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Foreign-Language Warnings Not Required for Nonprescription Drugs

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the product from afar, but whether the consumer would be confused in purchasing the product.

The Seventh Circuit also noted that Stanard's company sold its products through mail order and required a customer to make a check payable to "JUST DID IT" Enterprises. Accordingly, the court found that for confusion to occur, a customer must not only see "MIKE" as similar to "NIKE," but must continue to confuse the two while making a check payable to "JUST DID IT" Enterprises.

Stanard's Intent in Producing "MIKE" Products

The Seventh Circuit determined that a jury could reasonably find that Stanard intended to amuse consumers, not confuse them, by creating a parody of the "NIKE" trademark. The court maintained that parodies do not happen incidentally. Rather, a parody results from the actual knowledge of the trademark which the presenter, observer, and consumer possess. Stanard repeatedly admitted his awareness of Nike's trademarks and asserted that he only intended to mock Nike's image.

Additionally, the court concluded that the district court had erroneously based its decision on Stanard's statement that the whole point of the parody was to confuse observers viewing the shirts at first glance from across the room. The Seventh Circuit determined that the ultimate issue was whether a customer was confused when deciding to purchase an item, not whether a member of the general public was confused when viewing Stanard's product.

Additional Factors Considered

The Seventh Circuit examined additional factors to determine the likelihood of consumer confusion. In reviewing the marketing channels employed by "JUST DID IT" Enterprises, the Seventh Circuit recognized that Stanard specifically targeted an audience who would appreciate the distinction between "MIKE" and

"NIKE." Accordingly, a jury could conclude that Stanard's target market would intentionally purchase a product with the "MIKE" parody, but not the "NIKE" symbol. The court reasoned that consumers' conscious decisions would tend to show that they were not confused as to whether Nike endorsed Stanard's products.

The Seventh Circuit also disagreed with the district court's conclusion that the price of Stanard's products suggested that consumers would not exercise a high degree of care in making their purchases. Nike failed to offer evidence as to the degree of care consumers would exercise in purchasing T-shirts and sweatshirts. The court concluded that absent such evidence, a jury could find that customers used care when purchasing T-shirts and sweatshirts with different labels.

Finally, the court found that because Nike failed to provide any evidence of actual consumer confusion, a reasonable jury could determine that Stanard's parody was not likely to confuse consumers. Consequently, the Seventh Circuit reversed the district court's grant of summary judgment for Nike and remanded the case for further proceedings. ♦

Brian K. Wydajewski

Foreign-Language Warnings Not Required for Nonprescription Drugs

In *Ramirez v. Plough*, 863 P.2d 167 (Cal. 1993), the Supreme Court of California held that manufacturers of nonprescription drugs do not have a legal duty to include foreign-language warnings with their packaging materials.

Child Develops Reye's Syndrome

The minor plaintiff, Jorge Ramirez, brought suit through his mother against Plough, Inc., claiming that he developed Reye's syndrome by taking St. Joseph Aspirin for Children (SJAC), a nonprescription drug manufactured by Plough. In March 1986, when Ramirez was less than four months old, his mother gave him SJAC to relieve cold symptoms. Ramirez's mother did not seek the advice of a doctor before using SJAC, although the label stated that for children under two, the dosage was "as directed by doctor." She gave Ramirez three SJAC tablets over a two-day period. When she took Ramirez to the hospital on March 15, the doctor recommended that she use nonprescription drugs that did not contain aspirin. Ramirez's mother, however, continued to administer SJAC. Ramirez then developed Reye's syndrome, resulting in severe neurological damage, including cortical blindness, spastic quadriplegia, and mental retardation.

Reye's syndrome is a disease that is fatal in 20 to 30 percent of cases, with many instances of permanent brain damage. The cause of Reye's syndrome is still unknown, but by the early 1980s, research demonstrated a link between the use of aspirin during a viral illness and the development of Reye's syndrome. These results led the Food and Drug Administration (FDA) to require a warning label on aspirin products to inform parents about Reye's syndrome. The FDA

regulation took effect on March 7, 1986.

Even before the FDA required mandatory warning labels, packages of SJAC contained warnings about Reye's syndrome. These warnings were only written in English. In March 1986, Ramirez's mother purchased a SJAC package containing such a warning. Although Ramirez's mother was unable to read the warnings because they were in English, she did not ask other members of her household to translate the warnings for her. Plaintiff's mother had not been exposed to any advertising for SJAC in either English or Spanish.

Ramirez, through his mother, sued Plough in August 1989, claiming fraud, negligence, and product liability, all based on Plough's alleged failure to warn about Reye's syndrome. Although Plough admitted that a manufacturer of nonprescription drugs has a duty to warn about the dangers of its products, Plough denied that it had any legal duty to provide the warning in Spanish. Ramirez presented evidence that Plough knew that Hispanics, many of whom did not read or speak English, constituted an important segment of the market for SJAC and argued that Plough had acted on this knowledge by advertising in Spanish. Nevertheless, the superior court granted Plough's motion for summary judgment, and Ramirez appealed. The court of appeals reversed, stating that although the issue of duty is a question of law, the adequacy of the warning is a question of fact, which entitled Ramirez to present his case to the jury. The Supreme Court of California granted review.

Manufacturers of Nonprescription Drugs Have No Legal Duty to Include Foreign-Language Warnings

In reversing the appellate court's decision and affirming summary judgment for Plough, the Supreme Court of California held that manufacturers of nonprescription drugs have no legal duty to include foreign-language

warnings. The court stated that it could properly resolve issues relating to the scope of an established duty because the applicable standard of care is a question of law for the court.

The supreme court first considered what standard of care applied to Plough's duty to warn its customers about the dangers of Reye's syndrome. The court stated that the duty of care of a reasonably prudent person under like circumstances is normally the proper standard. In certain situations, however, the conduct of a reasonable person may be determined by referring to judicial decision, statute, or ordinance. Because the court ultimately determines the standard of care in a civil case, the standard prescribed by a statute becomes the standard in a civil suit only if the court adopts it. In this case, Plough argued that the court should apply the statutory standard to determine whether Plough's conduct was reasonable.

Plough asserted that by complying with statutory standards, its conduct was reasonable and therefore did not breach any duty to Ramirez. The court acknowledged that statutory compliance might be a valid defense in this case, but noted that if Ramirez could show a reasonably prudent product seller would have undertaken safety measures beyond the statutory minimum, Plough could be found liable. Plough argued that the standard of care was best determined by the vast number of statutes and regulations which had controlled all areas of its marketing. Plough asserted that under statutory guidelines, it had complied fully with the law. In response, the court reviewed the pertinent statutes and regulations.

The court first examined the Food, Drug, and Cosmetic Act (FDCA), which is a federal regulation stating that a drug is deemed misbranded if 1) its labeling is false or misleading; 2) its required labeling information is not conspicuously placed; and 3) its labeling is not easily read or understood by the average consumer. The FDA further requires that drug labels

state directions for use, list of ingredients, the identity, net quantity of contents, explanation of tamper-resistant packaging, and approved uses. Finally, a nonprescription drug must also give warnings about dangers, side effects, and adverse reactions in terms easily read and understood by the average consumer, including persons of low comprehension.

Although the FDA encourages foreign-language labeling, the FDA does not require such labeling, except for nonprescription drugs distributed only in Puerto Rico and in an area where the primary language is not English. The FDA requires, however, that if the labeling contains any representation in a foreign language, then other required information must also be conspicuously stated in that foreign language.

Turning to the statutory standards prescribed by California law, the court found that California law follows the federal labeling requirements, and like the FDA, does not require foreign-language labeling. In other areas, however, the California Legislature has dealt with foreign-language requirements by enacting laws to make sure that its residents are not disadvantaged by their lack of proficiency in English. In defining the situations in which a foreign language must be used, the court found that the legislature had clearly defined where foreign language information was required, and that labeling nonprescription drugs in a foreign language was not among those specified areas. Given the foreign language requirements in other areas, the court reasoned that had the legislature wanted to require foreign language warnings, it would have done so. Therefore, the court concluded that the legislature, as well as the FDA, had deliberately chosen not to require manufacturers to include foreign-language warnings on nonprescription drug labels.

The court then analyzed alternative standards of care that the court might apply if it rejected the FDA regulations and California law as the

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governing standards. The court suggested two alternative standards of care: 1) a case-by-case basis where juries would apply the reasonable person standard; or 2) a judicially created standard of care. The court rejected the first alternative, explaining that this open-ended rule would compel manufacturers to package all their nonprescription drugs with warnings in multiple foreign languages which would add to the costs and environmental burdens of the packaging. The court also declined to declare a particularized standard of care since the judiciary lacks the procedures and the resources to make relevant inquiries. Thus, the court concluded that the administrative and statutory standards provided the best standard of care.

Although it did not foreclose the possibility of tort liability premised upon the content of foreign-language advertising, the court held that manufacturers do not have a duty to warn that is broader in scope and more onerous than that currently imposed by applicable statutes and regulations because the associated problems and costs would be too great. The court adopted the FDA's position that "it is in the best interest of the consumer, industry, and the marketplace to have uniformity in presentation and clarity of message" in the warnings provided with nonprescription drugs. The court reasoned that to preserve this uniformity and clarity, to avoid the problems and costs of foreign-language requirements, and to defer to the legislature, it adopted the legislative standard of care that required nonprescription drug warnings only in English. Thus, the court held as a matter of law that Plough was not liable for failing to warn Ramirez in Spanish about the dangers of Reye's syndrome.

The court also denied recovery on the plaintiff's alternative theories. Ramirez also argued that the labeling was defective because it should have warned against the use of SJAC for children with colds. The court stated that because the plaintiff's mother conceded that she had not read the

label, plaintiff's injury could not have been caused by the labeling. In his other theory, Ramirez also asserted that Plough should not have distributed SJAC at all since the dangers of Reye's syndrome outweighed any benefits of SJAC. The court, however, rejected this theory, stating that Plough was not liable for keeping its product in the market when plaintiff's mother bought it. At that time, the FDA had not determined whether Reye's syndrome was caused by aspirin, and therefore, the FDA had concluded that product warnings were sufficient.

Concurrence Addresses Potential Liability of Foreign-Language Advertising

Justice Mosk wrote separately to address the issue posed but not answered by the majority: the potential liability arising from foreign-language advertising based on tort theories of recovery. The concurrence agreed, however, that if a nonprescription drug manufacturer gave reasonable notice of possible side effects in a foreign language to a consumer whose purchase was induced in that language, the manufacturer would meet the standard of reasonable conduct. ♦

Kathie Yoo

Officers and Directors of Failed Federally Chartered Financial Institutions Will Be Held to a Gross Negligence Standard of Liability

In *Resolution Trust Corp. v. Gallagher*, 10 F.3d 416 (7th Cir. 1993), the United States Court of Appeals for the Seventh Circuit held that Section 1821(k) of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) preempts federal common law and establishes a gross negligence standard of liability for officers and directors of failed federally chartered financial institutions. However, the court purposefully chose not to reach the issue of whether Section 1821(k)'s gross negligence standard preempts state law, cautioning that federalism concerns require greater evidence of congressional intent to preempt state law than federal common law.

District Court Dismisses All RTC Claims

In 1990, the Resolution Trust Corporation (RTC) placed the Concordia Federal Bank for Savings (Concordia), a federally chartered and insured thrift, into receivership. On February 14, 1991, the RTC brought suit against Concordia's former directors and officers, seeking to recover losses for alleged negligence, breach of fiduciary duty, gross negligence, and breach of contract. The RTC maintained that the defendants' conduct caused Concordia to incur substantial losses, resulting in the thrift's failure. The defendants, under Fed. R. Civ. P. 12(b)(6), filed motions to dismiss for failure to state a claim.

The District Court for the Northern District of Illinois dismissed the negligence, breach of fiduciary duty, and breach of contract claims, holding that