2-5</sup> In March 1972, after the congressionally mandated moratorium barring the FTC from issuing HWLs in cigarette advertising the FTC negotiated a consent decree with the cigarette industry to require the same HWL mandated by Congress on cigarette packs to be displayed in cigarette advertising.<sup>2</sup>

### Multiple Rotating HWLs

In 1981, FTC issued a comprehensive report on public understanding of the health risks of smoking and the adequacy of the HWL on cigarette packages and advertising.<sup>32</sup> Among its conclusions were that the public was not well informed about the specific risks of smoking, that the 1970 warning did not effectively communicate specific risks of smoking and that the public had been overexposed to the existing HWL. The report recommended a series of rotating HWLs that would be more prominently displayed using a circle and arrow format. Three years after the FTC report was issued and multiple congressional hearings, in October 1984, the Congress passed the Comprehensive Smoking Education Act of 1984, which mandated four rotating text-only HWLs but in the same style as

the previous HWL, again attributing the warning to the Surgeon General.<sup>2</sup> The 1984 Act also continued the preemption by other government entities (ie, state and local governments) from issuing different HWLs on cigarette packages or in advertising.<sup>2-5</sup> The law took effect October 12, 1985.

### The 2009 FSPTCA

The 2009 FSPTCA gave the FDA the authority to revise HWLs and required nine rotating text warnings. In addition, it also said FDA must issue regulations requiring graphics depicting the negative health consequences of smoking to accompany the text warnings within 24 months of passage of the act. The HWLs would be required to cover the top 50% of the front and back of the principal display areas of cigarette packs, and 20% of the area of advertisements.<sup>7</sup>

In June 2011, FDA unveiled nine graphic warnings, which the law specified must be placed on all cigarette packs and advertisements in the United States starting in September 2012.<sup>8</sup> However, the cigarette companies successfully challenged the specific proposed cigarette HWLs as a violation of their First Amendment rights. Following the August 2012 decision of the US Court of Appeals for the District of Columbia Circuit, which struck down the specific proposed warnings,<sup>33</sup> FDA said it would develop new proposed graphic HWLs that could survive constitutional challenge (a separate ruling on another tobacco industry challenge upheld the law’s underlying requirement for graphic warnings).<sup>34</sup> Years later, FDA still has not issued a new set of graphic HWLs, even though research shows them to be far more effective than text warnings alone. In October 2016, the Campaign for Tobacco-Free Kids and seven other health organizations filed suit to force the FDA to issue a final rule requiring graphic cigarette warnings, as required by the Tobacco Control Act.<sup>35</sup> On March 5, 2019, a federal court in Boston ruled that FDA must issue a final rule requiring graphic health warnings for cigarettes by March 15, 2020, reducing by over a year FDA’s proposed time line, which had a final rule being issued no sooner than May 2021.<sup>36</sup>

### Corrective Statements

In 1999, the US Department of Justice filed a lawsuit against the tobacco industry for violating the Racketeer Influenced and Corrupt Organizations (RICO) Act. The Department of Justice alleged that virtually all of the major domestic cigarette manufacturers had conspired to deceive the American public about the health risks of smoking in violation of the Federal RICO Act. In August 2006, US District Judge Gladys Kessler ruled in favor of the Department of Justice, concluding that the tobacco companies “conspired together to violate the substantive provisions of RICO . . . and . . . in fact violated those provisions of the statute.”<sup>16</sup> Judge Kessler ordered the Defendants to publish corrective statements in newspaper and television advertisements, on cigarette packaging, in retail displays, and on their corporate Web sites, to address and correct misperceptions on five topics: (1) the adverse health effects of smoking; (2) the addictiveness of smoking and nicotine; (3) the lack of any significant health benefit from smoking “low tar,” “light,” “ultra light,” “mild,” and “natural” cigarettes; (4) manipulation of cigarette design and composition to ensure optimum nicotine delivery; and (5) the adverse health effects of exposure to secondhand smoke.

After a decade of legal arguments about the language of the corrective statements, the court set forth the final language and implementing details on October 5, 2017.<sup>20</sup> The advertisements began to appear on television and in newspapers in November 2017. [Table 2](#) provides a chronology of the legal opinions that were issued relating to the corrective statements.

**Table 2.** Chronology of Legal Decisions Leading to the Final Language for the Corrective Statements

Date	Source	Findings
August 17, 2006	US Federal Court, District of Columbia <sup>16</sup>	Judge Kessler ordered the Defendants to publish corrective statements in newspapers, on television, on cigarette packaging, in retail displays, and on their corporate Web sites, to address and correct misperceptions on five topics <sup>1</sup> : the adverse health effects of smoking <sup>2</sup> ; the addictiveness of smoking and nicotine <sup>9</sup> ; the lack of any significant health benefit from smoking “low tar,” “light,” “ultra light,” “mild,” and “natural” cigarettes <sup>10</sup> ; manipulation of cigarette design and composition to ensure optimum nicotine delivery; and <sup>11</sup> the adverse health effects of exposure to secondhand smoke. The court requires the parties in the case to submit suggested language for the statements. The original order for corrective statement is put on hold while the case is appealed
November 27, 2012	US Federal Court, District of Columbia <sup>17</sup>	Judge Kessler issues order with the specific text of the corrective statements. The cigarette companies appeal to change the language of the statements
May 22, 2015	US Court of Appeals, District of Columbia Circuit <sup>18</sup>	The court issues a ruling upholding most of Judge Kessler’s order implementing the corrective statements. But the court rejected a preamble sentence that a federal court had ruled the tobacco companies “deliberately deceived the American public,” ruling it was not permissible under the scope of the RICO law
April 25, 2017	US Court of Appeals, District of Columbia Circuit <sup>19</sup>	The court issues a ruling on another appeal of the corrective statements language by the tobacco companies, again upholding most of the language but deleting use of the phrase “Here is the truth,” to which the tobacco companies had objected
October 5, 2017	US Court of Appeals, District of Columbia Circuit <sup>20</sup>	Judge Friedman signs consent order containing implementation details for making the corrective statements through court-ordered television and newspaper advertisements, and on tobacco company Web sites and cigarette packs. The deadline for tobacco companies to begin running corrective statements on their Web sites is June 18, 2018. The deadline for tobacco companies to begin running corrective statements on cigarette packs is November 21, 2018
December 21, 2017	Circuit Court for the 17th Judicial Circuit, in and for Broward County, Florida <sup>46</sup>	Philip Morris USA denies the request to stipulate to the truth of the following two corrective statements: 1. Philip Morris USA intentionally designed cigarettes to make them more addictive 2. Philip Morris USA intentionally designed cigarettes with enough nicotine to create and sustain addiction
	Circuit Court for the 17th Judicial Circuit, in and for Broward County, Florida <sup>6</sup>	R.J. Reynolds Tobacco Company denies the request to stipulate to the truth of the following two statements: 3. R.J. Reynolds Tobacco intentionally designed cigarettes to make them more addictive 4. R.J. Reynolds Tobacco intentionally designed cigarettes with enough nicotine to create and sustain addiction

RICO = Racketeer Influenced and Corrupt Organizations.

What is evident from this chronology is how the language in the corrective statements changed from the time Judge Kessler first ordered the specific language of the statements to the final language of the statements. One of the main changes in language had to do with the preamble of the statements. Originally Judge Kessler had suggested language that would say the Defendants “deliberately deceived the American public . . . e.g., by falsely selling and advertising low tar and light cigarettes as less harmful than regular cigarettes, . . . and has ordered those companies to make this statement. Here is the truth.”<sup>17</sup> However, in 2015 the US Court of Appeals for the District of Columbia Circuit ruled that this language was not permissible under the scope of the RICO law.<sup>18</sup> The final preamble language issued in October 2017 says “A Federal Court has ordered Altria, R.J. Reynolds Tobacco, Lorillard, and Philip Morris USA to make this statement about . . . e.g. the health effects of smoking.”<sup>19</sup> Again, much like the HWLs on cigarettes the final language of the preamble gives the cigarette companies the ability to deny their acceptance of the truth of the statements. The other significant change resulting from the cigarette companies’ legal appeals was in the introduction to the light and low tar statement, which changed from “. . . deliberately deceived the American public by falsely selling and advertising low tar and light cigarettes as less harmful than regular cigarettes”

in the original language, “. . . make this statement about low tar and light cigarettes being as harmful as regular cigarettes” in the final version. Again, the changed language in the corrective statement has allowed the cigarette companies to deny that they are responsible for deliberately misleading consumers about the marketing of their low tar and light cigarettes.<sup>19</sup> In a December 2017 court case in Florida, both Philip Morris and R.J. Reynolds refused to stipulate to the truth of the corrective statements ordered by the Federal Court.<sup>6,46</sup>

## Discussion

Previously secret internal cigarette industry business records reveal that in 1964 when cigarette companies were publically refuting the need for HWLs on cigarettes internally they were discussing how HWLs would be helpful to them in future litigation by shifting responsibility for the harms caused by cigarettes from themselves to smokers. Within days after the SGAC issued its 1964 Report, the cigarette companies were plotting together how they could use HWLs on cigarettes as a defense in future litigation. Industry lawyers discussed drafting legislation that would preempt the US FTC proposed rule that would have required HWLs in cigarette advertising and on cigarette containers telling smokers that cigarettes may cause cancer

and premature death. In July 1965, Congress did pass legislation which mandated a single watered-down cigarette pack HWL which excluded cigarette advertising, just as industry lawyers had recommended. Although ultimately Congress must take final responsibility for the original cigarette HWL, it appears the cigarette companies had a role in shaping and perhaps even drafting the final bill that was passed because the legislation included virtually everything the cigarette industry lawyers had originally decided should be part of any congressional action taken. A North Carolina Congressman Horace Kornegay (D-NC) was a key figure in negotiating the 1965 Federal Cigarette Labeling and Advertising Act, and in 1970 he became the president and chairman of the cigarette-industry-funded Tobacco Institute.

The US Congress continued to exert its control over the HWLs over the next several decades. When the FTC again made an effort to strengthen the specificity of HWLs on cigarettes in the late 1960s and again in the early 1980s Congress interceded by preempting FTC's authority and blocking other government entities (ie, state and local governments) from also doing so.<sup>2</sup> Although government and even industry sponsored surveys to document the fact that many millions of smokers were not adequately informed about the serious health risks that smoking posed to their health, industry lawyers used the congressionally mandated HWLs to argue that smokers had been adequately warned about the dangers of smoking and thus assumed all responsibility for any injuries resulting from their smoking.<sup>30,32,45</sup>

The more recent history surrounding HWLs as mandated in the 2009 FSPTCA and the language in the court-ordered corrective statements shows again how cigarettes companies continue to work to deflect responsibility for their failure to tell the truth about their products to their customers.<sup>6,46</sup> By almost any credible standard, cigarettes as currently designed are a defective product as current estimates indicated that half of long-term smokers die prematurely because of their use of cigarettes.<sup>47</sup> Importantly, people's persistence in smoking day in and day out is because of nicotine addiction.<sup>47,48</sup>

Although this study has helped to shed light on the origins of the original HWL and how industry has used HWLs to their benefit in litigation, our analysis of internal industry records as related the HWLs and litigation efforts is by no means comprehensive. More comprehensive reviews of internal industry documents and litigation strategies used by the cigarette industry can be found elsewhere.<sup>3-5,39</sup> However, we felt it was valuable nonetheless to focus attention on the high-level industry discussions that took place in the immediate days and weeks following the release of the 1964 SGAC where the cigarette company lawyers previewed what became their main litigation defense going forward which has attempted to shift blame from themselves to consumers under the theory that the consumers themselves knew and voluntarily assumed the health risks. Future studies might consider examining in greater detail public comments received about warning labels which could provide insights about how the cigarette industry framed its arguments to manipulate warning label language in legislation passed by Congress. Analyses of legal defenses by the industry might also be informative to see how industry actually implements its assumption of risk defense strategy through questioning of witnesses and in opening and closing statements in jury trials. Finally, it might also be informative to evaluate how perceptions about the benefits of HWLs on cigarette packaging and advertising might change after people are informed about the industry's efforts to manipulate the language of HWLs to defend themselves in litigation.

Ironically the very HWLs that the cigarette companies publicly opposed for decades have served as their primary line of defense in litigation where lawyers representing tobacco companies argue that cigarette companies have no responsibility for the harms caused to smokers because a warning is printed on the side of every cigarette package.<sup>45</sup> This line of defense is used despite the fact that research conducted by cigarette manufacturers reveals that most smokers do not notice the warnings placed in advertising.<sup>49</sup> In tobacco litigation, juries should be informed about the industry's coordinated effort to draft legislation and water down the original caution statements proposed on cigarette containers and in advertising even though Congress ultimately is responsible for the law that was enacted. In addition, even though the 1992 Supreme Court decision in the Cipollone case preempted post-1969 failure to warn claims against cigarette makers, this protection does not apply on pre-1969 warning claims where the evidence shows that cigarette companies understood they were selling a defective product that when used as intended would harm their customers.<sup>50</sup> Thus, those initiating smoking before 1969 and subsequently harmed by cigarettes can hold cigarette makers responsible for their failure to warn them about health risks.

## Funding

This work was carried out with funding from the National Institutes of Health (P30 CA138313).

## Declaration of Interests

*KMC provides expert testimony on the health effects of smoking and tobacco industry tactics in lawsuits filed against the tobacco industry. JG is an attorney who has represented plaintiffs in litigation filed against tobacco companies.*

## References

1. US Department of Health Education and Welfare. *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*. Washington, DC: U.S. Department of Health, Education, and Welfare, Public Health Service, Publication No. 1103; 1964.
2. US Department of Health and Human Services. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health; 1989.
3. Kluger R. *Ashes to Ashes. America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris*. New York, NY: Alfred A. Knopf, Inc; 1996.
4. Brandt A. *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America*. New York, NY: Basic Books; 2007.
5. Proctor RN. *Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition*. Berkeley, CA: University of California Press; 2011.
6. *Defendant R.J. Reynolds Tobacco Company's amended responses to plaintiff's first request for admission to defendant R.J. Reynolds Tobacco Company, In Re: Engle Progeny cases tobacco litigation pertaining to: Paige Monterrosa as personal representative of the estate of Polly Dawes*, 2007-CV-36725, Circuit Court for the 17th judicial circuit, Broward County Florida, December 21, 2017.
7. Family Smoking Prevention and Tobacco Control Act, Public Law No. 111-31. 2009. <https://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>. Accessed June 3, 2019.
8. FDA, Required Warnings for Cigarette Packages and Advertisements; Final Rule, 76 Fed. Reg. at 36628, June 22, 2011. <https://www.govinfo.gov/content/pkg/FR-2011-06-22/pdf/2011-15337.pdf>. Accessed June 3, 2019.

9. Haas FP. Memo from FPH to Toms regarding meeting of the Tobacco Institute Executive Committee. January 13, 1964. Bates Number: lg2008203-lg2008210. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/yqnf0028>. Accessed June 3, 2019.
10. Unknown. Attendance List Executive Committee Meeting of January 12, 1964. January 12, 1964. Liggett & Myers Records. Bates Number: lg0245511-lg0245512. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/ksyf0009>. Accessed June 3, 2019.
11. Temko SL. Minutes of the twenty-first meeting of the Executive Committee. January 12, 1964. Bates Number: 2025026198-2025026200. <https://www.industrydocuments.ucsf.edu/docs/#id=jxjf0114>. Accessed June 3, 2019.
12. Thompson JW. Draft of Voluntary Advertising Restrictions for Consideration by Cigarette Advertisers. January 14, 1964. Bates Number: RC-6007692-RC-6007698. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/rllb0040>. Accessed June 3, 2019.
13. Haas FP. Memo from FPH prepared at the request of Mr. Toms, summarizing meetings held on January 17, 1964, January 20, 1964 and January 23, 1964. Bates Numbers: lg20081157 to lg2008164. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/hklj0191>. Accessed June 3, 2019.
14. Unknown. Lawyers Committee. January 20, 1964. Bates Number: 500177572. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/pmdc0102>. Accessed June 3, 2019.
15. Tobacco Institute Memo to members of the Board of Directors, Legal Committee, and Public Relations Committee. June 23, 1964. Bates Number: TI08251933-1934. <https://www.industrydocuments.ucsf.edu/docs/#id=kkcj0043>. Accessed June 3, 2019.
16. Kessler G. *United States of America v Phillip Morris Inc., et al*. Civil Action No. 99-2496 (GK) amended final opinion, August 17, 2006. <http://www.publichealthlawcenter.org/sites/default/files/resources/doj-final-opinion.pdf>. Accessed June 3, 2019.
17. Kessler G. *United States District Court for the District of Columbia*. United States of American v. Philip Morris, USA, et al. Order #34-Remand. Case 1:99-cv-02496-GK Document 5991 Filed November, 27, 2012.
18. *United States Court of Appeals for the District of Columbia Circuit*. United States of American v. Philip Morris, USA, et al. Case. No. 1:99-cv-02496. No. 13-5028. May 22, 2015.
19. *United States Court of Appeals for the District of Columbia Circuit*. United States of American v. Philip Morris, USA, et al. Case. No. 1:99-cv-02496. No. 16-5101. April 25, 2017.
20. Friedman PL. *United States District Court for the District of Columbia*. United States of American v. Philip Morris, USA, et al. Order #72-Remand. Second superseding consent order implementing the corrective statements remedy for newspapers and television. Case 1:99-cv-02496-GK Document 5991 Filed October 5, 2017.
21. Federal Trade Commission. Report, "Trade Regulation Rule for the Prevention of Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking and Accompanying Statement of Basis and Purpose of Rule" Federal Trade Commission, June 22, 1964. 1964. Bates Number: JD 061508. <https://www.industrydocuments.ucsf.edu/docs/#id=pflk0154>. Accessed June 3, 2019.
22. Toth RC. *Health Hazard label on cigarettes backed*. Washington Post. June 21, 1964. Bates Number: 503401867. <https://www.industrydocuments.ucsf.edu/docs/#id=nsfl0103>. Accessed June 3, 2019. Unknown. The Tobacco Institute, Inc. 1964 June 23. Bates Number: TI08251933-TI08251935. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/kkcj0043>. Accessed June 3, 2019.
23. Foley TJ. *Cigarette Makers Asked to Draft Own Warnings*. Los Angeles Times. December 09, 1964. Bates Number: 501934071. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/qyll0023>. Accessed June 3, 2019.
24. Freeman WM. *Cigarette Ad Code Takes Effect*. New York Times. December 17, 1964. Bates Number: 1005040171. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/zvnx0124>. Accessed June 3, 2019.
25. Salt Lake City Tribune. *Cigarettes Still Kill (1965, July 1) and Harford Courant. The Cigarette Warning protects the Companies (1965, August 2)*. Bates Number: 501935221. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/kppl0005>. Accessed June 3, 2019.
26. Hill & Knowlton. Tobacco News Summary No. 66. July 1, 1965. Bates Number: 2016000939. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/jzkd0123>. Accessed June 3, 2019.
27. US House of Representatives. Federal Cigarette Labeling and Advertising Acts. July 1, 1965. Bates Number: TIMN0073386-TIMN0073392. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/ghkp0146>. Accessed June 3, 2019.
28. Congressional Record. Congressional Record-House. July 1, 1965. Bates Number: 1005036632-1005036633. <https://www.industrydocuments.ucsf.edu/docs/#id=zhwn0124>. Accessed June 3, 2019.
29. Federal Trade Commission. Vacation of warning requirement in Trade Regulation Rule Concerning Advertising and labeling of Cigarettes. July 1965. Bates Number: 92452430-92452431. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/rppp0073>. Accessed June 3, 2019.
30. *Federal Trade Commission Report to Congress Pursuant to the Federal Cigarette Labeling and Advertising Act*. Federal Trade Commission, June 30, 1967.
31. Federal Trade Commission. *Cigarettes in relation to the health hazards of smoking: Unfair or deceptive advertising and labeling*. Federal Register 34:7917-7918, May 20, 1969a.
32. *Federal Trade Commission Staff Report on the Cigarette Advertising Investigation*. Federal Trade Commission. May 1981b.
33. *R.J. Reynolds Tobacco Co. v United States Food & Drug Administration*, 696 F.3d 1205 (DC Cir 2012). <https://www.publichealthlawcenter.org/content/rj-reynolds-tobacco-co-v-us-food-drug-administration>. Accessed June 3, 2019.
34. Holder E Jr. *Letter to the Honorable John Boehner*, Re: R.J. Reynolds v. Food & Drug Administration, No. 11-5332 (DC Cir), March 15, 2013. <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/Ltr%20to%20Speaker%20re%20Reynolds%20v%20FDA.PDF>. Accessed June 3, 2019.
35. *American Academy of Pediatrics v U.S. Food & Drug Administration*, No. 16-11985 (US District Court for the District of Massachusetts 2016). [https://www.tobaccofreekids.org/assets/content/press\\_of\\_fice/2016/2016\\_10\\_04\\_fda\\_complaint.pdf](https://www.tobaccofreekids.org/assets/content/press_of_fice/2016/2016_10_04_fda_complaint.pdf). Accessed June 3, 2019.
36. American Academy of Pediatrics v U.S. Food & Drug Administration, Case:1:16-cv-11985-IT, United States District Court for the District of Massachusetts. Memorandum and order grant injunctive relief, March 5, 2019. [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/legal/2019\\_03\\_05\\_memo\\_injunctive\\_relief\\_re\\_FDA\\_Schedule.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/legal/2019_03_05_memo_injunctive_relief_re_FDA_Schedule.pdf). Accessed June 3, 2019.
37. US Department Of Health, Education, and Welfare. *Letter from Oren Harris, Chairman, Committee on Interstate and Foreign Commerce, House of Representatives*. June 22, 1964. Bates Number: 968146815-968146826. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/sgmj0017>. Accessed June 3, 2019.
38. Federal Trade Commission. Unfair or deceptive advertising and labeling of cigarettes in relation to the health hazards of smoking. Federal Register. 29:8324-8375, July 2, 1964b.
39. Cummings KM, Brown A, O'Connor R. The cigarette controversy. *Cancer Epidemiol Biomarkers Prev*. 2007;16(6):1070-1076.
40. Teague C. *Survey of Cancer Research*. R.J. Reynolds Tobacco Company, 2 February, 1953. Bates Number: 501932947-501932968. <https://www.industrydocuments.ucsf.edu/docs/lphb0086>. Accessed June 3, 2019.
41. Bentley HR, Felton DGI. Reid WW Report on Visit to U.S.A. and Canada. "Smoking and Health Research in U.S.A." British American Tobacco Company, 12 May, 1958. Bates Number: 105408490-105408499. <https://www.industrydocuments.ucsf.edu/docs/ksfd0040>. Accessed June 3, 2019.
42. Arthur D, Little Inc.; "L & M—a perspective review." 15 March, 1961. Bates Number: TINY0003153-TINY0003156. <https://www.industrydocuments.ucsf.edu/docs/ytlb0135>. Accessed June 3, 2019.
43. Wakeham H. Tobacco and Health R&D Approach, Presentation to R&D Committee by Dr. H. Wakeham, a meeting held in New York Office on November 15, 1961. 15 November, 1961. Bates Number: 2024947172-2024947196. <https://www.industrydocuments.ucsf.edu/docs/sjgx0106>. Accessed June 3, 2019.

44. Rodgman A. Chemical Research. "The smoking and health problem—a critical and objective appraisal." [undated] 1962. Bates Number: 504822823-504822846. <https://www.industrydocuments.ucsf.edu/docs/rmpp0092>. Accessed June 3, 2019.
45. Cummings KM, Brown A, Douglas CE. Consumer acceptable risk: how cigarette companies have responded to accusations that their products are defective. *Tob Control*. 2006;15(suppl 4):iv84–iv89.
46. *Phillip Morris USA, Inc.'s amended response to plaintiff's first request for admission to defendant Phillip Morris USA Inc., In Re: Engle Progeny cases tobacco litigation pertaining to: Paige Monterrosa as personal representative of the estate of Polly Dawes*, 2007-CV-36725, Circuit Court for the 17th judicial circuit, Broward County Florida, December 21, 2017.
47. US Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: 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.
48. US Department of Health and Human Services. *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*. Atlanta, GA: 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; 2010.
49. Lorio GB. Final Report. TelCom (eye camera) Savor and Niagara ad test Project #77–257. Brown & Williams Tobacco Company, March 31, 1978. Bates Number: 689011525-689011553. <https://www.industrydocuments.ucsf.edu/docs/gzyw0138>. Accessed June 3, 2019.
50. US Supreme Court. *Cipollone v Liggett Group Inc., et al.* No. 90–1038, argued October 8, 1991 and reargued January 13, 1992, and decided June 24, 1992 June 24. <https://supreme.justia.com/cases/federal/us/505/504/case.pdf>. Accessed June 3, 2019.