Short Communications

Editorial Process: Submission:12/10/2024 Acceptance:06/05/2025

Legal Principles and Causal Inference Issues in Tobacco Litigation: Lessons from Korea

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Abstract

This study examines the legal principles and causal inference challenges in tobacco litigation, with a focus on the South Korean context. Drawing on qualitative legal analysis and an epidemiological framework, it reviews landmark judicial decisions involving both individual plaintiffs and the National Health Insurance Service (NHIS) in lawsuits against major tobacco companies. The methodology includes a comprehensive doctrinal analysis of court rulings, evidentiary standards, and legal reasoning related to causality, alongside a comparative review of international case law. The study also incorporates epidemiological criteria and metrics such as relative risk, attributable fraction, and probability of causation to evaluate how scientific evidence has been presented and interpreted in legal proceedings. By interrogating the intersection of law and public health science, the paper highlights how the legal distinction between specific and non-specific diseases complicates the judicial recognition of causality in tobacco-related cases. It further draws parallels with environmental litigation to argue for a reduced burden of proof in tobacco lawsuits, advocating for greater evidentiary weight to be given to epidemiological findings. Through cross-national comparisons, the study calls for legal reforms that more closely reflect public health imperatives, ultimately promoting fairness, accountability, and stronger tobacco control.

Keywords: Occupational Disease, Cancer, Burden of Proof, South Korea

Asian Pac J Cancer Prev, **26 (6)**, 1881-1890

Introduction

In trials concerning liability for damages, it is crucial to establish facts that can be substantiated by scientific evidence. Courts often require proof of specific and individual causal relationships, rather than general correlations, and tend to recognize such causal relationships in a limited context. For example, despite epidemiological research indicating that smoking is a primary risk factor for lung cancer, domestic courts have often dismissed these findings due to counterarguments from cigarette manufacturers asserting that smoking is not the sole cause of carcinogenesis. The failure to acknowledge a causal relationship between smoking and lung cancer in tobacco litigation not only absolves tobacco manufacturers from liability but also raises questions about the validity of smoking cessation as a cancer prevention strategy. Thus, elucidating and affirming the causal link between smoking and lung cancer remains a critical endeavor for both epidemiology and health law. This study explores the legal issues that have emerged in Korean tobacco litigation from a public health perspective. In environmental litigation, legal doctrines have been developed to ease the burden of proving causality when plaintiffs claim health damages due to a company's emission of hazardous substances. Whether such doctrines, established in other areas of litigation, can be applied to tobacco litigation requires careful consideration of the structural characteristics unique to tobacco cases. To hold tobacco manufacturers liable for damages caused by lung cancer, it is essential to understand the dual structure of tobacco litigation. This is because the mere fact of cigarette manufacture does not automatically result in liability for lung cancer. Drawing a parallel to the automotive industry, manufacturers are not held liable for damages from accidents involving their vehicles unless specific circumstances apply. Similarly, tobacco litigation fundamentally revolves around two distinct issues: the causal relationship between smoking and lung cancer, and the attribution of liability for lung cancer to tobacco manufacturers [1].

The first tobacco lawsuit in Korea was initiated on September 6, 1999, by a group of five plaintiffs, including a terminal lung cancer patient with a 36-year history of smoking and his family, who filed a suit against the state and the Korea Tobacco & Ginseng Corporation (now KT&G). Shortly thereafter, on December 13, 1999, an additional lawsuit for damages was filed by 31 individuals, including six lung cancer patients, against the same defendants. During these proceedings, the Korea Anti-Smoking Campaign Council filed a lawsuit in August

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2002 demanding the disclosure of information from the Korea Tobacco & Ginseng Corporation. The court ruled in favor of the plaintiffs, granting direct access to 259 internal documents held at the Korea Ginseng & Tobacco Research Institute's Central Research Institute. This disclosure revealed internal and international research documenting the harmfulness, carcinogenicity, and addictive nature of tobacco. In June 2005, after mediation efforts failed, the plaintiffs lost both lawsuits. They appealed, leading to an on-site inspection of the KT&G cigarette manufacturing plant by the Seoul High Court on October 30, 2009. Although the case was referred to mediation on June 15, 2010, with the intention of establishing a public interest foundation for smoking cessation, the mediation was ultimately unsuccessful, and the appellate court dismissed the appeal on September 28, 2010. The Supreme Court delivered a final judgment in favor of the individual tobacco lawsuit on April 10, 2010. Following this, the National Health Insurance Service filed a damages suit amounting to 55.5 billion won against KT&G, Philip Morris International (PMI) Korea, and British American Tobacco (BAT) Korea in the Seoul Central District Court.

The National Health Insurance Service (NHIS) first considered pursuing a tobacco lawsuit in August 2013. During the "Health Insurance Policy Seminar," the NHIS indicated its intention to file a lawsuit to demonstrate the health damages caused by smoking, supported by examination and treatment data spanning 19 years. Subsequently, on April 14, 2014, the NHIS filed a damages lawsuit amounting to 53.3 billion won against the three leading tobacco companies in the domestic market. The lawsuit was grounded in comprehensive examination data from patients with lung cancer (specifically small cell lung cancer and squamous cell carcinoma) and laryngeal cancer (squamous cell carcinoma), conditions with a strong causal link to smoking, as well as data from the Korean Cancer Prevention Study cohort. The claim included 53.3 billion won in medical expenses that the NHIS had paid over a decade for patients with a smoking history exceeding 30 years and over 20 pack-years (equivalent to smoking one pack per day for 20 years). The primary motivation for the NHIS to initiate this legal action was its mandate to manage national health insurance, conduct health checkups, prevent diseases, and cover medical expenses. The NHIS argued it has a responsibility to prevent smoking-related health issues and curb financial losses. As of 2011, it was estimated that an additional 1.7 trillion won was being spent annually due to smoking-related health costs, a figure projected to rise, prompting the NHIS to act against this escalating financial burden. Over the past decade, total medical expenses attributable to smoking have more than doubled, reaching approximately KRW 3.5 trillion by 2021. While smokers contribute a national health promotion fee of KRW 841 per pack of cigarettes purchased, the financial burden of smoking-related health costs is also shared by non-smokers as health insurance subscribers. In contrast, tobacco companies, which both contribute to and benefit from these health outcomes, currently bear no financial responsibility. Addressing this imbalance is essential for achieving fairness and social justice. Furthermore, smoking poses significant health risks to the population, with particular concern for women, where smoking can lead to birth defects and brain cell damage, thereby threatening the nation's future and the sustainability of its health insurance system.

The first trial of the tobacco lawsuit involved 15 sessions, beginning with the initial oral argument on September 12, 2014. The court structured the proceedings around five key issues: first, whether the National Health Insurance Service (NHIS) had the legal standing to directly claim damages; second, the causal relationship between smoking and lung cancer; third, the product liability of the tobacco companies; fourth, the tort liability of these companies; and fifth, the extent of NHIS's damages. The primary issue, the causal link between smoking and lung cancer, was debated across five sessions. Although the lawsuit focused on cancer types (specifically squamous cell carcinoma and small cell carcinoma in lung cancers, and squamous cell carcinoma in laryngeal cancers) where causality had been previously recognized, the court did not acknowledge individual cases, leading to significant dissatisfaction. Despite NHIS presenting extensive evidence, including expert testimonies and medical records for each case, the court ruled on November 20, 2020, dismissing all of NHIS's claims and issuing a verdict in favor of the tobacco companies. The court neither recognized the responsibility of the tobacco companies for the harmful effects of smoking nor accepted the established causal relationship between smoking and the development of lung cancer. In response, NHIS promptly decided to appeal. Following the appeal on December 10, 2020, seven oral arguments were conducted, and the ongoing legal proceedings are focused on determining the admissibility of evidence to establish the tobacco companies' product liability and general tort claims. NHIS maintained that the causal relationship between smoking and lung cancer is a fact substantiated by scientific research. However, the court ruled in favor of the tobacco companies, concluding that other potential causes could not be excluded as contributing factors to the disease. The court asserted, "Even if an epidemiological causal relationship between smoking, a known risk factor, and the disease can be acknowledged based on various research findings, it is challenging to establish causality merely because the subjects smoked and developed the disease." This decision also referenced the Supreme Court's precedent, set on April 10, 2014, which upheld the dismissal of two lawsuits brought by 30 individual smokers and their families against the tobacco manufacturer KT&G and the state. This was the Supreme Court's first ruling on a tobacco-related case. The ruling stipulated that to establish a causal relationship between smoking and a disease, it must be demonstrated that other risk factors—such as the duration and extent of exposure to smoking, the timing of disease onset, pre-smoking health conditions, lifestyle habits, changes in disease status, and family history—are unlikely to have contributed.

This study investigates the legal and epidemiological challenges of proving causation in tobacco litigation, focusing on South Korea. Through doctrinal analysis and cross-national comparison, it examines major court rulings involving individual plaintiffs and the NHIS,

highlighting how evidentiary standards and the legal classification of diseases affect judicial reasoning. By integrating epidemiological metrics such as relative risk and probability of causation, the paper argues for legal reforms that strengthen the role of scientific evidence and promote fairer outcomes in tobacco-related cases.

Korean Tobacco Lawsuits

Unlike in many developed countries, individual tobacco lawsuits in South Korea did not commence until 1999. These lawsuits were initiated by smokers and their families seeking damages from the South Korean government and KT&G, citing the addictive nature of nicotine, manufacturing and design defects in cigarettes, labeling deficiencies, and other illegal practices. The plaintiffs also argued for a causal relationship between smoking and lung cancer. However, all four cases resulted in unfavorable verdicts for the plaintiffs. Following the Supreme Court's decision in case No. 2011Da22092, which addressed the appeal in these individual tobacco lawsuits, the NHIS promptly filed a separate lawsuit against KT&G, PMI Korea, and BAT Korea. This action attracted significant public attention. Despite this, the trial court ruled in favor of NHIS, and the case is currently under appeal.

1) Private Tobacco Lawsuits Filed by Smokers and Their Families[1] [2]

(1) First trial[2]

In an individual tobacco lawsuit, the court of first instance ruled that establishing a causal relationship between smoking and the development of lung cancer requires two specific causal links: first, a link between the tobacco companies' cigarette manufacturing and sales activities and the act of smoking; and second, a link between smoking and the onset of diseases such as lung cancer. However, the court did not recognize the first causal link, as it found that smokers' actions were not entirely devoid of free will. The second causal link was also not recognized because, even if an epidemiological association between smoking and the development of lung cancer a non-specific disease could be established, proving that an individual's smoking directly caused their lung cancer remains challenging. Consequently, the court denied the individual causal relationship as well. Furthermore, the first trial concluded that it is particularly difficult, if not impossible, for individual plaintiffs in tobacco lawsuits to scientifically prove a direct causal link between their smoking and the development of lung cancer. Conversely, the court noted that tobacco companies face similar challenges in investigating the causes of the plaintiffs' lung cancer and do not have a societal obligation to disprove a causal link between smoking and the plaintiffs' lung cancer. Therefore, the court determined that the legal principle of easing the burden of proof for causality, as applied in public nuisance lawsuits, could not be directly applied to tobacco litigation. In conclusion, the court ruled that plaintiffs must directly prove the individual causal relationship between smoking and lung cancer in accordance with the general principle of the burden of proof. While epidemiological research can demonstrate a statistical relationship and epidemiological causality between smoking and disease development, it cannot establish a legal causal link for disease development in individual plaintiffs.

The court of first instance outlined eight criteria for establishing an epidemiological causal relationship: (1) temporal relationship—smoking precedes the onset of lung and laryngeal cancers; (2) biological relationship—animal studies demonstrate that cigarette smoke induces cancer in the respiratory tract; (3) consistency—case-control studies consistently report a link between smoking and lung cancer; (4) strength—cohort studies indicate that the mortality risk for smokers is approximately ten times higher than that for non-smokers; (5) dose-response relationship—the incidence and mortality rates of lung cancer increase with the quantity of smoking and the age at which smoking begins; (6) specificity—the association between smoking and other cancer types is significantly weaker; (7) reversibility—the incidence or mortality rates of lung and laryngeal cancers are significantly lower among those who quit smoking compared to those who continue; (8) coherence—higher lung cancer mortality rates correspond with higher smoking rates in men and in populations with elevated lung cancer mortality rates, showing a temporal pattern of increasing lung cancer mortality that aligns with rising smoking rates, consistent with established scientific knowledge on lung cancer. Based on these criteria, the court concluded that an epidemiological causal relationship between smoking and the occurrence of lung cancer could be acknowledged. However, the court also noted that an epidemiological causal relationship represents a statistical association between a specific factor and a disease within a population, assuming all other factors are constant. Therefore, it is challenging to directly apply this to an individual causal relationship that identifies the specific cause of a disease in an individual. The court emphasized that non-specific diseases like lung cancer result from complex interactions among multiple factors, can be attributed to causes other than smoking, and may also occur in non-smokers. Consequently, the court determined that it is difficult to directly translate an epidemiological causal relationship into an individual causal relationship.

(2) Second trial[3] [3]

The appellate court, similar to the court of first instance, dismissed the plaintiffs' claims regarding

[1]Seoul Central District Court Decision 99GaHap104973, dated January 25, 2007; Seoul High Court Decision 2007Na18883, dated February 15, 2011; Supreme Court Decision 2011Da22092, dated April 10, 2014
[2]Seoul Central District Court Decision 99GaHap104973, dated January 25, 2007
[3]Seoul High Court Decision 2007Na18883, dated February 15, 2011

defects under the Product Liability Act and allegations of intentional negligence. However, it diverged slightly from the first instance court concerning the burden of proof for causality. Before determining whether the tobacco companies' actions were unlawful or whether a causal relationship existed between these actions and the onset of lung cancer, the appellate court first considered a foundational question: whether the lung cancer developed by the smokers in this case could be attributed to smoking. The court noted that the act of manufacturing cigarettes itself is not easily construed as an act of delivering harmful substances. Unlike pollution cases, where harmful substances (such as carcinogens) are directly imposed on victims, in tobacco cases, the delivery of such substances is mediated by the victims' own actions specifically, their purchase and consumption of cigarettes. Acknowledging the differences between tobacco and pollution cases, the appellate court also recognized certain similarities and determined that the legal principle of reducing the burden of proof in pollution lawsuits could be similarly applied to establishing causality between smoking and the onset of lung cancer in tobacco cases. The rationale for easing the burden of proof in pollution lawsuits is primarily because it is often difficult or impossible to scientifically establish a direct causal link between the harmful act and the resulting damage in such cases. Additionally, companies responsible for pollution typically have greater access to the resources needed to investigate causality than the victims, both technologically and economically, and they also bear a social responsibility to demonstrate that the substances they release are not harmful. Consequently, the appellate court argued that even if the standards for establishing causality in tobacco lawsuits do not align fully with the probabilistic framework applied in pollution cases, the burden of proof should still be relaxed, differing from the court of first instance's ruling that the doctrine of easing the burden of proof for causality in pollution lawsuits could not be directly applied to tobacco litigation.

As in the first trial, the appellate court acknowledged an epidemiological causal relationship between smoking and the development of lung cancer. However, it also noted that lung cancer, like other cancers, is a non-specific disease that can result from complex interactions among various factors. Consequently, the presence of a single factor, such as smoking, does not preclude the possibility that other factors could have contributed to the disease. Therefore, even if an epidemiological causal relationship between smoking and lung cancer is recognized, applying this relationship directly to individual cases remains challenging. Ultimately, the court considered the specific cancer types, smoking histories, and lifestyle habits of the plaintiffs. It recognized a causal relationship between smoking and lung cancer for plaintiffs who had smoked for over 30 years and developed small cell lung cancer or squamous cell lung cancer, both of which are strongly associated with smoking. In contrast, for plaintiffs diagnosed with non-small cell lung cancer or alveolar lung cancer—types more likely to have been caused by factors other than smoking—the court denied the causal link to smoking, despite the plaintiffs' extensive smoking histories.

(3) Third trial[4] [4]

The Supreme Court ruled that lung cancer is not a specific disease caused solely by smoking, but a non-specific disease that can be caused by a complex interaction of external environmental factors such as physical, biological, and chemical factors and internal factors of the body. Therefore, it must be proven that there is a possibility that the non-specific disease was caused by the risk factor, by additionally proving the individual's health condition, lifestyle, changes in disease condition, family history, etc. before being exposed to the risk factor. This decision once again confirmed the legal principle of causality judgment that distinguishes between specific and non-specific diseases, as ruled in the Agent Orange lawsuit[5]. In conclusion, the Supreme Court agreed with the lower court's decision that there was no causal relationship between smoking and the onset of the disease.

2) Tobacco Lawsuit Filed by NHIS[6] [5]

Based on the judgment in the appeal of the individual tobacco lawsuit discussed above that among the diseases that the plaintiffs suffered from, small cell lung cancer, squamous cell lung cancer, and laryngeal cancer, squamous cell lung cancer could be presumed to have an epidemiological causal relationship with smoking, NHIS selected only those diagnosed with the above diseases and filed a lawsuit in 2014. NHIS spent a total of approximately KRW 53.3 billion in the name of benefits (NHIS burden) from around 2003 to around 2012, which constitutes damages caused by the tobacco companies' torts or general torts under the Product Liability Act, and therefore argued that the tobacco companies should compensate for such damages, while also claiming compensation for tort damages and, as a preliminary measure, a subrogation payment under Article 58, Paragraph 1 of the National Health Insurance Act. However, the tobacco lawsuit filed by NHIS was almost identical to the position in the appeal of the individual tobacco lawsuit case, except for the additional issues raised due to the change of the plaintiff to NHIS. That is, in determining the causal relationship requirement, among the subjects' diseases, small cell carcinoma, squamous cell carcinoma, and laryngeal cancer, squamous cell carcinoma was not a specific disease. Ultimately, since the diseases that the subjects suffered were non-specific diseases, the plaintiff had to prove that the NHIS, as a result of an epidemiological investigation comparing the group exposed to smoking with the non-exposed non-smoking group, significantly exceeded the rate of diseases such as small cell carcinoma in the group exposed to

[4]Supreme Court Decision 2011Da22092, dated April 10, 2014
[5]Supreme Court Decision 2006Da17539, dated July 12, 2013
[6]Seoul Central District Court Decision 2014GaHap525054, dated November 20, 2020

smoking. Furthermore, it had to be proven that there was a possibility that the non-specific disease in this case was caused by the risk factor, smoking, by additionally proving the time and degree of exposure of individuals in the group to the risk factor, the time of onset, family history, etc. However, it was judged that it is difficult to prove the likelihood of acknowledging a causal relationship between smoking and the occurrence of diseases such as small cell carcinoma based solely on the epidemiological research results that the rate of diseases such as small cell carcinoma in the group exposed to smoking significantly exceeds the rate of diseases in the non-smoker group, and the evidence proving that the subjects smoked and developed diseases such as small cell carcinoma, by themselves, and therefore the causal relationship between smoking and the occurrence of diseases such as small cell carcinoma was not acknowledged.

Commentary

This section reflects on judicial interpretations from Korea's tobacco litigation, emphasizing how courts assessed the epidemiological evidence within the framework of causality. It notes the difficulties plaintiffs face in proving specific causation for non-specific diseases like lung cancer and highlights how smoking history, cancer type, and legal standards influenced outcomes across various court levels.

In the case of tobacco lawsuits filed by individuals in Korea, the court of first instance ruled that it is difficult or impossible for the plaintiffs to scientifically prove the causal relationship between smoking and the development of lung cancer, that it is difficult to directly apply epidemiological correlations to individual causal relationships, and that, considering the plaintiffs' places of work, medical history, and smoking history, it is difficult to acknowledge that the plaintiffs' lung cancer was caused by smoking solely based on the epidemiological correlation between smoking and lung cancer and the fact that the plaintiffs smoked for a long period of time[7]. The appellate court did not recognize the causal relationship between smoking and the development of lung cancer in the plaintiff who developed non-small cell lung cancer, which is likely to be caused by causes other than smoking, despite the plaintiff's long-term smoking history. However, based on the type of cancer, smoking history, and lifestyle of the plaintiffs, it recognized the causal relationship between smoking and the development of lung cancer in the plaintiff who smoked for over 30 years and developed small cell lung cancer, which is closely related to smoking[8]. The Supreme Court has stated its position that the burden of proof can be reduced in cases of defects in products that require advanced technology and are mass-produced. It acknowledged that it is scientifically, technologically, and economically difficult for the victim to prove the causal relationship between a defect in a product and damages.

Under the Product Liability Act, once a product is recognized as being highly technology-intensive, a victim can establish causation by demonstrating that the incident occurred in an area under the exclusive control of the manufacturer and that such an incident typically would not occur without someone's fault. The manufacturer, however, retains the right to defend itself by proving that the incident was caused by factors other than a product defect. Even within this legal framework, it is challenging to prove that a particular case involves a highly technology-intensive product. Among the criteria set by the trial court of the first instance in a tobacco lawsuit for easing the burden of proof under product liability, one requirement is particularly critical: proving that lung cancer typically does not occur without fault attributable to a specific party. Given that lung cancer is a non-specific disease arising from complex interactions of multiple factors and can develop due to reasons other than smoking, as well as in non-smokers it is difficult to establish that lung cancer generally does not occur without the defendants' negligence. Consequently, the court concluded that the doctrine of reducing the burden of proof, as applied in the Product Liability Act, could not be directly applied to this case, and thus, did not recognize a reduced burden of proof[9]. In a tobacco lawsuit, the appellate court stated, "In lawsuits for damages caused by pollution, it is often difficult or impossible to scientifically prove the causal link between the harmful act and the resulting damage. Moreover, the company responsible for the harm typically has greater technical and economic capacity to investigate the cause than the victim does, and it also bears a social responsibility to demonstrate that the substances it emits are not harmful." The court further argued that, even if the standard of proof does not meet the probability theory applied in pollution lawsuits, the burden of proof for establishing a causal relationship between smoking and diseases such as lung cancer should be relaxed, unlike in general tort cases. Consequently, the appellate court recognized the application of the doctrine of a relaxed burden of proof in environmental lawsuits[10].

In the United States, the Supreme Court in the Daubert case rejected a causal link between Bendectin and the alleged disease, establishing that general acceptance is not required for scientific evidence to be admitted in court (Daubert v. Merrell Dow Pharmaceuticals, 1993). This decision spurred debate over the level of relative risk needed to accept epidemiological findings as evidence. Subsequently, the Supreme Court initiated the 'Reference Manual on Scientific Evidence,' which suggests that a relative risk (RR) above 2 generally supports a factual causal relationship, while an RR of 2 or below is insufficient [6]. In common law, this standard is widely accepted. An RR of 1 indicates no increased risk, while an RR above 1 suggests a positive association. However, critics argue that strictly applying the RR > 2 threshold

[7]Seoul Central District Court Decision 99GaHap104973, January 25, 2007
[8]Seoul High Court Decision 2007Na18883, pronounced on February 15, 2011
[9]Supreme Court Decision 2011Da22092, pronounced on April 10, 2014
[10]Seoul High Court Decision 2007Na18883, pronounced on February 15, 2011

risks dismissing factors that may still be causally linked to disease.

In Boerner v. Brown & Williamson Tobacco Co., the court accepted expert testimony that lung cancer follows the dose-response criterion and found that Boerner's cancer resulted from cumulative genetic mutations induced by tobacco smoke carcinogens [7]. These mutations were linked to the cumulative dose and concentration of carcinogens, which in turn were associated with cigarette smoke concentration, inhalation patterns, chemical properties of the smoke, and cigarette quantity. Based on this, the court acknowledged an epidemiological causal relationship between smoking and lung cancer [8]. In September 2005, the Supreme Court of Canada upheld the constitutionality of lawsuits seeking reimbursement for medical expenses related to tobacco-related diseases. The Quebec class action against JTI-Macdonald Corp. (JTM), Imperial Tobacco Canada Ltd. (ITL), and Rothmans, Benson & Hedges Inc. (RBH) was based not on vicarious liability but on the government's right to recover costs. The ruling did not require proof of individual characteristics or diseases, allowing demographic, social, and epidemiological studies as evidence. Liability was apportioned by each company's market share (Physicians for a Smoke-Free Canada: https://smoke-free.ca/). Engle v. Liggett Group, Inc. found sufficient evidence of general causality from tobacco company documents and epidemiological studies [7]. The court recognized specific epidemiological links, concluding that smoking causes numerous diseases, including aneurysms, various cancers, cardiovascular and respiratory diseases, and pregnancy complications [7].

Causal inference in tobacco litigation

To prevail in a tort damages lawsuit, it is essential to establish that smoking caused the plaintiff's lung cancer. As research continues to identify health hazards, epidemiological evidence plays an increasingly vital role—sometimes as the only available evidence—in proving causation. Such evidence is often submitted in tort lawsuits, which commonly involve two features: a long latency between exposure and symptoms, and the possibility that other factors could cause the same disease. In logic, the 'law of causality' holds that every event has a cause, with the 'cause' leading to an 'effect.' While law adopts this basic concept, it emphasizes attributing responsibility—identifying who is liable, for what actions, and to what extent, particularly regarding damages.

In law, causality is generally divided into factual and legal causality. Factual causality may extend indefinitely, while legal causality limits the scope of damages considered legally significant. In Germany, these are termed 'causality establishing liability' (haftungsbegründende Kausalität) and 'causality determining the scope of liability' (haftungsausfüllende Kausalität) [9]. In Korea, the prevailing theory for legal causality is substantial causality, which defines causation based on the probability of an outcome occurring as understood through societal knowledge and experience. This approach avoids the overly broad application of the conditio sine qua non theory by recognizing causality only within empirically reasonable bounds. Substantial causality includes three main approaches: the subjective theory, which focuses on what the actor knew or should have known; the objective theory, which considers all circumstances and foreseeable outcomes from the judge's perspective; and the compromise theory, which combines both by considering what an ordinary person would have foreseen along with what the actor actually knew [9].

Epidemiology is the study of the occurrence and distribution of health-related conditions in populations, identifying their determinants and applying this knowledge to address health issues. Social epidemiology, a subfield, examines the social distribution and determinants of health, which are diverse, multilayered, and interrelated. These include environmental factors like social class and working conditions; institutional and cultural factors such as discrimination; psychological aspects like social networks; and political-economic elements like welfare systems. Health inequalities, shaped by these determinants, are systematic and potentially modifiable differences across socially, economically, or geographically defined groups. Without considering the social context of individual choices, promoting behavioral change is difficult.

If smokers are older than non-smokers, comparing lung cancer incidence without adjusting for age may overestimate the effect of smoking. Conversely, if smokers are younger, the effect may be underestimated. The extent to which an estimate deviates from the true effect is called bias. Variables like age, sex, and socioeconomic status (SES) that cause such bias are known as confounders. A confounding variable must be a risk factor for the disease, associated with the exposure, and not a mediator in the causal pathway. If all confounders are properly accounted for, regression analysis can estimate causal effects. However, in studies involving human populations, fully identifying and controlling for confounders is often unfeasible due to design and ethical limitations. Identifying causal links between social conditions and health is difficult because most social factors cannot be directly controlled through experiments. Social epidemiology thus relies on non-experimental or observational data, such as national surveys or administrative datasets like health insurance claims. To address this, methods like propensity scores and instrumental variables are used. Since randomization isn't possible, causal effects must be estimated through statistical adjustments, typically via multiple linear regression with covariates [10]. This adjustment simulates conditions where only the independent variable varies, enabling causal inference through counterfactual reasoning.

Judea Pearl explores the formal semantics of causation using structural models of counterfactuals [11]. He focuses on estimating the probability that event x was a necessary, sufficient, or both necessary and sufficient cause of event y. The paper begins with the legal standard that favors the plaintiff if causation is 'more probable than not,' and introduces a formal framework for interpreting necessary and sufficient causation. Pearl emphasizes the relevance of these models in fields such as epidemiology, law, artificial

intelligence, and psychology. Pearl introduces several key concepts related to causation:

1. Probability of Necessity (PN)

This is the probability that event y would not have occurred without event x, given that both x and y actually occurred. It is mathematically defined as:

$$PN = P(y'_{x'}|x, y)$$

where $y'_{x'}$ denotes the counterfactual scenario where y does not occur if xxx did not occur.

2. Probability of Sufficiency (PS)

This measures the capacity of x to produce y in situations where x and y were initially absent:

$$PS = P(y_x|y', x')$$

where y_x denotes the scenario where y occurs if x occurs.

3. Probability of Necessity and Sufficiency (PNS)

This is the probability that x is both a necessary and sufficient cause for y:

$$PNS = P(y_x, y'_{x'})$$

This captures the likelihood that y responds to x in both directions.

Pearl provides a detailed explanation of structural models and their use in representing and analyzing causality. A causal model is defined as a triple M = <U, V, F>, where *U* represents exogenous variables, *V* represents endogenous variables, and *F* is a set of functions describing the relationships between these variables. He discusses the use of submodels to represent the effects of actions or interventions, with counterfactual statements being interpreted in terms of potential responses in these submodels. A significant portion of the study is devoted to the conditions under which the probabilities of necessity and sufficiency can be identified from statistical data. Pearl highlights the challenges of identification in the presence of confounding factors and discusses methods to overcome these challenges. He introduces the concept of exogeneity, where a variable *X* is exogenous relative to *Y* if the potential response of *X* to different values of *X* is independent of the actual value of *X*. Under the assumption of exogeneity, Pearl derives bounds for *PNS, PN*, and *PS* and shows that these probabilities can be identified using data from experimental and non-experimental studies. He also discusses the role of monotonicity, where *Y* is said to be monotonic relative to *X* if a change in *X* cannot cause a decrease in *Y*.

Pearl applies its theoretical framework to practical cases, including epidemiological studies (e.g., radiation and leukemia) and legal scenarios (e.g., causation in a firing squad). These examples demonstrate how probabilities of causation can be calculated and interpreted in real-world contexts. Pearl concludes by emphasizing the importance of distinguishing between necessary and sufficient causes, arguing that both should inform causal explanations. He also highlights the relevance of these insights for fields like artificial intelligence, where systems may generate explanations based on probabilistic causality.

The Excess Risk Ratio (ERR) is a measure used in epidemiology to quantify the additional risk of a particular outcome (such as developing a disease) associated with exposure to a risk factor compared to the risk of the outcome without that exposure. It is essentially a way to express how much more likely an exposed group is to experience a particular outcome compared to a non-exposed group.

The formula for the excess risk ratio is:

$$\text{ERR} = \frac{P(\text{outcome} \mid \text{exposed}) - P(\text{outcome} \mid \text{not exposed})}{P(\text{outcome} \mid \text{exposed})}$$

In this formula:

P (outcome / exposed) is the probability of the outcome occurring in the exposed group.

P(outcome / not exposed) is the probability of the outcome occurring in the non-exposed group.

The ERR provides a relative measure of the additional risk due to exposure and is often interpreted in the context of assessing the impact of a risk factor on public health.

The Attributable Fraction (AF), also known as the Attributable Risk Percent (AR%) or the Population Attributable Risk (PAR), is a measure that estimates the proportion of the incidence of a disease in the exposed population that can be attributed to the exposure. It reflects the proportion of cases that would not have occurred in the absence of the exposure, assuming a causal relationship.

The formula for the attributable fraction among the exposed (AF) is:

$$\text{AF} = \frac{P(\text{outcome} \mid \text{exposed}) - P(\text{outcome} \mid \text{not exposed})}{P(\text{outcome} \mid \text{exposed})}$$

Or equivalently:

$$\text{AF} = \frac{\text{Risk Difference}}{P(\text{outcome} \mid \text{exposed})}$$

Where:

Risk Difference is *P(outcome / exposed)−P(outcome / not exposed)*.

The AF provides insight into the proportion of cases among the exposed that could be prevented if the exposure were eliminated. It is a useful measure in public health for determining the impact of removing a risk factor from a population.

To illustrate these concepts, consider a study examining the effect of smoking on lung cancer. If 30% of smokers develop lung cancer compared to 5% of non-smokers, the excess risk ratio and attributable fraction would be calculated as follows:

Excess Risk Ratio (ERR):

$$\text{ERR} = \frac{0.30 - 0.05}{0.30} = \frac{0.25}{0.30} = 0.833$$

This means that approximately 83.3% of the risk of

developing lung cancer in smokers is due to the excess risk associated with smoking.

Attributable Fraction (AF):

$$AF = \frac{0.30 - 0.05}{0.30} = 0.833$$

This indicates that 83.3% of lung cancer cases among smokers can be attributed to smoking. In other words, if smoking were eliminated, 83.3% of the lung cancer cases in smokers could potentially be prevented. Both of these measures are crucial in epidemiology for understanding the impact of risk factors and for designing effective public health interventions.

The excess risk ratio, or attributable fraction, is a key measure of causality in tobacco litigation. It quantifies the contribution of an exposure to the outcome prevalence within an exposed population, relative to the total prevalence in that group. Specifically, the excess fraction expresses how much greater the risk is in the exposed group compared to the unexposed, as a proportion of the exposed group's risk. The attributable fraction applies only when the exposure causally explains the net difference between groups [12]. In contrast, the population attributable fraction (PAF) accounts for both exposed and unexposed individuals in the general population.

A Positivist Review of Law

A tort is an unlawful act that causes harm, either intentionally or through negligence. In tort law, key elements of negligence include breach of duty, harm, illegality, responsibility, damage, and causality. To hold a defendant liable, there must be a recognized causal link between the harmful act and the resulting damage. Causality thus defines the scope of liability. Risk refers to both the likelihood and severity of harm from exposure to a hazardous agent. For example, asbestos carries a high probability of causing lung cancer, which often leads to severe outcomes like death. Risk is therefore understood as a combination of probability and severity [13]. The probabilistic nature of risk and inherent scientific uncertainty can hinder the ability to meet the burden of proof, revealing limitations within the judicial approach to risk.

Causation in American tort law consists of factual and legal components. Factual causation is established by showing that, but for the defendant's wrongful act, the plaintiff would not have suffered harm. The prevailing method is the 'but for' test, requiring the plaintiff to prove that the harm would not have occurred without the defendant's negligence. According to Restatement (Second) of Torts §431, the defendant's conduct must also be a substantial factor in bringing about the harm. Factual causality is based on conditionalism and determined by natural or scientific standards. However, it may unduly expand the scope of compensation. To prevent this, American courts limit liability by also requiring legal causality. Even when factual causation is proven, liability does not follow automatically; the act must also be a legally significant proximate cause. Thus, American tort law adopts a two-step approach, requiring both factual and legal causation [14]. Rosenberg, analyzing asbestos-related lawsuits in the U.S., argues that the tort system remains effective by exposing corporate misconduct and compensating victims, thus serving a preventive function [15]. Persival, referencing tobacco litigation, notes that while judicial decisions are retrospective, they shape future behavior by clarifying societal standards of reasonableness. Despite uncertainties in expert risk assessments, judges evaluate risk rationality through case-specific judgments, reflecting broader legal sentiments and aligning tort law with public understanding [16].

Applying Hill's criteria to research on smoking and lung cancer supports a causal relationship. Criteria satisfied include temporal sequence (smoking precedes cancer), strength of association (a 20-fold increased risk in heavy smokers), consistency across studies, dose-response relationship, and experimental evidence (animal studies showing carcinogenesis via cigarette tar) [17, 18]. When causation is disputed at the individual level, the attributable fraction from population data can estimate the probability of causation (PC), which is equal to or greater than the attributable fraction [12]. The Dictionary of Epidemiology defines PC as the probability that exposure contributed to disease in a given individual [19]. This concept is key in legal contexts, where PC represents the likelihood that a specific exposure caused disease in a randomly selected individual. In tobacco litigation in Korea, plaintiffs are often lung cancer patients with significant smoking histories, making the attributable fraction in the exposed group a relevant measure. For small cell and squamous cell lung cancers, and for individuals with ≥20 pack-years and ≥30 years of smoking, domestic studies estimate the attributable fraction at 80–90% or higher. If smoking is recognized as a causal factor, then for individuals meeting these criteria, the probability that smoking caused their cancer is at least 80–90%, offering a basis for individual-level causal judgment.

In litigation, epidemiological studies are often used to determine whether exposure to a substance caused harm. Such evidence helps identify risk factors at the population level, estimate the probability of causal relationships, assess exposure levels that exacerbate disease, and identify vulnerable subpopulations [20]. It can be critical in tort claims and sometimes serves as the only available evidence. For instance, in Richard Boeken v. Philip Morris, Inc., expert epidemiological testimony established legal causation between smoking and lung cancer [21]. Similarly, in Engle v. Liggett Group Inc., the court recognized epidemiological links between smoking and numerous diseases, including cardiovascular, respiratory, and various cancers [7]. However, establishing causation in tobacco litigation is challenging due to the delayed onset of disease after long-term exposure. Unlike cases involving immediate harm such as product defects or medical malpractice tobacco-related illnesses manifest after prolonged contact with carcinogens. In some cases, like humidifier disinfectant lawsuits, plaintiffs may not even be aware of their exposure. Furthermore, the time gap between exposure and disease onset, and the limited understanding of biological mechanisms, weaken the

perceived causal link. Consequently, proving causation requires complex scientific evidence and detailed analysis.

The Reference Manual on Scientific Evidence published by the Federal Judicial Center in the U.S. introduces case law recognizing individual and legal causality from epidemiological causality when the relative risk (RR) exceeds 2 or the attributable risk surpasses 50% [22]. The manual explains that the probability that a risk factor caused an individual's disease can be inferred from RR, applying the 'greater than 50% rule.' If RR ≥ 2.0, it implies that the probability of causation exceeds 50%, supporting the inference of a specific causal relationship. This inference is valid under certain conditions, including a reliable study and risk estimate, similarity between study subjects and the plaintiff, absence of disease acceleration, and the independent action of the agent. Based on the manual, if the plaintiff submits epidemiological evidence showing a causal probability over 50% or RR exceeding 2, the burden shifts to the defendant to present counter-evidence such as an alternative cause to refute the individual causal link. In principle, then, individual causality can be inferred from epidemiological causality, subject to the evidentiary context of each case.

In conclusions, this study critically examined the legal principles and challenges of causal inference in tobacco litigation, with a particular focus on South Korea. Drawing on doctrinal legal analysis and epidemiological reasoning, it reviewed a series of landmark cases both individual lawsuits and the National Health Insurance Service (NHIS) litigation against major tobacco companies. The analysis highlighted how Korean courts have consistently demanded a high evidentiary threshold for proving specific causation in tobacco-related disease, often dismissing robust epidemiological findings as insufficient for establishing individual legal causality. Through comparative case law analysis, particularly from the United States and Canada, the study demonstrated how epidemiological concepts such as relative risk, attributable fraction, and probability of causation have been effectively utilized in other jurisdictions to support claims in toxic tort and public health litigation. These international precedents suggest that epidemiological causality, when supported by consistent data and expert testimony, can serve as a legally meaningful standard—especially in cases involving diseases like lung cancer, which are multifactorial and develop over long latency periods. The paper argues that the Korean legal system's rigid distinction between specific and non-specific diseases, and its reluctance to reduce the burden of proof in health damage cases, fails to reflect both scientific realities and principles of procedural fairness. Given the asymmetric access to scientific knowledge between plaintiffs and tobacco companies, and the structural similarities between tobacco litigation and environmental litigation, the study advocates for a legal framework that allows greater weight to be placed on epidemiological evidence. Specifically, when epidemiological studies demonstrate a probability of causation greater than 50% or a relative risk exceeding 2.0, this should be sufficient to shift the burden of proof to the defendant. Ultimately, this study calls for a reevaluation of the current judicial approach to causality in tobacco litigation. Legal reforms should aim to align more closely with public health perspectives, enabling courts to better protect the rights of victims and strengthen accountability in the face of scientific uncertainty. Doing so would not only enhance the credibility and responsiveness of the legal system, but also contribute to more effective tobacco control and public health policy in Korea.

Author Contribution Statement

MJ wrote and revised the manuscript.

Acknowledgements

None.

Funding

This study was supported by the Dongduk Women's University grant (2024-06443).

Competing interests

I declare that I have no conflict of interest.

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