

## **Preemption: Buckman Company v. Plaintiffs Legal Steering Committee**

On February 21, 2001, the United States Supreme Court issued its opinion in Buckman Company v. Plaintiffs Legal Committee, 531 U.S. 431, 2001 U.S. LEXIS (Feb. 21, 2001). Buckman stands for the proposition that state law fraud-on-the-FDA claim's and nothing more, are impliedly preempted by the Food Drug and Cosmetic Act. See, Globetti v. Sandoz Pharmaceutical Corporation, 2001 WL 41960 (N.D. Ala. 2001).

Buckman involved facts where a manufacturer of spinal pedicle screws sought approval for its product under Section 501(k) of the Medical Device Act Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act (FDCA). (Additionally, it should be pointed out that Buckman arose out of the pedicle screw MDL proceedings.) By the Court's definition, the MDA has a lengthy and involved approval process for medical devices, but also includes Section 501(k), allowing for abbreviated approval when the product application relates to products that are "the substantial equivalent to a predicate device." A predicate device is one that was marketed prior to the enactment of the MDA Amendments to the FDCA in 1976. In Buckman the product sponsor (AcroMed) previously submitted two applications under Section 501(k) of the MDA for approval to market its pedicle bone screw device for use in spinal surgery, and AcroMed was denied both times for lacking sufficient grounds showing "substantial equivalence" to a predicate device. Undaunted by the FDA's position, AcroMed enlisted the assistance of Buckman Company in its third 501(k) application submission.

In an attempt to gain approval Buckman Company broke AcroMed's product down into its component parts, renamed them, and submitted a third 501(k) application on behalf of AcroMed. Despite AcroMed's two prior 501(k) applications for its product

use in spinal surgery, Buckman's application on behalf of AcroMed renamed the products nested bone plates and cancellous bone screws, and represented to the FDA that approval was sought for "use in long bones of the arms and legs." AcroMed and Buckman claimed 501(k) substantial similarity to predicate devices used in long bone surgeries, and received FDA approval. Defendant then immediately began off-label marketing of the screws for use in spinal surgery.

Plaintiffs in Buckman alleged that AcroMed and Buckman made fraudulent statements to the FDA regarding the intended use for the bone screws, and that as a result the screw was improperly approved for market use, all to plaintiffs' detriment.

The United States Supreme Court held that plaintiffs' fraud-on-the-FDA claims were impliedly preempted by the Food, Drug and Cosmetic Act (FDCA). Buckman, 531 U.S. at 348. The Court stated that:

the conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the administration and that this authority is used by the administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the administration can be skewed by allowing fraud-on-the-FDA claims under state tort law. Id.

The Court further noted that the relationship between the agency and the industry it regulates is "inherently federal in character", as all aspects originate under and as a result of federal law. Id.

The Court's decision states two primary policy reasons. The Court noted the difficult task the administration faces in administering the FDCA, while not interfering with the practice of medicine. The Court explained that the administration must regulate without controlling the practice of medicine and without restricting the "valid practice" of

off-label uses of products. It also noted that the FDA had at its disposal manners of dealing with fraud, but that it had not undertaken any action against Buckman or AcroMed -- a point the Court found extremely relevant. Secondly, the Court postulated that allowing state fraud-on-the-FDA claims put too much of a burden on defendants, and could have a chilling effect on applications for necessary and innovative medical products and devices.

Defendants in pharmaceutical actions have seized upon the policy themes set out in the Buckman decision in attempting to overreach and over-apply this very limited opinion. Until reined in by appropriate appellate decisions, plaintiffs will see Buckman as part of a defendant's standard 1-2 punch, along with Daubert motions.

In the dicta of this opinion, however, the Court provided plaintiffs in pharmaceutical and medical device actions with the upper hand when challenged with Buckman issues. In discussing the plaintiffs' reliance on Silkwood v. Kerr McGee Corporation, 464 U.S. 238, 104 S.Ct. 615 (1984), the Court distinguished the claims in Silkwood as relying entirely on "traditional state tort law principles," whereas in Buckman plaintiffs relied entirely upon the transactions between the defendant corporations and the FDA. Thus, while a plaintiff under Buckman can not predicate liability solely upon a defendant's transactions with the FDA, traditional state law tort claims are alive and well.

One Federal District Court decision that underscores the limited nature of Buckman rather well arose in the Northern District of Alabama, in Globetti v. Sandoz Pharmaceutical Corporation, 2001 WL 419160 (March 5, 2001). It is interesting to note first the rapidness with which defendants seized upon the Buckman ruling, and began

their collective attempts to stretch the opinion beyond its natural bounds; the Globetti opinion was rendered thirteen (13) days after Buckman. The issue presented in Globetti was whether Buckman precluded any *claim* or *evidence* of a defendant company's communications with the FDA. In essence, defendant was seeking summary judgment on plaintiffs' fraud on the medical community and inadequate warnings claims because such claims involved evidence of the interactions between the defendant corporations and the FDA, and as such defendants alleged the claims would be preempted under Buckman. The Court was "unpersuaded" with defendants' arguments that Buckman preempts state law tort claims of fraud, fraudulent suppression, negligence or inadequate warning. The Northern District, through the Chief Magistrate Judge, held that the only claim impliedly preempted under Buckman was a claim of fraud-on-the-FDA. The Court noted:

"Notwithstanding that information may have been misrepresented to or concealed from the FDA, once defendant undertakes to misrepresent those facts to plaintiff, or to conceal facts it was bound to disclose, the plaintiff's claim no longer rests simply on the assertion that the agency was defrauded, but on the additional fact that she was defrauded.

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"Thus, while plaintiff can not recover simply because defendant defrauded a federal agency, nothing in Buckman suggests that [plaintiff] can not recover where the misrepresentations or suppressions were directed *at her* (through her physician) or when the warnings given (even though FDA approved) inadequately disclosed the hazards of the product."

Regarding inadequate warning claims, and notwithstanding the package inserts are approved by the FDA, the Court noted that the company's duties ran to the consumer as

well, and inadequate warning claims -- presumably couched either in negligence or fraud theories -- survive Buckman as well. In this context, the Globetti opinion states:

“Defendant owed separate duties beyond simply full and fair disclosure to the FDA, duties not to market a defective and unreasonably dangerous product, not to misrepresent or suppress the facts needed by *physicians and consumers* to assess the safety of the product, and to adequately warn of the known risks associated with it.”

The Court also parenthetically noted that the allowance for traditional state law theories of recovery against pharmaceutical defendants presents an example of why the duty to warn is not limited simply to what has been approved by the FDA. In essence, the Court points out that allowing such a broad protection in the context of FDA approved labeling would create incentives for pharmaceutical companies to oppose administration generated updates to packet inserts, or in fact to ignore its duty to warn based on new information, while relying solely upon and outdated and perhaps inaccurate product insert. So, if you are filing a pharmaceutical action in the Northern District of Alabama confidently raise your state law tort claims.

From a fair reading of the limited number of cases wherein defendants have attempted to wave the Buckman banner of preemption, the theme that continues to surface is that defendants seek to push the courts' decision beyond its natural bounds, and argue for excluding *evidence* rather than preempting a singular *claim*. In distinguishing Silkwood, the Buckman Court made clear, as did the Globetti court, that traditional state law claims can and do survive Buckman, yet defendants continue to try to shape this aspect of the law through a continued insistence of evidence exclusion. As stated previously, this will continue to be a significant battleground for plaintiffs.

Be aware of aberrant decisions that will likely be cited by defendants in their attempts to stretch Buckman. One such case is Flynn v. American Home Products Corporation, 627 N.W. 2d 342 (MN Ct. App. 2001). Flynn involved a strange pleadings scenario; plaintiff sued American Home Products (AHP) for injuries she received while taking a generic equivalent of AHP's prescription diet medication, manufactured by an Italian corporation. Plaintiff Janet Flynn did not sue the Italian entity, but rather AHP based on the theory that but-for its representations to the FDA its -- nor the Italian corporation's generic -- product would have been approved for marketing, and thereby taken by plaintiff. Like Buckman, Flynn alleged a fraud-on-the-FDA claim specifically. The Minnesota Appellate Court found that implied preemption did in fact apply, and further noted that defendant AHP did not owe Flynn the same duty it owed to people who actually purchased and took AHP's product. Flynn, 627 N.W. 2d at 350. Flynn is clearly distinguishable from your traditional pharmaceutical products case, and should hold no authority for preemption in a typical scenario, where plaintiff in fact takes defendant's product.

In conclusion, we should all be mindful of Buckman, but we should not shy away from the strong evidence contained in the records evidencing defendants' dealings with the FDA. Remember, evidence is evidence, and claims are claims. Under the well pled complaint doctrine, it is defendant's obligation to show the Court that a case "arises under" federal law and is removable or pre-empted only if a federal claim exists on the face of plaintiff's complaint. Dukes v. U.S. Health Care, 57 F.3d. 350, 353 (3rd Cir. 1995). The Rules of Evidence, Rules 105 and 404(b) (Alabama or Federal) are our friends; they allow for the introduction of evidence for limited purpose. Rely on these

rules, follow the well pled complaint doctrine, and use this powerful evidence to support your state law theories of liability.