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**MASS TORTS (DRUG AND MEDICAL DEVICE) LITIGATION,
PUTTING A NEW FACE ON COMMON TORT THEORIES**

Finding a consistent and widely accepted definition of mass torts is a difficult task. To some, it is synonymous with pharmaceutical products liability litigation; to others, it is a pseudonym for toxic torts; to others, it is perhaps more than these, and to others less. But consistent through the incarnations that we place on this term (mass torts) is the fact that it relates to litigation of very specific products that are, for the most part widely used, and in the same manner -- or similarly so -- by all end users. Drug and medical device litigation clearly fits within this definition.

An overview of the theories of liability commonly used in drug and medical device litigation holds no great pearls of wisdom or secrets heretofore unknown to the members of the bar; the difference is the complexity of the factual underpinnings of these theories. That is, how do we allege and prove our legal theories against the makers or marketers of drugs and medical devices. This paper will attempt to briefly review the commonly plead theories of negligence, negligence per se, warranties (expressed and implied), AEMLD/strict product liability (this topic will be covered by another presenter in this seminar, and therefore, I will only touch briefly on this topic), fraud, and, briefly, deceptive trade practices claims.

Following a very cursory review of the general tort theories commonly pled in drug and medical device litigation, I will briefly touch upon two common defense strategies used to thwart plaintiffs' claims: Daubert v. Dow Merrill Dow Pharmaceuticals, *infra.*; and, Buckman Corp. v. Plaintiffs Legal Committee, *infra.* Additionally, this paper will offer some thoughts as to where to find the factual basis for plaintiffs' theories.

Negligence:

Universally, a claim for negligence consists of four (4) elements that must be established for plaintiff to prevail and recover:

1. The existence of a duty on the part of a defendant, running to plaintiff or a class of individuals of which plaintiff is a member;
2. A breach of that duty;
3. The existence of a causal relationship between defendant's conduct and plaintiff's injuries; and
4. Resulting damage to the plaintiff. W. Keeton, Prosser & Keeton on Torts § 28-30 (5th Ed., 1984); Ford Motor Company v. Burdeshaw, 661 So. 2d 236 (ALA. 1995).

Throughout the development of the relatively young body of law that has evolved in regard to pharmaceutical and medical device litigation, no defendant has successfully challenged the duty that exists between a manufacturer and end users of a drug or medical device; the substantive battles have been waged on other fronts -- namely, what evidence is sufficient to prove a breach and establish causation. These issues will be addressed in a later discussion over Daubert v. Merrill Dow Pharmaceutical, *infra.*, and Buckman v. Plaintiff Litigation Group, *infra.* **Negligence Per Se:**

The violation -- de jure or de facto -- of statutes, regulations or codes are often pled to establish tort liability of a defendant. However, in the context of a highly regulated industry, such as the

pharmaceutical industry, care must be taken in pleading a negligence per se claim or risk a battle over express or implied preemption. See, Buckman, *infra*.

Traditionally, to prove a claim for negligence per se in Alabama, a plaintiff must establish the following:

1. The trial judge must determine as a Matter of Law that the statute was enacted to protect a class of persons to which plaintiff belongs;
2. The trial judge must find the injuries to be of a type contemplated by the statute or regulation, and meant to a person contemplated to be protected by such regulation;
3. The party charged with the negligent conduct must have violated the statute; and
4. The jury must find that the statutory violation proximately caused the plaintiff's injury. M. Roberts, Alabama Tort Law §1.1.3 (2nd Ed. 1990), pp. 20-21 (specific citations omitted).

The Code at Federal Regulation (21 C.F.R.) provides ample bait to attract and entice plaintiffs' counsel into pleading a negligence per se count in their drug/device complaint. See, 21 C.F.R. § 201.56-201.57 (Labeling of Prescription Drugs); 21 C.F.R. § 330.10 (Labeling of Over-the-counter Drugs); 21 C.F.R. §369.10 (Label Warnings for Over-the-counter Drugs); and 21 C.F.R. § 314.180 et. seq. (Reporting Adverse Events), to name a few. Resist the urge to allege a negligence per se count.

Remember, both the Federal Rules of Evidence, Rule 105, and the Alabama Rules of Evidence, Rule 105, allow for the admission of evidence for limited purposes, where evidence is admissible for one purpose, but not for another. You will undoubtedly have to survive a Federal Rule of Evidence, or Alabama Rule of Evidence, Rule 403, challenge as well, however the objecting party will have to carry the burden of showing that substantial prejudice would result from the admission of this evidence. Remember as well that merely prejudicial impact is not enough; all evidence offered against a party will have some prejudicial effect, or it would not be worth offering at trial.

In an attempt to avoid a defense claim of preemption, consider staying away from asserting negligence per se claims for alleged C.F.R. violations. A defendant's actions may be regulated by the FDA, through the C.F.R., yet while the evidence of defendant's wrongdoing may be evidenced by its dealings with the FDA, the very same facts can form the basis for the your state claims. "While the violation of a statute or regulation can provide evidence of negligence, it is rarely an independent basis of liability." Ellen Relken, The Sword or The Shield: Use of Governmental Regulation, Exposure Standards and Toxicological Data in Toxic Tort Litigation, 6 Dick, J. Environmental Litigation and Policy, 1, 14-18 (1997).

Warranty Claims (Expressed and Implied):

Alabama Code § 7-2-313, Expressed Warranties by Affirmation, Promise, Description, Sample.

- (1) Expressed warranties by the Seller are created as follows:
 - (a) Any affirmation of fact or promise made by the Seller to the Buyer which relates to the goods and becomes a part of the basis of the bargain creates an expressed warranty that the goods shall conform to the affirmation or promise.
 - (b) Any description of the goods which is made part of the basis of the bargain creates a warranty that the goods shall conform to the description.

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Alabama Code § 7-2-314 creates the implied warranty of merchantability. This warranty can be summarized as a "warranty that the goods shall be merchantable . . . if the seller is a merchant with respect to the goods of that kind." What follows this simple definition is a series of qualitative characteristics create an implied warranty of merchantability. Included in this list, at subparagraph (f), is that the goods "conform to the promises or affirmation of fact made on the container or label, if any."

Id. This definition is crucial to plaintiff's state law claims as it clearly addresses the representations made to the consumer of the product, by the manufacturer, thus giving you another weapon in your arsenal for fighting defendants' broadly based claims of preemption under the recent Buckman decision.

Alabama Code § 7-2-315 defines Alabama's implied warranty of fitness for a particular use, where a defendant knows of the purpose for which the product is purchased, that the Buyer is relying upon the Seller's skill and judgment to furnish suitable goods, there is created an implied warranty of fitness for particular use, subject to the manufacturers' renouncing or excluding the applicability of such warranty under Alabama Code § 7-2-316. Given the rather limited purposes for which pharmaceutical products and medical devices are sold to consumers, there is scarcely a more narrowly tailored product definition, and limited use of products as there are with the subject of this seminar. Hence, stating state law claims for representations made on labels, product inserts, print advertising, other media advertising and through other avenues of direct-to-consumer advertising, the implied warranties of merchantability and fitness for particular use are common theories pled in this litigation. Additionally, insofar as defendants have been successful to a limited extent in attempting to absolve themselves of liability by casting blame on physicians as learned intermediaries, representations made to the physicians and pharmacists by the manufacturers of drugs, and to a lesser extent medical devices, should be used extensively in support of claims for breaches of these implied warranties.

Alabama Extended Manufacturers Liability Doctrine (AEMLD):

Because a separate topic point for the seminar is dedicated solely to the AEMLD, an in-depth discussion will not be undertaken here. Nonetheless, a claim of injury relating to pharmaceutical, nutraceutical (herbal products) or medical devices would not be complete in this state without a claim under the AEMLD. The elements of such a claim are:

- (1) Plaintiff must prove that he suffered injury and damage to himself or his

property by one who sold a product in a defective condition, unreasonably dangerous to the plaintiff as the ultimate user or consumer, if

- (a) the Seller was engaged in the business of selling such a product, and
 - (b) it was expected to, and did, reach the user or consumer without substantial change in the condition in which it was sold.
- (2) Having established the above elements, the plaintiff has proved a prima facie case although
- (a) the Seller had recognized all possible care in the preparation and sale of his product, and
 - (b) the User or Consumer had not bought the product from, or entered into any contractual relation with, the Seller. McClain v. Metabolife International, Inc., ____ F.Supp. 2d ____, 2002 WL 550024 (N.D. Ala. 2002); Brock v. Baxter Health Care Corp., 96 F.Supp. 2d 1352 (S.D. Ala. 2000); Caudle v. Partridge, 566 So. 2d 244 (Ala. 1990); Sapp v. Beech Aircraft Corp., 564 So. 2d 418 (Ala. 1990).

However, unlike pure strict liability theories under the Restatement of Torts (2nd) 402A, the AEMLD allows for the presentation of affirmative defenses such as contributory negligence, assumption of the risk, and lack of causal connection. McClain v. Metabolife International, Inc., 2002 WL 550024. While assumption of the risk and contributory negligence are highly untenable defenses, given the wide disparity of knowledge between manufacturer and end users of products, you can anticipate very strong causation defenses, and Daubert will only be the beginning of this fight.

McClain also points out that there may be two (2) separate instances in which failure to warn claims may arise in the context of this type of product liability litigation. First, that defendant's failure to warn may render a product defective or unreasonably dangerous, and second, separate and apart from a product liability claim, negligent failure to warn may stand as a substantive ground for recovery independent of the AEMLD. See McClain, Id.

Deceptive Trade Practices:

While Alabama does not currently have a deceptive trade practices act that allows for private actions and theories of recovery the way many states have, because engaging in the practice of pharmaceutical products liability often entails litigating in foreign jurisdictions, it is incumbent upon plaintiff's counsel to investigate and plead, where appropriate, deceptive trade practices claims. Consequently, I would encourage any person looking into this litigation to examine the states' law where you are filing or considering filing cases to add a separate claim for economic injury related to the deceptive trade practices of any given defendant. Quite often these claims are fertile ground for class action litigation, whereas individual claims for personal injury are not.

Fraud:

Fraud involves an intentional, reckless, negligent, or even innocent misrepresentations of material fact, upon which a plaintiff relies to his detriment. See, Alabama Code § 6-5-101 (1975). Fraud may also be premised upon the suppression of material facts by one who is under an obligation to communicate facts to the plaintiff. See, Alabama Code § 6-5-102 (1975).

The Alabama Code §§ 6-5-103 and 104 define the necessary elements of intentional deceit. Under these Sections, knowledge of the falsity of the representations is an essential element of a claim for deceit. Two specific elements of deceit that may be critical to a claim for fraud/deceit in the pharmaceutical/medical device arena are:

- (A) A suggestion as a fact of that which is not true by one who does not believe it to be true, or
- (B) When there is no reasonable ground for believing the fact to be true.

Additionally, suppressing material facts by one under the obligation to disclose, or the giving of other information as fact (i.e., inadequate warnings), which are likely to mislead for want of full

communication may provide the basis for a claim for fraud/deceit as well. Alabama Code § 6-5-104 (1975).

I have ended our list of common themes with fraud to allow for a natural segway into a discussion of one of the newer, and now more frequently raised, issues of Buckman v. Plaintiff's Legal Committee's implied pre-emption. The issue in the context of pharmaceutical and medical device litigation will be a front on which many new battles are fought.

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.

Daubert issues:

This paper, and the time allotted for an *overview* of theories and defenses does not offer the opportunity for a full analysis of *Daubert*. However, from a plaintiff's perspective, we must always be mindful of our burden of proof, and defendant's readiness to put our experts to the litmus test of *Daubert v. Merrill Dow Pharmaceutical*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed. 2d 469 (1993). Under *Daubert*, the trial judge is the gatekeeper of evidence, and charged with the duty of ensuring that all scientific and technical evidence be both relevant and reliable before being admitted. In setting out its opinion in *Daubert*, the Court gave us four (4) factors the trial judge should review in passing upon the admissibility of expert testimony:

1. Methodology: Has the expert's methodology been tested?

2. Technique: Has the expert's technique been subjected to peer review?
3. Rate of error: Is there a known rate of error in the expert's technique?
4. Acceptance: Has the expert's technique been generally accepted in a proper scientific field?

Daubert, supra.; Turner v. Iowa Fire Equipment Company, 229 F.3d. 1202, 1207-1208 (8th Cir. 2000).

Since the Court set out these four (4) "flexible" points of inquiry there has been a literal tidal swell of motions to exclude expert testimony; Daubert has created the trial within the trial. Defendants continue in their attempts to increase the rigidity of these four (4) factors, while plaintiffs continue to rely upon the "flexible nature" of the Court's inquiry into these factors. Consequently, it is in plaintiffs' interest to locate and secure experts for use at trial at the earliest possible opportunity. In litigation where defendants have ready access to thought centers and thought leaders in all fields, locating and securing Daubert proof expert testimony is, and will continue to be, one of plaintiffs' first obligations. This is especially true in the context of pharmaceutical products litigation where defendants ply the average practitioner with consultants' fees, honorariums and the like, and more prominent physicians in similar fashion to their standing.

In opposing Daubert motions, keep in mind the liberal interpretation urged by the Federal Rules of Evidence Advisory Committee. Additionally, cases such as Kumho Tire Company v. Carmichael 526 U.S. 137 (1999), and Pipitone v. Bio-Matrix, Inc., _____ F. 3d. _____ 2002 W L 500290 (5th Cir. 2002), emphasize the Daubert's elements of consideration are indeed flexible, and cross-examination is still the best tool for dealing with weak evidence. Id. Relevance and reliability are the Court's concern, not conclusions. Pipitone is a shining example of where a rigid adherence to the Daubert elements would simply not make sense. In this instance, when three (3) of the four (4) factors clearly fall against admission of the plaintiffs' expert's testimony, the expert went the extra step to

eliminate all alternative causes of plaintiff's injury -- through recognized scientific processes that meet the first two (2) prongs of Daubert -- and concluded on causation with near certainty. The Court in Pipitone noted:

"It bears reminding that 'the trial court's role as gatekeeper [under Daubert] is not intended to serve as a replacement for the adversary system.' Rather, as Daubert makes clear, 'vigorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. Thus, while exercising its role as a gatekeeper, a trial court must take care not to transform a Daubert hearing into a trial on the merits.'" Id.

As stated earlier, Daubert, along with Buckman, will be two of the most aggressive points of defense any attorney will see in pharmaceutical and medical device litigation. Consequently, it becomes increasingly important to keep a vigilant eye on the various court decisions relating to this area of the law that has such a heavy impact upon our practice.

[Additional information to be provided on day of seminar]