ARNOLD & PORTER LLP

# Product Liability Litigation Update

Recent Developments in the Law

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## Third Circuit Upholds Denial of Class Certification on Consumer Fraud and Unjust Enrichment Claims

In *Grandalski v. Quest Diagnostics Inc.*, --- F.3d ---, 2014 WL 4455034 (3d Cir. Sept. 11, 2014), the Third Circuit upheld the denial of class certification in a lawsuit where plaintiffs asserted dozens of state consumer fraud claims along with unjust enrichment claims, finding the district court correctly determined such claims required individualized treatment.

Plaintiffs alleged that defendant improperly overbilled patients for diagnostic and clinical testing. Plaintiffs sought to certify a class of all persons overbilled by defendant, asserting multiple causes of action on behalf of the proposed class including violation of dozens of state consumer fraud laws and unjust enrichment. The district court denied class certification: finding application of numerous different state consumer fraud statutes would be "unwieldy and inappropriate for class treatment at trial." 2014 WL 4455034, at *1. The district court further held that "the evidentiary showing required for each class member to show unjust enrichment would be highly individualized" and accordingly denied certification as to that claim.

The Third Circuit upheld the denial of class certification. First, the court held that the law of each consumer's domicile governed the claims at issue. Second, the court rejected plaintiffs' proposed grouping of the state consumer fraud statutes into two categories -- those proscribing "unfair or deceptive" conduct and those prohibiting false or misleading conduct -- recognizing that while "grouping, in general, may be a permissible approach to nationwide class action litigation, in this case [plaintiffs] did not provide enough information or analysis to justify the certification of the classes they proposed." *Id*. at * 7. Plaintiffs failed to carry their burden of showing the proposed grouping was workable because they merely asserted that the state law differences were "insignificant," but failed to provide analysis showing this was true. Third, as to the unjust enrichment claims, the Third Circuit held that the district court "properly found that individual inquiries would be required to determine whether an alleged overbilling" was unjust for each class member by providing expert testimony on this issue, and "[s]uch specific evidence is incompatible with representative litigation." *Id*. at *8.

The *Grandalski* decision is a welcome one to defendants resisting multi-state class certification of consumer fraud claims. No doubt plaintiffs will characterize it as a narrow decision based on the failure of the particular litigants to supply adequate proof that "grouping" by state law was feasible. But the court properly emphasized that -- outside of the settlement context where a class is to be tried -- "plaintiffs face a significant burden to demonstrate that grouping is a workable solution." *Id*. at *7 (citations omitted).

## U.S. Supreme Court to Consider Review of Federal Preemption for Generic Drug Manufacturers

As the October 2014 Term gets under way, the U.S. Supreme Court is awaiting the Solicitor General's views on whether it should grant a certiorari petition to resolve whether "failure-to-update" claims against generic

drug manufacturers are preempted. The petition, filed by generic drug manufacturer Teva Pharmaceutical USA Inc. ("Teva") in *Teva Pharmaceuticals USA Inc. v. Superior Court of California*, case number 13-956, asks the Court to provide clarity regarding the scope of its prior decision in *Pliva Inc. v. Mensing*, 131 S. Ct. 2567 (2011), holding that federal preemption bars failure-to-warn claims against a generic drug manufacturer whose labeling mirrors the Food and Drug Administration ("FDA") approved labeling for the brand-name equivalent of the generic drug. The question raised is whether plaintiffs can avoid preemption by arguing that the generic company did not timely change its label to mirror the brand equivalent's labeling. After briefing by the parties on the certiorari petition closed earlier this year, on June 30, 2014, the Supreme Court invited the Solicitor General to file a brief in this case expressing the views of the United States. That brief is expected to be filed in the coming weeks.

In the case leading to Teva's certiorari petition, a plaintiff sued several manufacturers of a generic form of the osteoporosis drug Fosamax, claiming they failed to immediately update their labeling to match the labeling of Fosamax or send a Dear Doctor Letter consistent with the updated labeling to healthcare providers, and thereby caused the plaintiff's alleged injuries. Teva argued that the plaintiff's claims were preempted as a thinly veiled attempt to enforce the Food, Drug, and Cosmetics Act ("FDCA"), which only the federal government has authority to do. Without the FDCA and the FDA, Teva argued, there would be no duty for generic companies to "update" their label. Teva also argued that it could not have sent a Dear Doctor Letter because it would have inaccurately implied a difference between the brand and generic drugs. But both a California state trial court and the California Court of Appeal rejected these arguments, holding that the plaintiff's claims were based on the alleged failure to properly update the label under California law, which parallels the federal safety requirements arising under the FDCA, and were not direct claims to enforce the FDCA. The California courts also reasoned that updating the generic label or sending a Dear Doctor Letter containing the same information as on the FDA-approved brand-name labeling would not have conflicted with Teva's federal duties.

Teva's petition for review with the California Supreme Court was rejected, and it subsequently filed a certiorari petition in the U.S. Supreme Court. The question presented by Teva is: "Whether the California Court of Appeal erred when it deepened an acknowledged circuit split and held . . . that federal law does not preempt state tort claims predicated on allegations that a generic drug manufacturer violated the FDCA by failing to immediately implement or otherwise disseminate notice of labeling changes that the [FDA] had approved for use on a generic drug product's brand-name equivalent."

Whether the U.S. Supreme Court grants Teva's certiorari petition should be closely watched because it may resolve a circuit split and the issue of whether failure-to-update claims are preempted under *Mensing*. The Solicitor General's forthcoming brief should provide insight into the likelihood of the petition being granted.

## Pharmaceutical Industry Calls FDA Draft Twitter Guidance Unconstitutional

PhRMA and other industry organizations took issue with the United States Food and Drug Administration's ("FDA") recent proposed guidance regarding promotion through character-limited communications such as the popular social media site Twitter. FDA issued draft guidance in June 2014, indicating that prescription drug and medical device manufacturers should not use Twitter unless they can include both benefit and risk information within the same tweet (a "tweet" is a maximum 140-character message posted via Twitter). *See Internet/Social Media Platforms with Character Space Limitations--Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices*, 79 Fed. Reg. 34759 (June 18, 2014).

Under the draft guidance, manufacturers of prescription drugs and medical devices should incorporate both benefit and risk information within the same communication, regardless of space or character constraints. If the manufacturer cannot do so, it "should reconsider using that platform for the intended promotional message." As for risk information, FDA stated that the communication should include, at a minimum, the most serious risks, which would include all risk concepts from a boxed warning, all risks known to be fatal or life threatening, and all contradictions from approved product labeling. Additionally, the communication should contain a direct link to a webpage devoted exclusively to the communication of risk information.

Several industry organizations have filed comments challenging the draft guidance as both unworkable and unconstitutional. The Medical Information Working Group ("MIWG"), for one, has commented that the draft guidance is "tantamount to a ban on the use of space-limited communications," like Twitter. Citing *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), MIWG argued that the draft guidance violates the First Amendment because it targets a certain class of speakers -- manufacturers -- and a certain type of speech -- truthful statements about medical products. MIWG, PhRMA, and the Bio Industry Organization also filed comments noting that the draft guidance appears to be inconsistent with how FDA itself has utilized character-limited

communications like Twitter. For example, PhRMA commented that FDA's own tweets announcing new drug approvals contained only benefit information and a link to the news release that describes risks and additional benefit information. PhRMA further commented that as "a matter of First Amendment law and logic, it cannot be truthful for FDA to use Twitter in this way but misleading for product sponsors to do the same."

The comment period closed on September 16, 2014. It is well worth watching how FDA will revise the final guidance based on these responses from the pharmaceutical industry.

For questions or comments on this newsletter, please contact the Product Liability group at product@aporter.com.