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Consumer News

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CONSUMER NEWS

by Mark Allan Baginskis

Hospital Transfer Rules Don't Care About Motives

In *Roberts v. Galen of Virginia, Inc.*, 119 S.Ct. 685 (1999), the United States Supreme Court recently held that a patient, suing a hospital under the Emergency Medical Treatment and Active Labor Act, ("EMTALA"), for improperly turning the patient away, does not need to establish that the hospital had an improper motive for doing so. EMTALA, 42 U.S.C. § 1395dd, requires hospitals and emergency rooms to screen and stabilize patients who are experiencing an "emergency medical condition." The EMTALA defines many terms, such as what constitutes an emergency room, and even a hospital. It also gives rise to a private cause of action for its violation.

The *Roberts* case arose when a victim of a car accident was transferred out of the treating hospital after a six week stay. Plaintiffs argued that the patient was not in "stable" enough condition, as defined in EMTALA, for the hospital to legally transfer her. The U.S. District Court for the Western District of Kentucky entered summary judgment in favor of the hospital, holding that plaintiffs had failed to show that the hospital had an improper motive behind either the medical opinion that the patient was stable, or the decision to transfer the patient. The U.S. Court of Appeals for the Sixth Circuit affirmed, noting possible improper motives as race, sex, or indigency.

The Supreme Court reversed the court of appeals. The Court distinguished the main case upon which the appellate court had

relied, *Cleland v. Bronson Health Care Group, Inc.*, 917 F.2d 266 (6th Cir. 1990). *Cleland* had interpreted section 139dd(a) of the EMTALA, but the Court found that section 1395dd(b) more properly applied. In this section, there is no specific requirement on the "appropriateness" of treatment, instead referring only to a "medical examination" and the treatment necessary to "stabilize" the patient's medical condition. On its reading of this code section, the Court could find no requirement of improper motive, and reversed the grant of summary judgment and remanded the case to the trial court for further hearings.

Even though the opinion of the Court is brief, it does show some sign of encouragement for patients who sue under EMTALA. The standard used by the Sixth Circuit was too stringent. It required a plaintiff to show both a violation of the statute, and that the cause of the violation was improper motive on the part of the transferring hospital. This goes beyond the original intent of EMTALA, which was passed to protect indigent or uninsured patients from being transferred, (or "dumped"), because of their ability to pay. By removing the strapped-on improper motive requirement, the Supreme Court's decision in *Roberts v. Galen* provides some hope for patients, and unifies the analyses of the several Circuits consistent with the original purpose of the EMTALA.

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EPA Mandates Changes in Gas Stations' Storage Tanks

On December 22, 1998, the United States Environmental Protection Agency, ("EPA"), required gas station underground fuel storage tanks, ("UST"'s), to be virtually leak free, though the underlying regulation had been in effect for years. 40 C.F.R. Part 280 (1988). In fact, Nina Habib Spencer, an EPA spokesperson quoted in the Buffalo News, stated that the ten year compliance deadline is the longest such deadline in EPA history. Chet Bridger, *Tank Rules Leave Some Filling Stations On Empty*, Buffalo News, Dec. 30, 1998.

The change in the requirements for UST's is being driven by public safety concerns. The EPA recorded over 300,000 leaks in the past 10 years from underground tanks. Leaking UST's are hazardous to the environment, especially to a community's water supply. The problem is so severe that the EPA names the primary source of ground water contamination as leaking underground steel tanks. Worse still, automobile gasoline, which may leak from an UST, contains Benzene, a known carcinogen.

The newly enforced regulation does not require tanks to be pulled from the ground to be upgraded. The regulation merely requires that new installations and existing tanks be non-corrosive. To accomplish this in an existing steel tank, an

epoxy liner can be sprayed into the tank while it remains buried in the ground. This presents a practical alternative to replacing an existing tank with a new, fiberglass tank, which can cost as much as \$85,000, usually significantly more than epoxy spraying.

Unfortunately, the cost for upgrading old UST's falls on the gas station owner and can still be quite expensive. Depending upon the particular situation, the cost of upgrading old tanks can range from several thousand dollars, to as high as hundreds of thousands of dollars. If a gas station owner is not in compliance with the new standards, the owner will either have to stop using the tank or pay a heavy fine. The EPA regulations allow for a fine of up to \$11,000 a day per violating tank.

A gas station owner may continue operating, even if his UST's are not in compliance with the regulation. To do this he must obtain a consent order from the EPA. A consent order is generally granted if the violating gas station can show good faith attempts to comply with the regulation. This might include verification that items to bring the UST's into compliance are on order, or that a contractor has been retained to upgrade the UST's, but has not yet been able to perform the task. Some gas station owners are

taking the opportunity to upgrade the size of their tank when replacing them for regulatory compliance. Some gas station owners have been able to take advantage of this business opportunity by getting low-interest loans from their respective municipalities.

The EPA has indicated that this regulation was to target stations owned by major oil companies. Richard C. Dujardin, *Complying With Federal Rules Strains Gas Stations' Budgets*, THE PROVIDENCE JOURNAL, Jan. 4, 1999. In Rhode Island, however, the Rhode Island Department of Environmental Management has indicated that it will initially look at those stations that pose a greater threat to their surroundings, including homes and underground water supplies, regardless of ownership. Id..

The undeniable impact of this regulation has been to drive some independent gas station owners out of business. In areas of New York this has been especially true because of the small profit margin within the gasoline business. Chet Bridger, *Tank Rules Leave Some Filling Stations On Empty*, BUFFALO NEWS, Dec. 30, 1998. This may extend beyond New York as wholesale gasoline prices continue to fall, pinching retailers. *Gasoline Prices Plummet*, JOURNAL RECORD, (Okla. City), February 9, 1999.

Some owners simply could not justify the cost of upgrading their existing tanks and have decided not to continue within the gasoline business. Fortunately, many gas stations owners were also involved in the automobile repair business, and even without selling gasoline, have been able to continue their businesses, albeit in a limited capacity.

Beyond the gas station owners who may be closed because of the high cost of bringing their UST's within regulatory compliance, retail gas consumers may also be affected. Consumers will feel the impact by losing the local, well-known neighborhood service station that was able to provide both fueling needs and automobile service needs. Further, those gas stations that are able to absorb the costs of upgrading their UST's will almost certainly attempt to pass it along to consumers at the pumps.

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Federal Trade Commission Defines Standards for Dietary Supplements

On November 18, 1988, the United States Federal Trade Commission, ("FTC"), released "Dietary Supplements: An Advertising Guide for Industry." Though these guidelines do not create any new policy, they do clarify the existing rule that manufacturers of dietary supplements must substantiate their advertising, just as all other manufacturers of consumer goods who fall under the FTC's regulatory umbrella. 21 C.F.R. Parts 20 and 101 (1994). Dietary supplements, however, are not covered by the same rigorous procedures that ensure the safety of other drugs, under the United States Food and Drug Administration, ("FDA"). The FTC regulations require advertisers to have scientific proof to support the claims they use in marketing their products. This newest FTC guide explains that in evaluating dietary supplements, the FTC will look to consumers' perceptions, and whether consumers would expect claims made by a promoter to be supported by such proof.

Dietary supplements cannot legally assert to treat or prevent diseases, lest they fall under rigorous FDA regulation. To get around that restriction, claims such as "lowering blood pressure" may not be used, replaced by the label "stress relief." Even so, the FTC demands that the manufacturer support even that claim with scientific proof.

While the medical establishment and dietary supplement manufacturers have not always agreed upon claims that are made in dietary supplement advertising, the FTC guide legitimizes the alternative medical benefits of dietary supplements by requiring scientific proof. The FTC recommends that what needs to be provided by such an advertisement is "what experts in the relevant area of study would generally consider to be adequate." If a government agency already evaluates, say, "stress relief," with certain tests and standards, then the FTC will look to those standards, rather than allowing dietary supplement manufacturers to slant their research. To this end the FTC will not be relying completely on the number of studies performed, but will also weigh the quality of the research.

The FTC will not only consider the literal representations made to consumers, but will also look to the implications in an advertisement. The recent FTC guide should put dietary supplement companies on notice so that they avoid misleading advertising. If a consumer, based on the advertising, believes that a product will do something, that consumer may be using that inference to avoid proven traditional medicine, namely doctors and prescription drugs. If that advertising was misleading and the product does not work, that consumer could end up in trouble

medically. In addition to requiring scientific proof for claims, the FTC demands that disclosures of the limits of a dietary supplement's effectiveness not to be hidden in small type, be printed in clear language, and be placed near to the claim being qualified.

Nonetheless, there has been feedback that the FTC guide does not go far enough in addressing other important policy issues. The Council for Responsible Nutrition notes that when experts are used in advertising, the FTC guide does not provide enough guidance on whether there has been adequate claim substantiation. A dietary supplement attorney, Tony Martinez, states that the FTC considers "implied" claims in the same category as explicit claims. *The Tan Sheet*, Vol. 6 Issue 47, Nov. 23, 1998 (Food and Drug Commission). This poses a challenge for supplement companies in Martinez' eyes, because different individuals may draw their own, personal, conclusions about what a given advertisement means to them. It may be difficult for a manufacturer to anticipate all possible perceptions.

While this type of information would help the average consumer, it poses a greater challenge for the supplement makers. If supplement makers are required to put more information upon their advertisements, or if the advertisements are to substantiate potential claims, this could lead to the advertisements having an overload of information. This may confuse consumer more than help them.

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