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Product Liability **Update**

August 2009

In This Issue:

Foley Hoag LLP publishes this quarterly Update concerning developments in Product Liability and related law of interest to product manufacturers and sellers.

Massachusetts Supreme Judicial Court Holds Sale Terms Mandating Individualized Arbitration of Claims Violate Public Policy of Unfair and Deceptive Practices Statute Favoring Classwide Resolution of Small-Value Consumer Claims

In *Feeney v. Dell, Inc.*, 454 Mass. 192 (2009), plaintiffs filed a putative class action claiming defendant computer manufacturer had violated Mass. Gen. L. ch. 93A, the Massachusetts unfair and deceptive practices statute, by collecting sales tax on plaintiffs' purchase of service contracts when no such tax was actually due. Defendant, which was represented by **Foley Hoag LLP**, successfully moved to compel arbitration of the named plaintiff's individual claims pursuant to a provision of the terms and conditions of sale mandating arbitration on an individual basis of any claim against defendant arising from the sale. After the arbitrator ruled for defendant on the merits, the trial court denied plaintiffs' motion to vacate the arbitration award and to reconsider the initial order granting defendant's motion to compel arbitration. Plaintiffs appealed and the Supreme Judicial Court granted their application for direct appellate review.

Plaintiffs first argued that the mandatory individual arbitration provision was unenforceable because it violated Massachusetts public policy. The court recited the legislative history of ch. 93A, particularly the 1969 amendments that first created a private remedy for unfair and deceptive acts and practices (previously, the attorney general had exclusive power to enforce the statute). The court reasoned that the amendments' provisions for a statutory minimum damages amount, attorney's fees, treble damages and class actions demonstrated a legislative purpose to provide a class-based remedy for small-value consumer claims that would be uneconomical to litigate on an individual basis. The court rejected defendant's argument that the attorney's fees and multiple damages provisions of ch. 93A were sufficient to vindicate a consumer's right to seek relief for an individual small-value claim, reasoning that those provisions would not guarantee that the consumer would be able to attract counsel willing to prosecute the claim without the ability also to aggregate any relevant class of claims. The court added that the mandatory individual arbitration provision also violated public policy by undermining the public interest in preventing wrongdoing and negatively affecting not only the rights of the consumer who is compelled to arbitrate, but also those of the "unnamed class members" whose rights the consumer seeks to vindicate. The court made clear that it was the individualized nature of the mandatory arbitration, not the fact of mandatory arbitration itself, that violated public policy.

After determining that the arbitration provision violated Massachusetts public policy, the court next refused to enforce the terms and conditions' choice-of-law provision requiring the

application of Texas law, the law of the state where defendant was headquartered. The court noted that the mandatory individual arbitration provision would likely be upheld under Texas law, but held that Massachusetts' interest in vindicating its "fundamental policy" favoring class actions for small-value consumer protection claims under ch. 93A was materially greater than Texas' interest in minimizing corporations' legal expenses, thus mandating application of Massachusetts law.

The court further concluded that its application of a public policy defense did not contravene the Federal Arbitration Act's guarantee that agreements to arbitrate are "valid, irrevocable, and enforceable, save upon such grounds that exist at law or in equity for the revocation of any contract," because a public policy defense is a generally applicable tenet of contract law. Finally, in reaching the merits, the court concluded that defendant's remitting the sales taxes it had collected on the service contracts to the Commonwealth of Massachusetts revealed that defendant's collection of the taxes was motivated by a perceived legislative mandate and hence was not unfair or deceptive under ch. 93A, and accordingly ordered plaintiff's complaint dismissed without prejudice.

Massachusetts Federal District Court Holds Requirement that Electronic Documents be Produced as Kept in Usual Course of Business Requires Production of Files in "Native" Format But Does Not Require Producing Party to Scan Electronic Documents for Optical Character Recognition, Refuses to Require Blanket Production of Electronic Documents' Metadata

In *Dahl v. Bain Capital Partners, LLC*, 2009 WL 1748526 (D. Mass. Jun. 22, 2009), plaintiffs initiated an antitrust action in the United States District Court for the District of Massachusetts against multiple private equity firms and investment banks regarding certain leveraged buyouts. After the parties failed to agree on aspects of electronic discovery sought by plaintiffs, plaintiffs sought entry of an order governing the discovery's format.

Turning first to the parties' dispute over who should bear the costs of producing electronic discovery, the court stated the general presumption that a party must bear its own discovery costs, but further noted that costs may be shifted as to electronic discovery if the responding party identifies the source of the requested documents as not reasonably accessible due to undue burden or cost. As defendants had not identified any such accessibility issue, the court held that defendants had to bear their costs of electronic production. The court also held, however, that defendants did not have to bear the costs of optical character recognition ("OCR") scanning of responsive paper documents or electronic documents that lack text searching capability, as requested by plaintiffs, because Fed. R. Civ. P. 34 only required defendants to produce responsive documents as they are kept in the usual course of business, so that plaintiffs must pay defendants for any requested scanning.

In two paragraphs that appear to address issues not raised by plaintiffs' motion, the court added that, while Rule 34 suggests that a responding party should "translate" electronic documents where necessary to make them "reasonably usable," plaintiffs had not demonstrated that translation was necessary. The court also stated that, if defendants elected to change the format of any electronic documents for their own use in the litigation, they should offer plaintiff access to those altered documents.

Turning next to the parties' disputes about the form in which the electronic documents would be produced, the court rejected plaintiffs' request for all metadata (i.e., electronic information reflecting the document's drafting history, ownership, location, etc.) associated with e-mails and word processing documents, noting that multiple courts and the Advisory Committee notes to the 2006 amendment to Rule 34 have all expressed concern that metadata production is expensive, burdensome and inefficient. The court instead encouraged plaintiffs to tailor their metadata request to specific documents or sets of documents. The court further held that spreadsheets must be produced in their "native" format in accordance with Rule 34's requirement that documents are to be produced as kept in the usual course of business. The court observed that production in native format is necessary to assure that integral elements of the spreadsheets, such as formulae, remain undisturbed. Finally, the court ordered defendants to produce privilege logs in native format.

Massachusetts Federal District Court Holds Plaintiffs' Pharmaceutical Causation Experts' Opinions Admissible Because Based on Extrapolation of Collective Epidemiological Study to Drug at Issue, Evidence of Biological Plausibility and Adverse Event Reports

In *In re Neurontin Marketing, Sales Practices, and Products Liability Litigation*, 612 F. Supp. 2d 116 (D. Mass. 2009), numerous plaintiffs sued the manufacturers of an anti-epilepsy drug in various courts alleging they or their decedents had suffered various injuries including suicidal behavior or ideation ("suicidality"). The federal court actions were consolidated in the United States District Court for the District of Massachusetts, where defendants moved to exclude the testimony of three of plaintiffs' expert witnesses pertaining to the plaintiffs' product liability claims. The experts intended to opine that the drug increased the level of the chemical neurotransmitter GABA in the brain, which in turn led to a decrease in the level of several other neurotransmitters, particularly serotonin, causing adverse mood and behavioral disturbances, some of which ultimately led to suicidality. The opinions pertained only to the issue of the drug's alleged general causation, rather than plaintiff-specific causation, of suicidality.

The court first described its "gatekeeping" role under Federal Rule of Evidence 702 and *Daubert v. Merell Down Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The court emphasized that its task was to assess the reliability of the plaintiffs' experts' methods and data, not the proffered opinions' ultimate correctness. The court used as a framework for its analysis the "Bradford Hill criteria" developed by the British epidemiologist of the same name, particularly the criteria pertaining to the strength of the association between the drug's use and an increased risk of suicidality and the biological plausibility of a causal relationship. Applying that framework, the court found that plaintiffs' experts' opinions were based on sufficiently reliable methods and data to be admissible.

The court first considered defendants' contention that, because no epidemiological or other evidence associated the drug with suicidality, any expert testimony regarding how the drug causes suicidality was irrelevant and inadmissible. The court observed that, although epidemiological studies are not necessary, establishing causation without some evidence associating alleged cause with alleged effect "can be an uphill battle." The court, however, credited plaintiffs' invocation of a 2008 Food and Drug Administration study ("FDA study") that found that a group of anti-epilepsy drugs, which included the drug at issue, was associated with an increase in suicidality, but that the drug at issue was associated with suicidality events only in a non-statistically-significant fashion. The court acknowledged defendants' criticisms of aspects of the study's methodology and analysis—notably that its conclusion was driven by drugs other than the one at issue—but concluded that these criticisms went to the weight of the study rather than its admissibility. The court also concluded that, although the FDA study found no statistically significant association between the drug at issue and increased suicidality, plaintiffs' experts could reliably opine that the study's conclusion that a sub-group of drugs including the drug at issue had a statistically significant association with increased suicidality could be extrapolated to apply to the drug at issue. The court, however, acknowledged that the study alone was insufficient to establish causation because the FDA's standard for finding association differed from the standards for establishing causation for the purpose of tort liability.

The court then assessed the biological plausibility of the experts' causation theory. As to the first step of that theory, the court noted that it was undisputed that the drug increased the level of GABA in the brain. As to the second step, that the increase in GABA led to a decrease in other neurotransmitters including serotonin, the court noted that plaintiffs' experts claimed that certain published, peer-reviewed *in vitro* animal studies showed such a decrease, while defendants' experts disputed that those studies applied to humans; and defendants' experts claimed that certain published, peer-reviewed *in vivo* human studies showed no such decrease, while plaintiffs' experts interpreted those studies differently. The court concluded that the studies cited by plaintiffs' experts, as well as certain internal and external communications by defendants which supported the conclusion that an increase in GABA led to a decrease in serotonin, constituted "good grounds" to support that conclusion. The court further noted that the difference in opinion between plaintiffs' and defendants' experts suggested that reasonable experts might differ on the issue and therefore supported the court's conclusion to submit the issue to the jury. Finally, as to the third step, the court noted that there was wide acceptance in the scientific community that decreased levels of serotonin were associated with depression, aggression and suicide, and that defendants' expert admitted as much.

Defendants challenged plaintiffs' proffer in support of their causation theory of reports of alleged adverse events experienced in patients taking the drug as irrelevant, on the ground that many of the events concerned patients' depression, hostility, confusion and other behaviors short of actual suicidality. The court, however, concluded that such events were relevant because such abnormal behaviors were antecedent to actual suicidality under plaintiffs' causation theory. Finally, the court concluded that one of plaintiffs' experts—who had a doctorate in pharmacology and toxicology and served as a consultant to pharmaceutical companies in preparing submissions to the FDA and evaluating post-marketing adverse event reports—was qualified to testify about the adverse event data and "other sources of information regularly used by the FDA and industry professionals," even if not as to the medical aspects of plaintiffs' theory of causation.

Massachusetts Federal District Court Denies Certification of Putative Class of Consumers and Third-Party Payors Alleging Fraudulent Marketing of Drug Because Causation Could Not Be Demonstrated by Classwide Statistical Evidence and Hence Common Issues Regarding Marketing Would Not Predominate Over Individual Issues of Causation

In *In re Neurontin Marketing, Sales Practices and Products Liability Litigation*, 257 F.R.D. 315 (D. Mass. 2009), plaintiffs sued the manufacturers of an anti-epilepsy drug in various courts alleging that defendants had engaged in a fraudulent campaign to market and sell the drug for "off label" indications for which defendants knew the drug was ineffective. Plaintiffs sought economic damages on theories of common law fraud, unjust enrichment, violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO") and violation of the New Jersey Consumer Fraud Act ("NJCFA"). Plaintiffs moved to certify a nationwide class consisting of all consumers and third-party payors ("TPPs"), such as health plans, that paid for a prescription of the drug to treat an off-label indication.

Applying the class certification requirements of Fed. R. Civ. P. 23(a) and 23(b)(3), the court first found that the "questions of law or fact common to the class" criterion required only the existence of a single issue common to all putative class members and is a "low bar." The court held that plaintiffs satisfied that requirement by proposing separate consumer and TPP sub-classes for each of five identified off-label indications (i.e., for a total of ten sub-classes) and proposing effective dates of the sub-classes to correspond with the dates on which defendants allegedly knew the drug to be ineffective for the relevant off-label indication.

In support of the criterion that the class be "so numerous that joinder of all members is impracticable," plaintiffs submitted an expert report estimating the number of consumer prescriptions written for each off-label indication for a portion of the time period covered by the proposed consumer sub-classes, all of which were in the millions. The court held based on this report that the proposed consumer sub-classes satisfied the numerosity requirement. The same report also calculated: (1) how large a TPP health plan would need to be to state with 99%, 95%, and 90% certainty that the TPP paid for a prescription of the drug for at least one of its members for each off-label indication; and (2) the number of TPPs that fit that description based on publicly available information about TPPs' sizes. Although defendants argued that plaintiff's methodology assumed that the membership of each TPP mirrored the composition of the general population, the court held that the number and geographic diversity of the proposed class of TPPs easily rendered their individual joinder as plaintiffs impracticable and that defendants' argument related to the typicality and predominance requirements, which the court turned to next.

On the first of those issues, the court held that the consumers and TPPs proposed as sub-class representatives were typical of their respective sub-classes, despite defendants' argument that some of the consumer sub-class representatives had praised the drug, or never expressed concern about its effectiveness, while they were taking the drug.

Finally, the court noted that the prong of Rule 23(b)(3) requiring that "questions of law or fact common to class members predominate over any questions affecting only individual members" posed the most substantial hurdle to class certification, because both RICO and the NJCFA required that a defendant's conduct be the proximate cause of a plaintiff's injury. Although the court had expressed willingness in a 2007 decision in which it denied an earlier motion for class certification to accept a statistical analysis showing that "essentially all" prescriptions of the drug for an

off-label indication were a result of defendants' alleged fraud, the court backtracked from that position, citing a recent New Jersey Supreme Court decision forbidding the use of statistical evidence to establish a presumption of causation under the NJCFA and recent United States Courts of Appeals decisions casting doubt on the use of a "fraud-on-the-market" or similar theory to establish a classwide presumption of causation.

Nonetheless, plaintiffs offered a statistical report as to the proposed consumer sub-classes based on the assumption that physicians prescribed the drug for off-label indications based on four factors: (1) the retail price of the drug; (2) the retail price of the drug's competitors; (3) the amount spent by defendants to market the drug, especially by sending sales "details" to physicians' offices; and (4) the amount spent by defendants' competitors to market their competing drugs. After noting that a recent decision of the United States Court of Appeals for the First Circuit required the trial court to closely scrutinize a novel or complex theory of injury at the class certification stage rather than wait for a *Daubert* motion and hearing addressing the theory on the merits, the court held that plaintiffs' statistical analysis was too limited to provide a shortcut to causation and satisfy the predominance requirement as to the proposed consumer sub-classes. In reaching this holding, the court observed that only one of the five physicians who prescribed the drug to the consumer sub-class representatives had been visited by a sales "detail," and two of the five had explicitly prescribed the drug for some reason other than the drug's marketing.

With respect to the proposed TPP sub-classes, the court held that causation was properly analyzed not at the level of the prescribing physician but rather at the level of the committee that authored the "formularies," or pharmaceutical reimbursement schedules, used by the TPP. The court held that the only evidence plaintiffs had provided that defendant's marketing activities influenced the formulary committees was a blanket assertion that defendant had perpetrated a fraud on the entire pharmaceutical market, an assertion that the court held insufficient to satisfy the predominance requirement as to the TPP sub-classes. Because plaintiffs failed to demonstrate the predominance of common issues over individualized issues of causation as to any of the proposed consumer or TPP sub-classes, the court denied plaintiffs' motion for class certification in its entirety.

Massachusetts Federal District Court in Action Alleging Off-Label Promotion of Drug Dismisses Fraud Claims For Failure to Allege Physicians' Reliance on a Particular Misrepresentation, Refuses to Dismiss Fraudulent Concealment Claims as Duplicative of Failure-to-Warn Claims Because of Scienter Requirement of Fraudulent Concealment

In *In re Neurontin Marketing, Sales Practices, and Products Liability Litigation*, 618 F. Supp. 2d 96 (D. Mass. 2009), numerous plaintiffs sued the manufacturers of an anti-epilepsy drug in various courts alleging that plaintiffs or their decedents suffered various injuries including suicidal behavior or ideation ("suicidality"). The federal actions were consolidated in the United States District Court for the District of Massachusetts, where defendants moved to dismiss the fraud claims in twelve amended complaints, which generally alleged that defendants engaged in a fraudulent scheme to market the drug for off-label uses by misrepresenting to physicians the drug's safety and effectiveness for such uses and failing to disclose details of the drug's side effects including suicidality.

As a preliminary matter, the court emphasized the requirement of Fed. R. Civ. P. 9(b) that circumstances alleged to constitute fraud be pleaded with particularity. The court also held as a preliminary matter that a drug manufacturer has a duty affirmatively to disclose to physicians and patients material facts about the risks of a drug, especially when it is engaged in marketing the drug for non-FDA-approved uses, if it knows the plaintiff and/or his prescriber does not know or cannot reasonably discover the undisclosed facts.

The court observed that seven of the twelve amended complaints failed to allege any particular connection between the physician's decision to prescribe the drug for an off-label use and defendants' marketing and advertising campaign. The court rejected plaintiffs' argument that defendants' campaign was so pervasive that any prescribing physician was "most likely influenced" by it or by another physician who was in contact with defendants, analogizing that argument to the securities law theory of "fraud on the market" and holding that different concepts and policies underlie securities markets than the pharmaceutical industry. The court thus dismissed these seven amended complaints' fraud claims for failing to allege that a physician relied on a specific statement or misrepresentation.

Turning to the amended complaints that alleged that defendants visited a physician's office to promote the drug for off-label use, the court found that one amended complaint alleged an affirmative misrepresentation with particularity and accordingly was not subject to dismissal. Plaintiffs argued the remaining amended complaints did not need to allege an affirmative misrepresentation to make out fraud because defendants had a duty to disclose details of the drug's side effects, including suicidality, where defendants knew that over 90 percent of the drug's use would be off-label. Although defendants responded that plaintiffs' argument rendered such fraudulent concealment claims duplicative of plaintiffs' failure-to-warn claims, the court disagreed, finding that such claims, unlike failure to warn, required scienter in the form of an intent to deceive. The court accordingly declined to dismiss plaintiffs' fraudulent concealment claims.

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