1992

Health Warnings, Smoking, and Cancer - The Cipollone Case

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LEGAL ISSUES IN MEDICINE

HEALTH WARNINGS, SMOKING, AND CANCER

The *Cipollone* Case

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THE figures have become familiar. Tobacco use has been declared "the single most important preventable cause of [premature] death in the United States, accounting for one of every six deaths, or some 390,000 deaths annually."[1] The health goals of the nation for the year 2000 call for reducing the prevalence of cigarette smoking to 15 percent among adults (a 48 percent decrease from the current 29 percent) and reducing the rate of beginning smoking among teenagers to 15 percent (a 50 percent decrease from the current rate of 30 percent).[2] The goal of reducing smoking in the United States is not controversial from a medical or public health standpoint. But controversy continues about the most effective methods to achieve this goal and the part tort law should play in discouraging or controlling smoking.[3]

Product-liability litigation has been instrumental in encouraging automobile manufacturers to make safer cars and drug manufacturers to test products carefully, and in increasing awareness of safety in industry generally. To date, however, product-liability lawsuits involving patients with smoking-related illness have not been successful. Although more than 300 cases have been filed against cigarette manufacturers for compensation for harm caused by smoking, the companies have yet to pay one cent in awards.[4] In fact, in only one case, *Cipollone* v. *Liggett Group*,[5] has a jury awarded any damages at all. *Cipollone* is by far the most important smoking product-liability case, and the recent decision of the U.S. Supreme Court both sets the rules for future lawsuits and illustrates many of the difficulties faced by injured cigarette smokers and their families who bring the lawsuits.[6]

THE CASE OF ROSE CIPOLLONE

Rose Cipollone began smoking in 1942 when she was 17. She smoked Chesterfields until 1955, L & M filter cigarettes from 1955 to 1968, Virginia Slims and Parliaments from 1968 to 1974, and Trues until 1982, when part of her lung was removed because of lung cancer. She finally stopped smoking in 1983 and died in 1984 of metastatic cancer. From the time she began smoking, Cipollone smoked between one and two packs a day; she switched brands primarily for safety reasons, in large part on the basis of cigarette advertisements. In August 1983, Mrs. Cipollone and her husband Antonio filed suit against Liggett Group, Philip Morris, and Lorillard for damages caused by her lung cancer. After Mrs. Cipollone's death, her husband continued the suit both individually and as executor of her estate. And more recently, after Mr. Cipollone's death, their son Thomas continued the lawsuit as the executor of their estates.

Before the trial, the Third Circuit Court of Appeals had ruled that most actions against cigarette manufacturers after 1965 were preempted by federal statutes that mandated health warnings on cigarette packages.[7] After a 4½-month trial in 1988, a jury nonetheless concluded that before 1966 Liggett did breach its duty to warn of health hazards, but that Mrs. Cipollone was 80 percent at fault for her injuries because "she voluntarily and unreasonably encountered a known danger by smoking cigarettes."[5] The jury, however, awarded $400,000 to Antonio Cipollone to compensate him for damages he sustained from Liggett's breach of warranty. Both parties appealed.

The appeals court reversed the decision on technical grounds and remanded the case for a new trial.[8] The case was accepted by the Supreme Court in order to resolve a question that had been decided differently by state supreme courts and U.S. circuit courts of appeal: Does the preemption language in the 1965 federal Cigarette Labeling and Advertising Act and the Public Health Cigarette Smoking Act of 1969 bar smokers and their families from suing cigarette manufacturers on the basis of state tort laws?

PREEMPTION

The Constitution grants the federal government some exclusive powers (such as coining money and raising an army); other powers are retained by the states. In some areas, such as nuclear power, the federal government can, at its option, exercise exclusive authority over a subject matter and override or "preempt" the states' power to regulate in that area. This power to take over a specific area of the law is set forth in the Supremacy Clause of the Constitution, which provides that federal laws shall be the "supreme" law of the land, any laws of the states notwithstanding. There is no question that Congress can preempt the states' powers in the area of regulating smoking, health labeling, and advertising under its interstate-commerce powers. The question before the Supreme Court was how much of this area Congress had assigned exclusively to the federal government and thus what powers, if any, remained with the states.

The 1965 act required all cigarette packages to contain the label "Caution: Cigarette smoking may be hazardous to your health." In regard to preemption, the act provided that no other statement "relating to smoking and health" could be required on any cigarette package. The 1969 act amended the 1965 act by requiring a statement that cigarette smoking "is dangerous" and banned cigarette advertising in any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission. It stated: "No requirement or prohibition based on

smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act."[9]

The Federal Trade Commission extended the warning-label requirement to print advertisements for cigarettes in 1972, and Congress required the rotation of four warnings in print advertisements and on packages in the 1984 Comprehensive Smoking Education Act.

The effect of the 1969 preemption clause was so difficult for the Supreme Court to determine that no interpretation of this clause had five adherents. Instead, the Court split into three groups: one a four-justice plurality and two that wrote opinions that were partly concurring and partly dissenting (there were three justices in one and two in the other).[6] The writers of both partly concurring opinions, although they disagreed with each other, agreed that the opinion of the plurality would be extremely difficult for lower courts to understand and thus to implement.

The Supreme Court's Opinion

Justice John Paul Stevens wrote the plurality opinion for himself and Justices William H. Rehnquist, Sandra Day O'Connor, and Byron R. White. In earlier cases the Court had generally decided what was preempted on the basis of the language of the entire statute in question, sometimes called the "statutory scheme," and often used the statute's legislative history as well to help it in determining congressional intent. If this was not clear, preemption could be implied if there were irresolvable conflicts between federal and state law, if state law acted as an obstacle to federal law, or because of the federal nature of the subject matter itself.

The plurality in this case, however, issued a new and narrow rule of statutory interpretation regarding preemption: when Congress includes a preemptive provision in a statute, that language alone should be used to determine the scope of the preemption, keeping in mind "the strong presumption against pre-emption." Using this approach, the plurality concluded that the 1965 act prohibited the states only from "mandating particular cautionary statements . . . in cigarette advertisements," so as to avoid "diverse, nonuniform, and confusing labeling and advertising regulations."[6] The Cipollones had four basic causes of action against the cigarette manufacturers: failure to warn, breach of express warranty, fraudulent misrepresentation, and conspiracy to misrepresent or conceal facts. The plurality's ruling required the judges to examine each to determine whether the preemption language of the 1969 act barred a suit on those grounds.

As to failure to warn, the plurality decided that any state law that established a duty to warn consumers of health hazards in order to make the product reasonably safe was preempted by the language specifying "no requirement or prohibition" in the 1969 federal Public Health Cigarette Smoking Act. In other words, after 1969 no lawsuits alleging failure on the part of cigarette companies to include additional health warnings or clearer warnings than required by Congress on cigarette packages could succeed, because any state law requiring additional warnings was preempted by that act.[6]

The claim of breach of express warranty holds the seller responsible for any "affirmation of fact or promise" made to the buyer. The plurality decided that these promises are not imposed by state law, but are "voluntarily undertaken" and made by the seller. Therefore, suits on such grounds are not preempted by the 1969 act. Fraudulent misrepresentation was alleged on two bases: first, that advertising neutralized the effect of the federally mandated warnings, and second, that the manufacturers falsely misrepresented and concealed material facts related to smoking and health. As to the first, the plurality found it "inextricably related" to the failure-to-warn allegation, and thus preempted by federal law as well. As to the second, however, the plurality found it not preempted, primarily because it was not a rule "based on smoking and health." Rather, "state law proscriptions on intentional fraud rely only on a single uniform standard: falsity." Thus, claims based on fraud involving the concealment or misrepresentation of material facts are not preempted. For the same reason, the plurality concluded that claims based on conspiracy to misrepresent or conceal material facts were not preempted by federal law either.[6]

The Concurring–Dissenting Opinions

Another opinion was written by Justice Harry A. Blackmun for himself and Justices Anthony M. Kennedy and David H. Souter. Blackmun argued that given the plurality's insistence on reading preemptive language narrowly, out of respect for state sovereignty, its conclusion that some damage-claim rights under common law were preempted was "little short of baffling." In his opinion, it is not possible to interpret words properly in isolation; rather, the statute must be read as a whole. Moreover, Blackmun noted, the Court had previously distinguished statutory prohibitions from common-law actions; he noted as well that the effects of the former were direct, and those of the latter indirect: "Although an award of damages by its very nature attaches additional consequences to the manufacturer's continued unlawful conduct, no particular course of action [such as the adoption of a new warning label] is required."[6] Essentially, Blackmun read the 1969 amendments as simply clarifying the 1965 act. And using legislative history, Blackmun found no indication that Congress meant to leave consumers without any remedy at all for injuries suffered as a result of smoking. He would thus have found none of the states' common-law remedies preempted by the 1969 federal act.

In contrast to the Blackmun opinion, Justice Antonin Scalia, joined by Justice Clarence Thomas, would have found that all the common-law tort claims

at issue were preempted by the 1969 language. Scalia argued that the proper rule for interpreting preemption provisions should be the same as the general rule of all statutory interpretation: "Their language should be given its ordinary meaning."[6] Of course, if this were as easy as it sounds, all the justices would have agreed on the meaning of the statute's language. In Scalia's view, both the 1965 language and the 1969 language are broader than the writers of the other two opinions believe. Moreover, he suggested an alternative way to determine whether specific state rules or common-law actions are preempted — the "proximate application" method, which asks "Whatever the source of the duty [statute or common law], does it impose an obligation in this case because of the effect of smoking on health?"[6]

Because of the way the Court split, whenever the Stevens plurality decided that a common-law cause of action was preempted, it had six votes for this position (its four and those of Justices Scalia and Thomas); and whenever it determined that a common-law cause of action was not preempted, it had seven votes (its four and those of Justices Blackmun, Kennedy, and Souter). Thus, although it is still unclear whether the Court will ever adopt the plurality's "new" method of interpreting Congress' language on preemption, the Court's conclusion about the availability of state tort remedies for smokers and their families is beyond dispute: lawsuits that allege breach of express warranty, intentional fraud and misrepresentation, and conspiracy under state law can be filed against cigarette manufacturers. Lawsuits that are preempted, and thus cannot be brought against cigarette manufacturers, are those alleging failure to warn of the dangers of smoking and the neutralization of federally mandated warnings, to the extent that those claims rely on statements made in or omitted from advertising or promotions.

Implications of the Opinion

The fact that smokers can bring lawsuits against cigarette manufacturers does not, of course, mean that they will win. Two serious hurdles remain. The first is the need to prove fraud or misrepresentation. Neither the false representation of a material fact nor the concealment of a material fact by the cigarette manufacturers has been proved. But in a related case, the trial judge in *Cipollone*, H. Lee Sarokin, was removed from hearing the rest of the case (and ultimately withdrew from rehearing *Cipollone* as well) because of his statements relating to this issue. In a pretrial determination in February 1992 that the cigarette manufacturers were not entitled to use the attorney–client privilege to shield certain documents from discovery, Judge Sarokin wrote:

> All too often in the choice between the physical health of consumers and the financial well-being of business, concealment is chosen over disclosure, sales over safety, and money over morality. Who are these persons who knowingly and secretly decide to put the buying public at risk solely for the purpose of making profits and who believe that illness and death of consumers is an appropriate cost of their own prosperity! As the following facts disclose, despite some rising pretenders, the tobacco industry may be the king of concealment and disinformation.[10]

An appeals court later ruled that these words constituted at least the appearance of bias against the cigarette companies, and removed Judge Sarokin from the case.[11] Although his statement was judicially intemperate, many — perhaps most — physicians and public health professionals would agree with the judge's assessment. His conclusion seems reasonable:

> A jury might reasonably conclude that the industry's announcement [in 1954, continued to 1970] of proposed independent research [by the Council for Tobacco Research] into the dangers of smoking and its promise to disclose its findings was nothing but a public relations ploy — a fraud — to deflect the growing evidence against the industry, to encourage smokers to continue and nonsmokers to begin, and to reassure the public that adverse information would be disclosed.[10]

Injured smokers face a second hurdle to successful litigation as well, one Rose Cipollone could not overcome in the first jury trial — the need to convince the jury that they smoked or continued to smoke because they relied on the representations of the cigarette companies and that they would not have smoked or continued to smoke had there not been misrepresentations or concealment on the part of the tobacco companies. This is perhaps the chief obstacle to a successful product-liability suit against a cigarette manufacturer, and it helps explain why the Cipollone family withdrew their lawsuit in November 1992. Nonetheless, there seems to be no valid reason to deny citizens their right to a jury trial on this issue if they can show that their smoking, and thus the injury, was caused by industry fraud (even if this can be done only rarely).

A Better Strategy

Tort law provides remedies for past harm. Public health strategies are much more effective when designed to prevent future harm. Tort suits should certainly be available to consumers in cases of breach of express warranty and fraud, regardless of the existence of required warning labels, as the Supreme Court has now affirmed. It is unreasonable to suggest that Congress meant to protect cigarette manufacturers from being held responsible for damages caused by fraud and deceit when they required health warnings on cigarette packages. On the other hand, the possibilities for success in such suits are very limited. Both Rose and Antonio Cipollone died long before their lawsuit neared resolution. Moreover, it is probably true that physicians and public health professionals have been so successful at publicizing the health risks of smoking and encouraging smokers to stop that members of an average jury now know the health risks and expect everyone else to know them, too. Nonsmoking jury members will probably not be impressed by an argument that advertising makes people smoke.

Smokers who have stopped will find it difficult to believe that smoking is too addictive to give up, and smokers will probably know the risks they have decided to continue to take. Thus, it is unrealistic for the medical and public health community to think that tort litigation against tobacco companies is ever likely to be successful enough to force the industry to stop manufacturing and selling cigarettes. Given all the publicized health risks of smoking, it is also unlikely that warning labels now have much effect on the decision to smoke or not to smoke.

This is not to say that health warnings should be abandoned, but only that no matter how harshly they are phrased, they probably long ago reached their peak effectiveness. Meeting the smoking-reduction goals of *Healthy People 2000* will require more effective interventions.[2] These should focus primarily on discouraging teenagers from starting to smoke and making it difficult for them to continue. In this effort it is, of course, also unrealistic to expect any support from the tobacco industry. As one fictional cigarette-industry executive says in an antismoking advertisement televised in California, "We're not in this business for our health."[12]

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BOOK REVIEWS

Diagnosis of Salivary Gland Disorders

Edited by K. Graamans and H.P. van den Akker. 175 pp., illustrated. Boston, Kluwer Academic, 1991. $70. ISBN 0-7923-1384-4.

Why should a book entitled *Diagnosis of Salivary Gland Disorders,* written by two surgeons (one an otolaryngologist and the other an oral surgeon), be reviewed in the *Journal* by an internist? Neither by training nor by inclination are internists likely to care or think much about the salivary glands. During my one week of otolaryngologic training in medical school, I was so entranced by the differential diagnosis of sneezing and so encumbered by the difficulties of using a reflecting head mirror that I failed to progress to diseases of the salivary glands. Thus, my romance with the salivary glands has been entirely a postgraduate experience.

The salivary glands are like the liver, only bilaterally symmetrical. They are encapsulated and have nowhere to run when an infiltrative process (be it granulomatous, fatty, neoplastic, or lymphoid) comes their way. They are exocrine glands and therefore ductile, subject every bit as much as the bile ducts to the insoluble problems of calculi. They come in major and minor varieties, serous or mucous, and with only minor discomfort can readily be biopsied on the palate or in the lower lip, thus revealing their hidden pathologic processes. Furthermore, they are subject to autoimmune attack in the disease described by Johann Mikulicz and Henrik Sjögren, which is labeled an autoimmune exocrinopathy.

The most common general medical condition presenting as a salivary-gland disorder is Sjögren's syndrome. The differential diagnosis includes not only calculi, fatty infiltration, sarcoid, amyloid, tuberculosis, leukemia, and lymphoma, but now also a Sjögren's syndrome–like disorder related to the human immunodeficiency virus and linked to HLA-DR5 and CD8 lymphocytosis.

Sjögren's syndrome is a chronic autoimmune disease associated with the production of rheumatoid factor and other autoantibodies. Characterized by lymphocytic and plasma-cell infiltration and destruction of salivary and lacrimal glands, it causes the characteristic symptoms of dry mouth and dry eyes. Because the lymphocytic infiltration can extend to other, more vital organs and can at times become malignant, the syndrome is both a systemic and a localized autoimmune disorder.

On January 23, 1888, Dr. Johann Mikulicz, a surgeon, reported to the Society for Scientific Medicine at Königsberg the case of a 42-year-old farmer from East Prussia who presented with painless swelling of the lacrimal, parotid, and submandibular glands. Complete surgical excision of the lacrimal and submaxillary glands was performed. All surgical specimens contained numerous small round cells suggestive of lymphoma.

Henrik Sjögren was born in 1899 in Stockholm and received his M.D. degree from the Karolinska Institute in 1927. He was aware of case reports of patients, mostly females, with dry eyes and mouth, some with arthritis. Sjögren made two major contributions to the understanding of the disease that now bears his name. He used rose bengal to stain the corneal lesions and introduced the term "keratoconjunctivitis sicca" to describe the eye involvement. He also performed important pathological studies and recognized that the disease was indeed a generalized systemic disorder.

Morgan and Castleman concluded, after examining pathological specimens, that Mikulicz's disease and Sjögren's syndrome were in fact the same entity. Morgan stated that "the condition characterized by chronic enlargement of the salivary or lacrimal glands, which in the past has been called Mikulicz's disease, may be a less highly developed variant of a larger symptom complex, Sjögren's syndrome" (N Engl J Med 1954;251:9). Subsequent studies have demonstrated that patients with Sjögren's syndrome are at increased risk for lymphoma and that monoclonal B-cell populations are an intrinsic feature of the disorder.