Lung Cancer: History And Litigation - *New Jersey Law Journal*

May 19, 2025

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Lung cancer has been and continues to be a major cause of death in both men and women in the United States and around the world. The causal relationship between tobacco and lung cancer was first reported in medical literature in the 1930s. The number of lung cancer deaths has been increasing and is related not only to tobacco intake but also to air pollutants.

As with most cancers, the early diagnosis and treatment of lung cancer increases a patient's chances of survival. Therefore, the issue for the medical community has been how to discover lung cancer early, leading to treatment that can both prolong life and potentially cure the patient.

The issues for the legal community are twofold. First, what are the potential responsibilities of the patient's physician? Second, what other entities may bear responsibility for either causing a patient's cancer or delaying a patient's diagnosis?

Medical Community

Individuals who smoke, depending upon the amount smoked and the duration of the smoking (known as pack years), are at an elevated risk of developing lung cancer. However, individuals who do not smoke also are at risk, though that risk is substantially lower.

Prior to the development and introduction of the CT scan, the only method for determining whether a patient had a pulmonary lesion was the chest X-ray. Such studies were often routinely done on admission to the hospital for any reason and periodically in a physician's office as part of a routine examination but without specific indications. While these X-rays could uncover cancerous lesions, the routine use of chest X-rays carried with it the risk that patients would receive high doses of radiation. Moreover, the films would often be interpreted in a practitioner's office by someone other than a trained radiologist, thereby diminishing their effectiveness.

With the ability to minimize radiation levels, CT screening became a key to the early diagnosis of lung cancer. Two physicians, Dr. Claudia Henschke and Dr. David Yankelevitz from Mt. Sinai Hospital in New York, first began the Early Lung Cancer Action Program, or ELCAP, followed by I-ELCAP, an international version of the program. The concept was that screening appropriate patients repeatedly could lead to an early-stage diagnosis of lung cancer and a cure. Then in 2015, appreciating the importance of the work done by ELCAP, the Centers for Medicare & Medicaid Services (CMS) announced insurance coverage for high-risk individuals, which included those between the ages of 50-77, with 30 pack years of smoking, who continue to smoke or have quit within 15 years. In 2016, the number of pack years was lowered to 20.

Physicians are required to take smoking histories from their patients. That information is recorded in a patient's chart, and the patient should be counseled and offered the ability to access a smoking cessation program. The physician is responsible for discussing the smoking history with the patient and referring that patient for screening. The patient has the choice of

accepting the recommendation or declining screening. According to recent data, only 5% of the individuals who should be screened, are screened.

To the authors' knowledge, no study has determined why the referral rate for screening is so low. Perhaps it is because some groups in the medical community do not believe screening is efficacious and that there are risks of overdiagnosis and complications as a result. However, research has proven that screening is effective, i.e., it will lead to the early diagnosis of lung cancer and cures for the affected patient.

As medical records are now electronic, access to such records could easily reveal those individuals who fall into the category of "should be screened," as well as those who have been screened, referred for counseling on smoking cessation, and have declined screening. Such an analysis of existing records could provide valuable information that could be used to increase positive patient outcomes.

Legal Community

Prior to the advent of CT screening, cases with the following scenarios were familiar to malpractice attorneys.

The first involved a male patient who was admitted to an emergency room because of a job-related injury. He was a police officer. A routine chest X-ray was performed, and the patient was discharged home. After the patient was discharged, the X-ray was read and reported as showing a lesion. The report was entered into the chart and forgotten. A year-and-a-half later, the patient was diagnosed with lung cancer, leading to the discovery of the earlier report. The radiologist was found liable for not communicating the positive result to the patient, which would have led to an earlier diagnosis and treatment, and a better outcome.

The second involved a woman who had a chest X-ray done as part of a routine annual examination. The films were read by a general practitioner and filed away. A year later, the patient returned to the practitioner's office with complaints, a new film was taken, and a much larger lesion was found. It was discovered that the earlier X-ray, in fact, showed the tumor at an earlier stage when diagnosis and treatment would have led to a better outcome. The practitioner was liable for failing to advise the patient of the earlier positive finding.

In the 1990s, litigation was brought against the tobacco industry by various state attorneys general. They argued that the tobacco companies should be liable for the cost of treating their citizens who developed cancer because they knew but failed to disclose that their products could cause cancer. That litigation was settled in 1998 by way of a master agreement that allowed the companies to continue to sell their products but with warning labels. The tobacco companies paid substantial amounts to the states involved in the litigation.

We now have a third phase of the litigation process, one in which patients who are candidates for screening under CMS guidelines are nevertheless not referred for screening. Records have shown that such patients are not informed that screening is available, or that they should be screened, or that they have declined screening. In such cases, practitioners are being held responsible.

Lawsuits involving such allegations have been filed in multiple jurisdictions, and it is anticipated that this number will increase. However, the probability of individual lawsuits significantly increasing the low level of screening of appropriate individuals is low.

Health networks have access to patient information through electronic medical records. Insurers know the numbers of their insureds who have developed lung cancer and those who have been screened. These entities could easily keep track of who should be screened and who among that population has not been screened. Therefore, consideration should be given to initiating litigation against the entities controlling the delivery of health care as they possess the patient data that reveals when appropriate care is not being offered or provided.