

Mass Torts

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Does Reverse Bifurcation Inherently Favor Plaintiffs?

Angela L. Abel, M.A., and Robert F. Bettler, Jr., Ph.D.

How does reverse bifurcation, where a jury deliberates injuries and damages to a verdict before hearing liability evidence, impact that eventual liability decision? A handful of empirical studies have examined straight bifurcation (Devine et al., 2001), where damages or punitive damages are argued *after* a liability verdict, but the peer-reviewed literature has yet to address reverse bifurcation. The common belief in venues where it is employed, like Los Angeles, New York City and Philadelphia, is that a jury who has already decided to award damages is more inclined to find someone at fault. Further, many suspect damages can be artificially inflated by this procedure's narrow focus on the plaintiff's injuries.

These suspicions, voiced especially by defense counsel and their corporate clients, have some *prima facie* validity. The social scientific literature on straight bifurcation suggests a slight advantage for the defense, so it is conceivable that reversing the bifurcated stages could reverse this defense advantage. This fear would also appear to be confirmed in a recent report examining trial information from about 5,500 asbestos trials in several states between the years 1987 and 2002 (White, 2002). White reports that reverse bifurcation results in a 29% increase in liability verdicts and a \$628,000 increase in compensatory damages.

Depending as it does on innumerable case-specifics, the choice, where there is one, of whether to enter a reverse bifurcation situation cannot be fully resolved in this review. At the same time, a better understanding of the social cognitive mechanisms by which reverse bifurcation can potentially increase or decrease your client's exposure can, along with many other considerations, help to inform that decision.

How might reverse bifurcation impact jurors' thinking?

While not addressed in the peer-reviewed literature, these two questions, does reverse bifurcation increase liability; and whether there is an impact on damages exposures to defendants, have been examined in proprietary DecisionQuest research. Interestingly, the defendants' fears were not confirmed. Jurors who rendered a damages verdict in Phase One of a reverse bifurcated trial were not necessarily more likely to find against a defendant in the liability phase, compared to a typical unitary trial structure where jurors consider injury, liability and damages simultaneously. Similarly, with respect to the second question, damages awarded in Phase One were not necessarily higher than the damages awarded by jurors who deliberated liability and damages at the same time after a unitary trial. Nevertheless, some of the dynamics presumed to underlie an increased risk to a defendant in reverse bifurcation were clearly at work. For example, reverse bifurcation jurors did indeed exhibit a heightened concern about compensating the plaintiff. On the other hand, other mechanisms were observed that tended to favor the defendant. One issue, for example, that could militate in the defendant's favor is the absence of some of the "bad conduct" information that jurors might ordinarily hear in a unitary trial: Often a factor that increases the defendant's exposure, given the well-established link between jurors' anger and damages (e.g., Kahneman, Schadke and Sunstein, 2002).

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**SECTION of
LITIGATION**
AMERICAN BAR ASSOCIATION

Message from the Chairs

Welcome to the 2006-07 Bar Year and the expanded Mass Torts Committee! You may have noticed that we have updated the format of the Mass Torts newsletter a bit. This is just the tip of the iceberg for the Mass Torts Committee in the 2006-07 bar year. We have committed ourselves to making the Committee a valuable part of your professional life. As you will see from the box elsewhere in this newsletter, we have added new subcommittees and subcommittee chairs, and if your interests fall in any of these categories, by all means, let us or the subcommittee chairs know so you can become more active.

“Mass Torts” litigation presents thorny questions for lawyers and judges. Take all of the ordinary challenges of litigation and amplify them by several orders of magnitude, add the additional problems that come with managing large numbers of parties and claims, and then add the social and political undercurrent that attends most Mass Torts. That’s a potent mix. Our goal for the Mass Torts Committee is to be your one-stop shop for articles, information, and CLE that will help you, the Mass Torts practitioner, develop and expand your knowledge base, so that you can stay ahead of the curve in this challenging field.

Our most important asset is you. This committee is successful because of the contributions and expertise of people like yourself. We have numerous opportunities for all who want to get involved with the committee. If you would like to get more involved, please do not hesitate to contact us. We’d love to hear from you.

New Committee Co-Chairs

As we start the new ABA year, we want to introduce all our members to our new committee co-chairs. John Manard and Byron Mason have been appointed to succeed Kevin Durkin and join Alan Rudlin as co-chairs of our committee. Kevin resigned to devote his full attention to being President of the Chicago Bar Association for this year. Alan Rudlin has been re-appointed and will continue to serve as co-chair of our committee. We will certainly miss Kevin’s leadership, but we

should not suffer from this since he will continue to remain active in the committee and be a great resource to us.

We are very excited by Byron and John’s appointment. They bring a great deal of knowledge and experience to our committee. John has actively participated on our committee events for several years. He is a partner of Phelps Dunbar, LLP in Louisiana, where he has been practicing law following graduation from Tulane Law School. His practice includes environmental litigation, toxic tort defense, and pharmaceutical defense. Byron is a graduate of Indiana University and the University of Iowa College of Law. He is a partner at Baker & Daniels LLP in Indianapolis where he concentrates his practice in the areas of product liability law, mass torts and commercial litigation. Byron has been a very active member of the Product Liability Subcommittee and has co-chaired and spoken at several programs.

January 2007 – Joint CLE Summit/Snowbird

You should have received in August a save-the date email from the ABA Section of Litigation concerning our Joint CLE Summit being held January 11-13, 2007. We want to again remind you to mark your calendars and plan to attend. The meeting will be held at The Cliff Lodge and Spa, located slope-side in Snowbird, Utah. This is the premier event held by the committee each year and, as in the past few years, we are holding this meeting jointly with the Products Liability and Environmental Litigation Committees.

Program planning is complete, and the brochure is out. It can be found online at <http://www.abanet.org/litigation/jointcleseminars/>. In addition to participation by a number of federal circuit and district court judges, there also will be participation this year by many in-house counsel from a number of companies, including Altria, Allergan, Aventis, Amgen, Dow, DuPont, Firestone, Georgia Pacific, Johnson & Johnson, and Shell Oil. A strong focus of the meeting will be on hearing from these in-house counsel, starting with the kick-off plenary session which will consist of a roundtable discussion by in-house

Committee Co-Chairs

D. Alan Rudlin, Esq.

Hunton & Williams LLP
Riverfront Plaza, East Tower
951 East Byrd Street
Richmond, VA 23219-4074
Tel: 804-788-8459;
Fax: 804-788-8218
arudlin@hunton.com

Byron K. Mason, Esq.

Baker & Daniels LLP
300 North Meridian Street, Ste 2700
Indianapolis, IN 46204
Tel: 317-237-1277;
Cel: 317-501-7080
Fax: 317-501-7080
byron.mason@bakerd.com

John P. Manard, Jr., Esq.

Phelps Dunbar, LLP
365 Canal Place, Ste 2000
New Orleans, LA 70130-6534
Tel: 504-584-9253
Fax: 504-568-9130
manardj@phelps.com

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counsel. A special program has also been added for young lawyers concerning marketing to in-house counsel. John Manard (manardj@phelps.com) is serving as our Committee's liaison in the planning process this year and we thank him for his great work and on-going efforts in this regard.

We encourage you, your colleagues and your friends and family to attend. Please spread the word! Not only will we have excellent CLE programming, but the location is ideal for relaxing with family and friends, with such opportunities built into the schedule. Did we mention this is on the Martin Luther King, Jr., holiday weekend? So plan on staying a few extra days. There is limited space available at the resort and we would hate to have any of our members closed out. Make your reservation early. You can reserve now by calling the resort at 800/232-9542 or 801/933-2222. Mention you are attending this meeting to receive the tremendously discounted rate of \$199 per night.

You can also check our website periodically for updates and new information: www.abanet.org/litigation/committees/masstorts/. HAWAII ABA ANNUAL MEETING

Programming for the Honolulu ABA meeting in August 2006, was more limited than for past ABA meetings in order to allow the attendees and their families to enjoy the breathtaking beauty of Hawaii. Notwithstanding the ever-present allure of the sunshine and beaches, however, all the programs presented by the Section of Litigation were well attended. This is a tribute to the hard work of the meeting and program planners in the section.

Alan attended the Section's meetings and in addition, met with the ABA Standing Committee on Federal Judiciary, on which he is the Fourth Circuit Member.

Upcoming Events

There are a number of upcoming events being presented by our committee, the Section of Litigation and the ABA. We ask you put them on your calendars and plan to attend. First and foremost is our Joint CLE Summit meeting being held in Snowbird, Utah, January 11-13, 2007. Details on this meeting are discussed above.

The next Section of Litigation Annual Conference takes place April 11-14, 2007 at the Marriott Rivercenter in San Antonio, Texas. The next ABA Annual Meeting will be held August 9-14, 2007, in San Francisco, California. We expect to be sponsoring or co-sponsoring a number of programs at these meetings. Please mark your calendars and plan to attend.

In addition to these meetings, there are scores of upcoming meetings being presented by other committees of the Section of Litigation, including regional and local meetings and teleconference CLE programs, which may be of interest to you. For more information on all upcoming activities, please visit the Litigation Section's website: <http://www.abanet.org/litigation/home.html>.

Subcommittee Appointments

This fall we revisited our subcommittee structure and appointments. Last year we reduced and restructured our subcommittees and tried to focus on appointing subcommittee chairs to those areas that reflected their practice so our subcommittees could be as active and vibrant as possible. We invite all our members who want to be more active in the

committee this coming year to let us know and we will find a place for you. Our committee is especially interested in involving more young lawyers and lawyers of color in our activities and leadership.

We continue to work on making all of our subcommittees active and involved. In this regard, we have charged each subcommittee with the responsibility for contributing at least one article for our newsletter each year. We are also asking each of our subcommittees to provide to us for consideration and potential submission program proposals for future Section of Litigation and ABA annual meetings. In addition to programs at these meetings, we are also interested in holding regional meetings and telephone conference CLE programs, which also required submission of proposals for approval by the section. With regard to these programming activities, John Manard (manardj@phelps.com) and Byron Mason (byron.mason@bakerd.com) will be serving as co-chairs of our established Programming Subcommittee. They will be a great resource for those interested in putting program proposals together. If you have ideas for future programs, please contact Byron or John.

Newsletter

James Beck, Tara Demetriades and Trey Sibley continue as our newsletter editors. We encourage you to contact them and submit articles to them for publication in our newsletter. Publication in our newsletter represents a great opportunity for young lawyers and seasoned veterans alike. We thank James, Tara and Trey for their tireless efforts in putting together our quarterly newsletter.

Website

Kirk Hartley and Bruce Barze are our website editors. Please visit our website early and often. You will discover much new information. For instance, we have added links to valuable mass tort law sources and other law research information. Did you know you can now access from our website summaries of all recent decisions of the federal appellate courts and the United States Supreme Court concerning mass tort law, as well as obtain copies of the opinions? Try it out and give us feedback on this and the other things you see or want to see on our website.

Please visit our Mass Tort Litigation Committee website on a regular basis for news and updated information on the committee, the committee's activities and upcoming events. Again, our committee website is: www.abanet.org/litigation/committees/masstorts/. If you have comments or suggestions concerning the content on our website or changes you would like to see, please do not hesitate to contact Kirk at khartley@butlerrubin.com or Bruce at bbarze@balch.com.

Membership Drive

As always, we are here to serve you, the members of the Mass Tort Litigation Committee. If you have thoughts and ideas of how the committee might provide more benefits to you, please let us know. And get involved. We look forward to seeing you in Snowbird, Utah, January 11-13, 2007.

Alan Rudlin

John Manard

Byron Mason

Reverse Bifurcation *continued from page 1...*

To further explicate how juries might think in such situations, we turn to the social psychology of how responsibility is assessed (Bettler & Spievak, 2005). This model posits several conceptually separable decisions faced by jurors: Judgments about the severity of the plaintiff's injuries, about the causality that can be attributed to the various parties, about the parties' ability to prevent the injuries, judgments about responsibility for the injuries and finally judgments about restitution for the injuries. A reverse bifurcated trial focuses jurors, with a somewhat unnatural exclusivity, on the first and last decisions in this series, injury and restitution. Although the model, and the verdict form in a unitary trial, depicts these decisions as a linear sequence, jurors are certainly able to approach these decisions in reverse, working backwards from a desire to put a certain amount of money in the plaintiff's hands to finding a way to accomplish that goal through findings of liability and cause against the defendant(s). Still, looking at the average tendencies of a group of people, the safest conclusion is that these decisions evolve in the jurors' minds more or less simultaneously. Regardless of the order, or lack thereof, research suggests that "fixing" some of these key decisions results in a bias for the other decisions to be resolved in the same direction (Simon, 2004). In other words, in situations where the injury and damages decisions are made in favor of a plaintiff, the other decisions, regarding cause and liability among others, would have a disproportionate tendency to favor the plaintiff's as well.

In line with these predictions from the peer-reviewed literature, DecisionQuest's proprietary research on reverse bifurcation has shown that when the plaintiff's injuries are less severe, the "pull" as it were, to resolve the other verdict decisions in the plaintiff's favor is weaker. When those injuries are more severe, the defendant's liability risk increases. Thus, the same mechanisms that can increase a defendant's exposure in reverse bifurcation can also decrease it.

Another key finding of DecisionQuest's research was that the reverse bifurcated scenario could actually result in lower comparative liability to the defendant particularly targeted in Phase Two, as compared to a unitary trial. This observed mitigation of a targeted defendant's liability in a reverse bifurcated trial may derive from a somewhat self-defeating characteristic of a plaintiff's Phase One case. Medical causation in reverse bifurcated toxic tort cases often requires that, in order to succeed in Phase One, the plaintiff must show a link between the substance in question, irrespective of source, and the plaintiff's injuries. Further, in order to increase damages, the plaintiff must emphasize injury severity, something that is often inferred from the duration or intensity of the alleged exposure. This forces plaintiffs, at times, to "pile on" or present as much evidence as possible on the extent of the injurious exposure. This also occurs in a unitary trial, of course, but much more attention

is simultaneously focused on the actions, or inaction, of a small number of targeted defendants, often just one. Thus, in a unitary trial, the evidence on exposure intensity and duration, along with injury severity, has a greater likelihood of being simultaneously attached to a targeted defendant. In effect, then, reverse bifurcation forces the plaintiffs themselves to lay the foundation for a critical component of the targeted defendant's later liability case: Unless the plaintiff only worked with the one defendant's product, it can appear that alternative exposures were more (if not entirely) responsible for the plaintiffs' injuries. Note also that DecisionQuest research findings do not contradict White's (2002) observation of higher damages and increased liability risk since she does not address injury severity or comparative liability in her report.

In summation, then, contrary to the common belief among some defense attorneys and their corporate clients, it may not be that reverse bifurcation per se is hazardous to their causes. Instead, the same cognitive mechanisms that "drive" jurors' decisions in a unitary trial are doubtless at work in a reverse bifurcated one, but the outcome in the latter scenario is not just a function of the type and quality of the evidence, but also a function of the manner and order in which that evidence is presented. A more complete evaluation of any reverse bifurcated case, then, must include some appreciation of how these factors might inextricably influence one another in the jurors' minds and a realization that, although the court can bifurcate a trial, it cannot totally bifurcate human thinking processes.

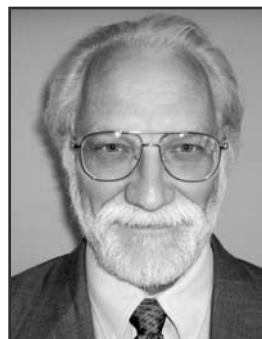
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Angela L. Abel, M.A. is the Vice President in charge of the Atlanta office of DecisionQuest, the nation's most experienced trial consulting firm. Over the past decade, she has worked on nearly a thousand high-risk engagements.



Dr. Robert L. Bettler, Jr., a trial consultant in the same office, conducts qualitative and quantitative research projects on litigation matters nationwide. For more information, please visit www.decisionquest.com.

FDA's Preemption Preamble Breathes New Life Into Preemption Defense Against Drug Labeling Claims

R. David Walk, Jr.

For many years, the debate over whether federal regulation of prescription drug labeling preempts state law product liability claims has been one-sided, with most courts ruling that federal approval does not preempt state law claims for failure to warn.¹ After primarily sitting out this debate,² the federal government became an active participant in 2002, when the Food and Drug Administration ("FDA") began filing amicus briefs urging courts to hold that federal approval of drug labeling preempts certain types of state law claims based on alleged deficiencies in the labeling.³ Those briefs persuaded an occasional court,⁴ but most courts refused to grant any deference to the agency's position, in part because that position had not been established through formal agency proceedings.⁵

On January 24, 2006, partially in response to these court decisions,⁶ the FDA published in the Federal Register a preamble formally stating its preemption position ("Preamble").⁷ The Preamble echoes the terms of the Supreme Court's preemption jurisprudence in describing how state law product liability litigation conflicts with federal regulation of prescription drug labeling. The Preamble argues that this conflict means that state law claims are preempted. Although plaintiff-oriented commentators have tried to dismiss the Preamble as having "no legal effect whatsoever,"⁸ state and federal judges have paid attention and in some cases deferred to the FDA's position that state law claims are preempted. The Preamble has turned a one-sided discussion into a real debate.

The Preamble was published as part of the FDA's explanation for amending its regulations governing the content and format of labeling for human prescription drug and biological products.⁹ Those final regulations completed an overhaul to the FDA's labeling regulations that began on December 22, 2000, with the publication of proposed rules.¹⁰ Among the most significant changes were changes to the format of labeling and a requirement that the labeling include an introductory section entitled "Highlights of Prescribing Information."

In the course of those rulemaking proceedings, the FDA asked for comments on the product liability implications of revising the label-

ing rules.¹¹ Some manufacturers expressed concern that highlighting selected information could make them vulnerable to product liability claims for failure to highlight other information; others asked the FDA to state more generally whether FDA approval of labeling would preempt state law.¹² The FDA responded: "FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be the old or new format, preempts conflicting or contrary State law."¹³ The FDA noted that its amicus briefs had made this point and used the Preamble to provide a full explanation of "the government's long standing views on preemption."¹⁴

The Preamble started its explanation by emphasizing how the regulation of labeling is central to the regulatory scheme established by Congress. Under the FDCA, according to the Preamble, "FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading."¹⁵ The FDA makes labeling decisions under the FDCA and FDA regulations based on its analysis of the drug and its label, which includes consideration of clinical issues and public health issues.¹⁶ The Preamble concludes that labeling is "the centerpiece of risk management for prescription drugs generally."¹⁷ This demonstration of labeling's importance to federal drug regulation was the first step in the FDA's case for conflict preemption, which occurs when state law interferes with the operation of a federal scheme¹⁸ or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."¹⁹

The Preamble then stressed the amount of time and attention the FDA puts into labeling decisions. The FDA stated that a decision to approve a label "reflects thorough FDA review of the pertinent scientific evidence" and "a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling."²⁰ The labeling "communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively."²¹ The FDA "carefully controls the content of labeling for a prescription drug" and "continuously works to evaluate the latest available scientific information to monitor the safety of products and incorporate information into the product's labeling when appropriate."²² This emphasis on the time and care the FDA devotes to labeling decisions calls to mind the generally accepted preemption standard under the Medical Device Amendments ("MDA"), which gives preemptive effect to the FDA's rigorous, time-consuming decisions under the pre-market approval process but not to the FDA's quicker, less rigorous decisions under the "substantial equivalence" process.²³



R. David Walk, Jr. is Counsel in the Mass Torts and Products Liability Group of the Philadelphia office of Dechert LLP. His e-mail address is david.walk@dechert.com.

After showing that the FDA's regulation of labeling is central to the regulatory system established by Congress and that the FDA devotes great time and attention to labeling, the Preamble explains how product liability litigation could "directly threaten[]," "conflict with," "frustrate," and "present an 'obstacle' to" the agency's ability to regulate labeling.²⁴ Those terms echo the terms used by the Supreme Court to describe state laws that conflict with federal law and are therefore preempted.²⁵ The Preamble gives the following examples of conflicts created by state law product liability lawsuits:

- courts have permitted claims based on the failure to include warnings the FDA had specifically considered and rejected as scientifically unsubstantiated;
- "liability concerns were creating pressure on manufacturers to expand labeling warnings to include speculative risks and, thus, to limit physician appreciation of potentially far more significant contraindications and side effects";
- state law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act";
- state law actions "encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA"; and
- the threat of significant damage awards or penalties pressures manufacturers "to attempt to add warnings that FDA has neither approved nor found to be scientifically required."²⁶

With this list of conflicts, the FDA established at least a *prima facie* case of conflict preemption, as it showed that the state laws interfere with the operation of a federal scheme.

The FDA then addressed the primary reasons courts have given in refusing to find that FDA approval preempts failure-to-warn claims. Courts commonly state that manufacturers can strengthen warning statements without prior FDA approval. The Preamble responds: "In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act."²⁷ While sponsors in theory may add risk information without prior FDA approval, the FDA stated that it reviews all such revisions and could disapprove them and bring enforcement actions if the amended label was false or misleading.²⁸ The FDA stressed repeatedly that "in

practice, manufacturers typically consult with FDA prior to adding risk information to labeling."²⁹

Another ground often cited by courts, that FDA labeling requirements are minimum safety standards,³⁰ is a "misunderstanding of the act," according to the Preamble. "In fact, FDA interprets the act to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading."³¹ The Preamble states that requirements to disclose additional information "are not necessarily more protective of patients" and "can erode and disrupt the careful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug."³²

The Preamble gives several examples of claims that would be preempted by FDA labeling regulation, including claims that a manufacturer failed to include "warnings that are not supported by evidence that meets the standards set forth in this rule" or failed to include a statement that had been proposed to the FDA but that the FDA did not require (unless the FDA had determined the sponsor withheld material information).³³ The Preamble concludes by acknowledging that FDA regulation of drug labeling will not preempt all state law actions and cites as an example the Supreme Court's holding in *Medtronic, Inc. v. Lohb*³⁴ that state law requirements that parallel FDA requirements may not be preempted.³⁵

Because it is published in the Federal Register, the Preamble must be accorded mandatory judicial notice by all courts.³⁶ Thus, courts cannot choose to ignore the FDA's formal position, as some did with the Agency's *amicus* briefs.

The first court decisions to consider the Preamble demonstrate how it has given a boost to the preemption defense. The two state court decisions are split. In *Ambromowitz v. Cephalon, Inc.*, the New Jersey Superior Court relied on the Preamble in concluding that the FDA's decision to approve the defendant's label preempted a state law claim for failure to warn.³⁷ The court respected the FDA's decision about preemption because the agency was acting within the scope of its authority and intended to preempt state law.³⁸ Two months later, however, the Rhode Island Superior Court in *Coutu v. Tracy* reached a contrary conclusion and held that the plaintiff's claims based on the labeling were not preempted.³⁹ The court discounted the FDA's position because the FDA had stated a contrary position

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six years before and because courts had held that such claims were not preempted.⁴⁰

The three federal decisions are also split, with two decisions dismissing the Preamble after cursory analysis, and one decision following the Preamble after extensive discussion and analysis. The first federal decision to mention the Preamble, *Laisure-Radke v. Par Pharmaceutical, Inc.*,⁴¹ cited the Preamble as providing that FDA approval preempts conflicting or contrary state law. The court rejected the defendant's preemption claim on the ground that the state law at issue did not conflict with federal regulations.⁴² The court did not discuss the Preamble further, apparently on the belief that the lack of conflict with state law did not require consideration of the Preamble. The court in *Jackson v. Pfizer, Inc.*,⁴³ gave short shrift to the preamble, calling it "not persuasive."⁴⁴ The court stated in a footnote that the FDA had failed to comply with the requirements of Executive Order 13132 "to communicate with the states and to allow the states an opportunity to participate in the proceedings prior to a preemption decision."⁴⁵ The court did not explain why this failure to communicate would render the Preamble nugatory, or even why it could make such an administrative law determination in a civil lawsuit between private parties.⁴⁶

The most comprehensive analysis of the Preamble and its effect came in *Colacicco v. Apotex, Inc.*⁴⁷ Plaintiff Joseph Colacicco's wife committed suicide after taking a generic version of the anti-depressant Paxil, and he sued the maker of the generic and the maker of the innovator alleging that they failed to warn of the increased risk of suicidal behavior. After defendants moved to dismiss on federal preemption grounds, the court asked the FDA to file an amicus brief addressing several questions, including the legal force of the Preamble and whether the court could consider the Preamble given that it was issued after the conduct giving rise to the litigation.⁴⁸ The FDA's amicus brief, filed at the request of the court on May 10, 2006, stressed that the FDA had repeatedly rejected attempts to strengthen the drug's warning of an association between suicide and Paxil use because the FDA concluded that there was not reasonable evidence of an association.⁴⁹ The FDA also argued that the court could consider the Preamble and that, even if it could not, plaintiff's claims were preempted based on established preemption principles.⁵⁰

On May 26, 2006, the court agreed with the FDA that plaintiff's claims were preempted and grant the defendants' motions to dismiss. The court noted the "many conflicting court decisions on this topic" but found that "a series of Supreme Court decisions point this Court in the direction of deference [to the FDA's views], and

require dismissal of this case."⁵¹ The court made it clear that its decision turned on the FDA's positions on preemption and relevant statutes and regulations: "The FDA's view is critical to this Court's analysis because Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference."⁵² The court noted that the Supreme Court had found the FDA's position on the preemptive scope of its regulatory authority "dispositive" in one case⁵³ and had deferred repeatedly to the FDA's views in other recent preemption cases.⁵⁴ The court also found that the Supreme Court had deferred to a preemption position that an agency communicated in amicus briefs "as well as in 'regulations, preambles, interpretive statements and responses to comments.'"⁵⁵

The court noted that its governing court of appeals, the Third Circuit, had not ruled on the deference that should be afforded to the FDA's views on this issue; however, that court had recently considered deference to the FDA's views about the express preemption provision of the MDA in *Horn v. Thoratec Corp.*⁵⁶ The court in *Horn*, according to the *Colacicco* opinion, deferred to the FDA's position that state law claims were preempted by the express preemption provision of the MDA.⁵⁷ The Third Circuit held that deference was required even though the FDA's current position was a departure from its prior position.⁵⁸ The Third Circuit found that even a revised agency position was entitled to deference if the change is supported by reasoned analysis, "because an initial agency interpretation is not instantly carved in stone."⁵⁹ Although the issue presented in *Horn* concerned the express preemption provision of the MDA, the *Colacicco* court found that "the *Horn* court broadly

announced a policy of affording deference to the FDA's position on preemption, and did not narrow the holding only to cases involving express preemption."⁶⁰

After determining the amount of deference required, the court considered the FDA's views expressed in its amicus brief in the *Colacicco* case, its amicus briefs filed in two other cases in 2002 and 2005,⁶¹ and the Preamble. From the amicus briefs the court drew the conclusion that the generic drug makers could not have added the warning plaintiffs argued should have appeared, both because an additional warning would have constituted misbranding, in light of the FDA's prior rejection of additional warnings as contrary to the scientific evidence, and because generic drug makers, according to the FDA, cannot unilaterally change drug warnings without prior FDA approval.⁶² The court recognized that other courts had held that generic drug makers could change the label without prior approval, but concluded "that principles of deference do not allow

Because it is published in the Federal Register, the Preamble must be accorded mandatory judicial notice by all courts. Thus, courts cannot choose to ignore the FDA's formal position, as some did with the Agency's *amicus* briefs.

us to question the FDA's interpretation of its own regulations—e.g. that generic drug manufacturers can not make changes without prior approval.”⁶³

The court also found it appropriate to defer to the FDA's conclusion in the Preamble that the FDCA preempts state failure-to-warn claims, as well as its subsidiary conclusions that FDA labeling standards are not just minimum standards and that drug manufacturers do not, in practical terms, have the ability to change the labeling without FDA approval.⁶⁴ The court rejected plaintiff's argument that the Preamble was merely legal argument, finding that the court was obligated to “respect its expert judgment that an October 2003 warning label other than approved by the FDA would have been in direct, actual conflict with federal law.”⁶⁵ The court further rejected plaintiff's claim that the FDA's current position should be discounted because the FDA previously had stated in 1996 and 2000 that its regulations did not have preemptive effect.⁶⁶ The court relied on the Supreme Court's holding in *Chevron* that an agency's interpretation can warrant deference even if the agency had changed its interpretation and on the fact that the FDA's position after 2000 had been very consistent.⁶⁷

In response to Colacicco's argument that the Preamble could not be retroactively applied to a case arising out of a death in 2003, the court looked to federal administrative law principles to conclude that the Preamble was an interpretive rule that merely clarified exist-

ing law and therefore did not have prohibited retroactive effect.⁶⁸ The court further explained that its ruling on the retroactivity of the Preamble was not dispositive because the FDA's position was also stated in its amicus briefs and because the court would have come to the same conclusion without considering the Preamble.⁶⁹

The court then considered the “numerous cases” by courts other than the Third Circuit concluding that state failure-to-warn claims are not preempted by the FDCA and FDA regulations.⁷⁰ The court “concluded not that their analysis itself is wrong, but rather that it is improper for a federal district judge to engage in this analysis in the first place.”⁷¹ The court stated that those other courts did not have a clear amicus brief from the FDA and the Preamble, both of which clearly stated that claims such as Colacicco's were preempted by the FDCA, and both of which the court found “dispositive.”⁷² Accordingly, the court concluded that plaintiff's failure-to-warn claims were preempted by federal law.⁷³

Colacicco, *Abramowitz*, *Jackson*, *Laisure-Radke*, and *Coutu* are only the first in what is likely to be a series of decisions concerning the scope and significance of the FDA's Preamble. If it does nothing else, the Preamble has reinvigorated the debate over whether FDA approval of prescription drug labeling preempts state law failure to warn claims. If the appellate courts are as divided as the first courts to decide these cases, a circuit split will arise within the next few years, and the debate may have to be resolved by the Supreme Court.

Endnotes continued on page 15...



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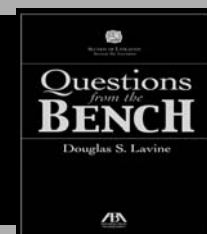
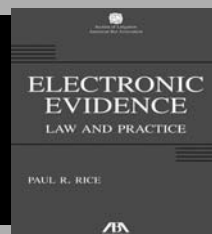
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Rx For The Courts—Healthy Dose Of The Restatement Third In Pharmaceutical And Medical Device Cases

Karen Daley

For years the Restatement (Second) of Torts provided courts with little guidance in analyzing and adjudicating design defect claims involving prescription drugs and medical products. Whether strict liability should be imposed for design defects in prescription drugs and presumably prescription medical devices was determined under the infamous comment k of § 402A of Restatement Second. Unfortunately, comment k was vague and ambiguous and often provided more questions than answers. Consequently, since the adoption of § 402A and comment k, there has been significant disagreement among the courts regarding its interpretation and application, resulting in confusion, ambiguity and inconsistencies in this area of law.

Nearly thirty five years after the adoption of § 402A, the American Law Institute introduced the Restatement (Third) of Torts seeking to unify and more clearly define the law by setting forth a new rule pertaining solely to prescription medical products. Many anticipated that the long awaited Restatement Third would clarify the law with respect to design defect claims in prescription drugs and medical devices. While the Restatement Third may have clarified the law in this area, it has been heavily criticized and generally rejected by the courts. This article will explore the differences between the Restatements pertaining to the law of design defect claims in pharmaceutical and medical device cases and explain why courts have been reluctant to adopt the Restatement Third's position on liability.

Restatement (Second) Torts, Section 402A, comment k

Section 402A of Restatement (Second) Torts was adopted in 1965. Section 402A globally addressed strict liability for the seller of a product that causes physical harm to a user or consumer. Comment k of §402A specifically addressed the law regarding unavoidably unsafe products, including prescription drugs. Comment k provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly

leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product properly prepared, and accompanied by proper directions and warnings is not defective and is not unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. *The seller of such products, again with the qualifications that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held strictly liable for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.*

Section 402A Restatement Second Torts, comment k (1965) (emphasis added). Comment k limited the scope of liability for design defect claims regarding unavoidably unsafe products to a negligence standard provided that certain conditions in the rule were met. Specifically, that the products were properly prepared and marketed and appropriate directions and warnings were provided. Comment k also addressed the public policy issues surrounding the availability of such products. As noted by the courts, the purpose of comment k was to “encourage the manufacture of ethical drugs, and the research and development of new drugs without the threat of strict liability.” *Toner v. Lederle Laboratories*, 732 P.2d 297, 339 (Idaho 1987).

Despite its seemingly clear direction and purpose, courts have struggled considerably with the interpretation and application of comment k. While the vast majority of courts agree that comment k applies only to design defect claims, there is divergence with respect to the question of whether comment k provides blanket immunity from strict liability for all prescription drugs.

The majority of jurisdictions hold that comment k does not provide blanket immunity from strict liability for prescription drugs. *See Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir 1989); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741 (W. D. Pa. 2004); *Taylor v. Daneck Medical, Inc.*, Civil Action 95-7232, LEXIS 20265 (E.D. Pa. Dec. 29, 1998); *Mele v. Honmedica, Inc.*, 808 N.E.2d 1026 (Ill. 2004); *Bryant v. Hoffman-*



Karen A. Daley is an associate with the law firm of Updike, Kelly & Spellacy, P.C. in Hartford, CT. Ms. Daley's practice focuses on the defense of medical malpractice, product liability, construction and mass torts cases.

LaRoche, Inc., 585 S.E.2d 723 (Ga. 2003); *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827 (Neb. 2000). Instead, most of these jurisdictions hold that comment k is an affirmative defense and its applicability must be determined on a case-by-case basis employing various tests. A majority of “case-by-case” jurisdictions employ a risk/utility analysis to evaluate the applicability of the comment k affirmative defense. See *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir 1993); *Hill v. Searle Lab.*, 884 F.2d 1064 (8th Cir 1989); *Adams v. G.D. Searle & Co.*, 576 So.2d 728 (Fla. 1991); *Toner v. Lederle Labs.*, 732 P.2d 297 (Idaho 1987); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A. 2d 775 (R.I. 1988).

For instance, in *Toner*, the court discussed its interpretation of comment k and the application of the risk/utility analysis. It explained that the preconditions to applying comment k required a determination as to whether the product at issue was properly prepared and was accompanied by proper warnings and directions. *Toner*, 732 P.2d at 305. If these preconditions were met, “the [manufacturer] must then establish that the product’s risk was in fact unavoidable.” *Id.* Establishing that the product’s risk was unavoidable requires a showing that “at the time of distribution of the product, no feasible alternative design which on balance accomplishes the subject product’s purpose with a lesser risk” was available. *Id.* at 306 (internal citations omitted). Therefore, a manufacturer is shielded from strict liability if the risks are unavoidable but the product is apparently useful and desirable with known but reasonable risks.” *Id.* The court recognized that “[comment k] contemplates a weighing of the benefit of the product against its risk...where the scales must clearly tip in favor of the benefits for comment k to apply.” *Id.*

In contrast, a minority of jurisdictions hold that comment k is not an affirmative defense, but rather that it provides blanket immunity from strict liability. The seminal case setting forth the minority view is *Brown v. Superior Court*, 751 P.2d 470 (Cal.1988). In *Brown*, the California Supreme Court held that drug manufacturers should not be held strictly liable for design defects if the elements of comment k are met. See *Brown*, 751 P.2d at 477. California’s Supreme Court held that exempting drug manufacturers from strict liability would best serve the public interest in the “development, availability and reasonable price of drugs.” *Id.* Another sound argument for the blanket immunity approach centers upon the fact that most drugs undergo a rigorous evaluation by the Food and Drug Administration prior to being marketed. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991). Presumably, such drugs are already deemed to be not unreasonably dangerous upon receipt of FDA approval for marketing.

Jurisdictions adopting the majority view of comment k are highly critical of this minority view and find that such blanket immunity severely limits the discretionary powers of the court. *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000). Courts critical of the minority view have also held that comment k does not apply to all prescription drugs and requires a case-by-case risk/benefit analysis to determine if its application is appropriate. *Adams v. G.D. Searle & Co., Inc.*, 576 So.2d 728, 732 (Fla. 1991). In general, these courts find that blanket immunity does not advance public policy and may in fact harm consumers by discouraging manufacturers from developing safer products. *Id.*

Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices, Section 6(c) of Restatement Third (Torts)

In 1997, after decades of debate surrounding the interpretation and applicability of comment k, the Restatement (Third) Torts, §6(c) was adopted in an attempt to clarify and unify the law regarding liability for prescription drugs and medical devices. While the intended purpose of § 6(c) was to add clarity regarding liability for prescription medical products, it can hardly be called a restatement of the law. Rather, § 6(c) involved a rewriting of the law on design defect claims for prescription medical products. This departure from the existing law has created as much controversy as comment k and has been rejected by the majority of courts that have considered it.

Section 6 (c) is more closely aligned with the minority view of comment k, providing prescription drug and device manufacturers with a *de facto* exemption from strict liability for

design defect claims. Unlike the majority view of comment k, § 6(c) does not employ a risk/utility analysis, but instead uses a reasonable physician standard to determine potential liability. Section 6(c) provides:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Restatement (Third) Torts, §6(c) (1998). As noted in the Restatement’s comments, Section 6(c) falls short of providing blanket immunity to prescription drug and medical device manufacturers for

[T]he Restatement (Third) Torts, §6(c) was adopted in an attempt to clarify and unify the law regarding liability for prescription drugs and medical devices. While the intended purpose of § 6(c) was to add clarity regarding liability for prescription medical products, it can hardly be called a restatement of the law. Rather, § 6(c) involved a rewriting of the law on design defect claims for prescription medical products.

design defects, providing that a prescription drug or medical device is defectively designed only when it does not provide a net benefit to any class of patients. *See* Restatement (Third) Torts, § 6(c), comment b.

The Reporters for the Restatement based their decision to rewrite the law in this area on the unique nature of prescription drugs and medical devices. In adopting § 6(c), the Reporters considered how prescription drugs and medical devices differed from ordinary products. First, they considered that unlike ordinary products, drugs and medical devices are sold only pursuant to a prescription and the warnings and/or directions attendant to the use of the drug or device are provided to the health-care practitioner. *Id.* The Reporters also recognized that only health-care practitioners are in a position to appreciate the significance of the risks of prescription medical drugs and devices, to address their advantages and disadvantages, and to effectively report this information to the patient. *Id.* Therefore, it necessarily incorporated the learned intermediary rule into § 6(c).

The Reporters also considered the Food and Drug Administration's ("FDA") role in permitting the marketing of prescription drugs and medical devices. *Id.* Prescription drugs and medical devices undergo rigorous evaluation by the FDA before being placed on the market, thus, the Reporters concluded that their approval is a "legitimate mechanism for setting the standards for drug design." *Id.* The idea that the FDA heavily regulates the prescription drugs and devices, however, presupposes that the FDA will keep unreasonably dangerous prescription products off the market. *Id.* It also presupposes that the prescribing health-provider has been adequately informed about the prescription device and will assure that the right drug and/or device will reach the right patient. *Id.*

Finally, the drafters of § 6(c) recognized that the "unique nature of prescription [products] calls for a different test that attempts to maximize the benefits provided by unavoidably risky [products] and minimize the harm." *Bryant v. Hoffman-LaRoche*, 585 S.E.2d 723, 734 (2003). Section 6(c) employs a reasonable physician standard, which considers whether a reasonable physician would prescribe the drug to any class of persons. The basis for the adoption of such a standard is the belief that physicians are in the best position, given their knowledge of the risks and benefits of such products, to ensure that they are prescribed to the right patients under the right circumstances. Indeed, the drafters recognized that proving a design defect claim under a reasonable physician standard would be difficult and only under "unusual circumstances would liability be imposed." *See*

Section 6(c), comment f. The drafters of § 6 also took into consideration that plaintiffs would still have a causes of action against a drug manufacturer for manufacturing defects and failure to warn. *See* Restatement (Third) Torts, §6, comments c and d.

Despite the logical basis for adopting § 6(c), it has come under intense criticism and has generally been rejected by most courts. *See Mele v. Hommedica, Inc.*, 808 N.E.2d 1026, 1038-39 (Ill. 2004) (refusing to adopt § 6(c) and overturn years of common law precedent in this area of law); *Bryant v. Hoffman-LaRoche, Inc.*, 585 S.E.2d 723, 728 (Ga. 2003) (declining to adopt § 6(c) without prior case law); *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827 (Neb. 2000) (rejecting § 6(c)). In *Freeman v. Hoffman-LaRoche, Inc.*, the Nebraska Supreme Court discussed several criticisms of § 6(c). *See Hoffman-LaRoche*, 618 N.W.2d at 839-40. First, the Nebraska Supreme Court points out that § 6(c) does not restate the law, whatsoever, but formulates new law without support in existing case law. *Id.* at 839. The court also points out that the Restatement fails to acknowledge the majority view under

Restatement Second, comment k that recognizes a risk/utility test for determining whether strict liability applies in a design defect case. *Id.* A reasonable physician test is simply not contemplated by the majority view. *Id.*

Second, the Nebraska Supreme Court also found that the reasonable physician test was "artificial and difficult to apply." *Id.* Essentially, the Court held that the test would require a fact finder to assume that a physician has as much or more information about a prescription drug than the manufacturer. *Id.* The Court also expressed the concern that the reasonable physician test ignored the fact that "physicians tend to prescribe drugs they are familiar with or for which

they have received advertising material, even when studies indicate that better alternatives are available." *Id.*

Third, the Court found that the reasonable physician test "lacks flexibility and treats drugs of unequal utility equally." *Id.* That is, drugs with serious side effects but different levels of utility, such as a drug used for cosmetic purposes and one that treats a deadly disease, could both escape strict liability if either was deemed useful to a class of patients and would be prescribed by a reasonable physician. *Id.* Such a rule, according to the Court, ignores that the cosmetic drug, with less utility, should be "subject to liability if a safer yet equally effective design was available." *Id.* The Court found that the reasonable physician standard would never allow such liability, unlike a risk/utility test that would permit liability in appropriate, though limited, cases. *Id.* Similarly, the Nebraska Supreme Court noted that a design defect claim could be easily defeated by a defense expert's

The Reporters for the Restatement based their decision to rewrite the law in this area on the unique nature of prescription drugs and medical devices. In adopting § 6(c), the Reporters considered how prescription drugs and medical devices differed from ordinary products.

testimony that the drug was beneficial to some class of persons. *Id.* at 840. In essence, the Court took serious issue with the fact that § 6(c) shields manufacturers from “a wide variety of suits that could have been brought under comment k.” *Id.*

To the contrary, a few courts have accepted § 6(c) or would have supported its application. *See Sita v. Danek Medical, Inc.*, 43 F.Supp.2d 245, 256 (E.D.N.Y. 1999) (finding insufficient evidence to support design defect claim under § 6(c)); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180 (D. Ariz. 1999) (denying design defect claim under § 6(c)); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 852 (NY 2003) (supporting § 6(c) analysis and its rationale for adoption); *Taylor v. Danek Medical, Inc.*, Civil Action 95-7232 LEXIS 20265 at *23 (D. Pa. Dec. 29, 1998) (analyzing a design defect claim under § 6(c) and predicting that the Supreme Court of Pennsylvania would eventually adopt this rule). Additionally, at least one court that rejected 6(c) discussed the merits of the new Restatement for design defects of prescription products in the concurring opinion. *See* concurring opinion in *Bryant*, 585 S.E.2d at 733. Judge Andrews of the Georgia Appellate Court, in his concurring opinion in *Bryant*, states that he would have adopted § 6(c). *Id.* Judge Andrews agrees with the notion that prescription drugs and medical devices are unique in nature. *Id.* His view is that in light of the unique nature of these products, § 6(c) contemplates a reasonable alternative design test in which a prescription drug could be found defective if the plaintiff proves that a safer designed prescription drug that has received FDA approval, was on the market and was available for prescription by a reasonable health care provider. *Id.* The test, he explained, is not whether the manufacturer *could* have designed a safer prescription product but whether one actually exists. *Id.* (emphasis added).

Judge Andrews believed that the design defect test in § 2 of Restatement Third, which employs a risk/utility test, is not appropriate to judge whether a design defect exists in a prescription medical product. *Id.* He explained that § 2 would allow a plaintiff to show that a drug was defectively designed by proving that a manufacturer could have designed a safer product. *Id.* This would necessarily require the courts to answer the question of whether a “new alternative drug would have won FDA approval in time to help the plaintiff.” *Id.* Judge Andrews stated that a court could not possibly answer that question without “replicating the FDA approval process,” a task that the court is not qualified to undertake. *Id.*

Also, Judge Andrews agrees that § 6(c) furthers the public policy behind this rule in making drugs or devices available even to a small class of patients who might benefit from them. *Id.* He remarked that

In light of the continued confusion surrounding comment k and the non-acceptance of § 6(c), commentators have proposed alternatives to the tests set forth in Restatements Second and Third. These alternative approaches envision a “middle ground” between strict liability and § 6(c)’s seemingly blanket immunity.

because the products are available only by prescription and provided by a physician that the right drug will reach the right patient. *Id.*

Finally, Judge Andrews recognized the fact that there are instances in which a physician will prescribe the wrong drug causing a plaintiff harm or prescribe a wrong drug because the manufacturer failed to provide adequate warnings. *Id.* Either way, Judge Andrews stated that the plaintiff has recourse against the physician for negligence or the manufacturer for inadequate warnings and is not foreclosed from being made whole for his injury. *Id.*

Overall, Judge Andrews found that § 6(c) provided a “better reasoned alternative to the risk/utility test employed under comment k.” *Id.*

Alternative Approaches

In light of the continued confusion surrounding comment k and the non-acceptance of § 6(c), commentators have proposed alternatives to the tests set forth in Restatements Second and Third. These alternative approaches envision a “middle ground” between strict liability and § 6(c)’s seemingly blanket immunity. For example, commentators have suggested a negligence standard for design defect claims. It is believed that a negligence standard would “assure plaintiffs and command defendants that reasonable care is expected and required; it assures plaintiffs that defendants who act unreasonably will not escape liability, while assuring potential defendants that act reasonably will be insulated from liability.” Dustin R. Marlowe, Note: *A Dose of Reality For Section 6(c) of the Restatement (Third) of Torts: Products Liability*, 39

Ga. L. Rev. 1445, 1480-81. What is not clear from the commentators viewpoint is what the analysis would be under a “straightforward” negligence standard. It seems that whether a manufacturer acted reasonably would include whether a safer alternative design was available. A pure negligence standard does not, therefore, seem to remove that ambiguity and confusion surrounding liability for design defects for prescription medical products.

Another commentator has suggested that prescription drugs should be held to the alternative design test in § 2(b) of Restatement Third. *See Freeman*, 618 N.W.2d at 567-68 (internal citations omitted). Section § 2(b) applies to products in general and adopts a risk/utility test requiring the plaintiff to show the existence of a reasonable alternative design. *Id.* Under the test in §2(b), “a product can be found defective upon proof that, at the time the product was manufac-

Young Lawyer's Corner

Last year, Committee Co-Chair Alan Rudlin asked myself and two other attorneys to head up the development of a Mass Torts Young Lawyer subcommittee. As a relatively new entity, we thought the Mass Torts newsletter would make a natural outlet for getting the word out about our group. Thus, the following is a short primer on who we are, our plans for the next year and how to get involved.

Who are we?

The Co-Chairs for this subcommittee are:

- **Eric E. Hudson:** Eric is a member of Butler, Snow, O'Mara, Stevens & Cannada in the firm's Memphis, Tennessee office. His practice focuses on toxic torts, mass torts, and complex litigation.
- **Terry L. High:** Terry is an associate for Baker, Donelson, Bearman, Caldwell & Berkowitz in the firm's Jackson, Mississippi office. Terry's practice includes mass torts, products liability, premises liability, and insurance defense.
- **Harley V. Ratliff:** When not writing this issue's column, I am an associate at Shook, Hardy & Bacon in Kansas City, Missouri. The bulk of my practice is devoted to cardiac medical device product liability litigation..

On the Horizon for 2007:

As we wrap-up 2006, we are looking forward to a busy and exciting 2007. Our plans include:

- **Increase Membership:** Right now the Mass Torts Young Lawyer subcommittee is a lonely group—you basically have Eric, Terry and myself. To get this subcommittee off the ground, we have made it one of our primary goals to increase awareness,



Harley V. Ratliff is an associate at Shook, Hardy & Bacon in Kansas City, Missouri. Mr. Ratliff's practice focuses on the defense of cardiac medical device product liability claims.

develop interest and, hopefully, make strides in terms of total membership. At a minimum, we would like to have at least 20 members before the end of bar year 2007/2008. To that end, we are in the process of identifying, contacting and recruiting new members. In addition, we are attending and encourage others to attend the 2007 Environmental, Mass Torts and Products Liability Litigation Committees Joint CLE Summit in Snowbird, Utah (more below), as well as the Litigation Section meeting in San Antonio in April. To the extent you would be interested in joining or contributing to the Young Lawyers subcommittee, please contact one of us via email. You can reach me at hratliff@shb.com. Likewise, if there is a young lawyer in your section whom you think might be interested, let us know.

- **Sponsor at least one teleconference in 2007:** Our plan is to sponsor at least one one-hour, phone-in CLE in the next year. We are presently discussing topics and potential speakers, and we are looking for other members to become involved with this effort (this is a great way to increase your visibility among other attorneys in your practice area). Our goal is to find issues that are focused on young lawyers generally, but that also have particular relevance to the mass tort practice area. Keep an eye out and let us know if you can help.
- **Continue to Contribute to the Newsletter:** This will be our second article for the newsletter. In light of the subject matter, it probably should have been our first. We look forward to being regular contributors to future newsletters, and we would like to have other members of the sub-committee contribute. This is another great way to increase your visibility in your practice area.
- **Environmental, Mass Torts and Products Liability Litigation Committees Joint CLE Summit:** For those of you that attended the Environmental, Mass Torts and Products Liability Joint CLE last year in Beaver Creek, you know that it is one of the ABA's best annual conferences. Great programs. Great speakers. Great skiing.

This year's conference should be no different.

The 2007 conference will take place from January 11-13, 2007 at the Cliff Lodge & Spa in Snowbird, Utah. This year's panelists include, among others: The Honorable Eldon Fallon, Altria Vice President and Associate General Counsel William S. Ohlemeyer, and Sandra Phillips of Pfizer, Inc. Make your reservations now. Space fills up quickly. Registration and program materials can be found at <http://www.abanet.org/litigation/jointcleseminar/home.html>.

Last year there was a small, but active presence of ABA Young Lawyers at the Joint Summit. This year, we are working to increase attendance at this conference among young lawyers. The goal is to make the winter Joint Seminar the CLE of choice for young lawyers in these respective practice areas. As part of that goal, a new wrinkle for this year's Joint CLE will be the inclusion of a break-out session with a specific emphasis on issues relating to young lawyers. The program—entitled “Making the Right Pitch: How to Make it to the Big Leagues by Avoiding a Rain Delay”—is focused on developing strategies for young lawyers for attracting and maintaining clients in an increasingly competitive legal market. Navigating the legal world is difficult enough. But as you make your way up the ladder, few challenges seem as daunting as developing a client base and, more importantly, ensuring those clients remain happy.

As part of our role as co-chairs, we have actively participated with the program's sponsors, the Products Liability Young Lawyers Subcommittee, to secure panelists and develop written program materials. Although the program will clearly have a young lawyer slant, lawyers of all ages and experience are encouraged to attend. We are hoping that a young lawyer break-out session will become a staple of this conference.

The Panelists for this year's program include in-house attorneys Jerry G. Bradford of Alcon Laboratories, Inc. and William N. Scarff of Allergan, Inc. The two outside counsel panelists will be Megan Wynne of Morris, Polich & Purdy in Los Angeles and Timothy Pratt at Shook, Hardy & Bacon in Kansas City. Megan is chair of her firm's Products Liability practice group and is a regular contributor at ABA functions. Tim is co-chair of Shook, Hardy's Pharmaceutical & Medical Device division and serves as national counsel for a major manufacturer of cardiac medical devices. The panel will be moderated by associates Bhavi A. Shah of Snell & Wilmer in Phoenix, Arizona and Penelope Dixon of Carlton Fields in Tampa, Florida.

If you plan to attend the conference in Snowbird, let one of us know. We'll include you in our regular conference calls discussing the work of the subcommittee and, so long as you're willing, we promise ample opportunities for involvement.

We are looking forward to a more active 2007. With any luck, our paths cross in the new few months.

—Harley Ratliff

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Endnotes

- 1 See, e.g., *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000) (no preemption of failure-to-warn claim concerning Zolofit); *Feldman v. Lederle Labs.*, 592 A.2d 1176 (N.J. 1991); *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir. 1993); *Graham v. Wyeth Labs.*, 906 F.2d 1399 (10th Cir. 1988); *Hurley v. Lederle Labs.*, 863 F.2d 1173 (5th Cir. 1988); but see, e.g., *Dusek v. Pfizer, Inc.*, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004) (holding that Food, Drug & Cosmetic Act (“FDCA”) preempts failure to warn claims relating to the prescription drug Zolofit); *Needleman v. Pfizer Inc.*, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004) (same); *Ehblis v. Richmond, Inc.*, 233 F. Supp. 2d 1189 (D.N.D. 2002) (holding that FDCA preempts failure-to-warn claims relating to prescription drug Adderall), *aff’d on other grounds*, 367 F.3d 1013 (8th Cir. 2004).
- 2 The FDA made occasional statements about preemption before 2002. In a 1998 preamble to a regulation on the Patient Medication Guides provided to patients by pharmacies, the FDA stated that its regulations did not preempt state law, which traditionally has regulated pharmacists. 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998). In the 2000 preamble to the initial proposed prescription drug label regulations, the FDA stated that its regulations were minimum standards and did not preempt state tort claims. 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000). In the Brief for the United States as Amicus Curiae in *Buckman v. Plaintiffs’ Legal Committee*, 2000 WL 1364441 (U.S. filed Sept. 13, 2000), the FDA argued that federal law preempted the plaintiff’s claims for damages based on alleged fraud on the FDA.
- 3 See, e.g., Brief for United States as Amicus Curiae Supporting Defendant, *Motus v. Pfizer, Inc.*, Nos. 02-cv-55372, 02-cv-55498, 2002 WL 32303084 (9th Cir. Sept. 10, 2002); Brief for United States as Amicus Curiae Supporting Defendant, *Dowhal v. SmithKline Beecham Consumer Healthcare*, No. S109306, 2003 WL 23527781 (Cal. July 18, 2003); Brief for United States as Amicus Curiae Supporting Defendant, *Kallas v. Pfizer, Inc.*, No. 2:04-cv-0998 (D. Utah. Sept. 15, 2005). Strictly speaking, the Department of Justice filed the briefs, but they stated the views of the FDA.
- 4 See *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 10 (Cal. 2004) (finding preemption in case FDA briefed); *Needleman v. Pfizer, Inc.*, 2004 WL 1773697, at *4 (finding Motus amicus brief “compelling”).
- 5 See *Jackson v. Pfizer, Inc.*, 2006 WL 1506886, at *4 n.4 (D. Neb. May 31, 2006); *McNellis v. Pfizer, Inc.*, 2005 WL 3752269, at *10 (D.N.J. Dec. 29, 2005) (declining to treat statements in FDA amicus brief “as declarations to be afforded the preemptive force of law”); *Witozak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 730 (D. Minn. 2005) (same); *Zikis v. Pfizer, Inc.*, 2005 WL 1126909, at *3 (N.D. Ill. May 9, 2005) (dismissing FDA amicus brief as “nothing more than legal argument by counsel”).
- 6 The FDA also may have wanted to satisfy a requirement suggested in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), by four dissenting Justices—all current members of the Court. The dissenters “would require a formal agency statement of pre-emptive intent as a prerequisite to concluding that a conflict exists.” *Id.* at 884; see *id.* at 908-10 (Stevens, J., dissenting). The dissenters would not defer to an agency’s position that was stated only in an amicus brief. *Id.* at 910.
- 7 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006); see also *id.* at 3967-69 (discussing how the final regulations satisfy the federalism concerns expressed in Executive Order 13132, 64 Fed. Reg. 43255 (Aug. 4, 1999)).
- 8 Leslie A. Brueckner and Leslie A. Bailey, “Much ado about very little,” *National Law Journal*, May 1, 2006, at 22.
- 9 “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,” 71 Fed. Reg. 3922 (Jan. 24, 2006).
- 10 65 Fed. Reg. 81082 (Dec. 22, 2000); see also 71 Fed. Reg. at 3922-23 (providing background for final regulations).
- 11 71 Fed. Reg. at 3933. In addition to seeking comments through publication of the proposed rules in the Federal Register, the FDA “consulted with a number of organizations representing . . . state and local governments about the interaction between FDA regulation of prescription drug labeling . . . and state law.” *Id.* at 3969. The FDA stated that these steps complied with the requirements of Executive Order 13132, which directs federal agencies to consult with state and local officials about regulations with federalism implications. Executive Order 13132, 64 Fed. Reg. 43255 (Aug. 4, 1999). 71 Fed. Reg. at 3969.
- 12 71 Fed. Reg. at 3933.
- 13 71 Fed. Reg. at 3934.
- 14 *Id.*
- 15 *Id.*
- 16 *Id.*
- 17 *Id.*
- 18 See, e.g., *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987).
- 19 *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); accord *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000).
- 20 71 Fed. Reg. at 3934.
- 21 71 Fed. Reg. at 3934.

- 22 71 Fed. Reg. at 3934.
- 23 *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-79 (1996); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001).
- 24 71 Fed. Reg. at 3934-35.
- 25 *See, e.g., Geier*, 529 U.S. at 873.
- 26 71 Fed. Reg. at 3934-35.
- 27 71 Fed. Reg. at 3934.
- 28 *Id.*
- 29 *Id.*
- 30 *See, e.g., Witzak*, 377 F. Supp. 2d at 732.
- 31 71 Fed. Reg. at 3935.
- 32 *Id.*
- 33 *Id.* at 3936.
- 34 518 U.S. 470 (1996).
- 35 71 Fed. Reg. at 3936.
- 36 44 U.S.C. § 1507 (“[t]he contents of the Federal Register shall be judicially noticed”).
- 37 2006 WL 560639, at *3 (N.J. Super. Ct. March 3, 2006). This ruling was an alternate holding, as the court first found that there was insufficient evidence to support plaintiff’s failure to warn claim. *Id.*
- 38 *Id.*
- 39 2006 WL 1314261, at *4 (R.I. Super. Ct. May 11, 2006).
- 40 *Id.*
- 41 2006 WL 901657, at *3 (W.D. Wash. March 29, 2006).
- 42 *Id.* at *6.
- 43 2006 WL 1506886 (D. Neb. May 31, 2006).
- 44 *Id.* at *3.
- 45 *Id.* at *3 n.3. The court may have overlooked a different section of this lengthy Federal Register entry in which the FDA summarized its efforts to consult with state and local officials. 71 Fed. Reg. at 3969.
- 46 Challenges to the process followed by an agency before promulgating regulations normally must be raised in an action against the agency under the Administrative Procedure Act based on the complete rulemaking record. *See* 5 U.S.C. § 703; *NVE, Inc. v. Dep’t of Health & Human Serv.*, 436 F.3d 182, 189-91 (3d Cir. 2006). The FDA was not a party to *Jackson*, and the rulemaking record was not before the court. Moreover, an agency need not follow formal notice and comments procedures before issuing interpretive statements such as the Preamble. *See Colacicco*, 2006 WL 1443357, at *13; 5 U.S.C. § 553(b). Finally, the Executive Order itself provides that a failure to consult with the states would not provide grounds to ignore or invalidate the Preamble. Executive Order 13132 specifically states that it “is intended only to improve the internal management of the executive branch and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States.” 64 Fed. Reg. at 43259.
- 47 No. 05-5500, 2006 WL 1443357 (E.D. Pa. May 25, 2006). The author’s law firm, Dechert LLP, represented defendant Smith-Kline Beecham Corp. in this case.
- 48 *Id.* at *1.
- 49 Brief for *Amicus Curiae* United States of America, at 1, *Colacicco v. Apotex, Inc.*, No. 05-CV-05500-MMB, 2006 WL 1462152 (E.D. Pa. filed May 10, 2006).
- 50 *Id.*
- 51 2006 WL 1443357, at *1.
- 52 *Id.* at *7 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984)).
- 53 *Id.* at *7 (citing *Hillsborough County v. Automated Med. Labs. Inc.*, 471 U.S. 707, 714 (1985)).
- 54 *Id.* at *7 (citing *Medtronic Inc. v. Lohr*, 518 U.S. 470, 496 (1996), and *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2000)).
- 55 *Id.* at *7 (quoting *Hillsborough County*, 471 U.S. at 718).
- 56 376 F.3d 163 (3d Cir. 2004).
- 57 2006 WL 1443357, at *8 (citing *Horn*, 376 F.3d at 179).
- 58 *Id.*
- 59 *Id.* (quoting *Horn*, 376 F.3d at 179).
- 60 *Id.* The Third Circuit recently reiterated, in a different context, that courts should defer to the FDA’s interpretations of the statutes and regulations it administers. *NVE Inc. v. Dep’t of Health & Human Services*, 436 F.3d 182, 186 (3d Cir. 2006).
- 61 *Id.* at *9 (citing Brief for United States as Amicus Curiae Supporting Defendant, *Kallas v. Pfizer, Inc.*, Civ. No. 2:04-cv-0998, 34, 37-38 (D. Utah Sept. 15, 2005), and Brief for United States as *Amicus Curiae* Supporting Defendant, *Motus v. Pfizer, Inc.*, Civ. Nos. 02-cv-55372, 02-cv-55498, 2002 WL 32303084, at *16 (9th Cir. Sept. 10, 2002)).

- 62 *Id.* at *8-10.
- 63 *Id.* at *10.
- 64 *Id.* at *10-11.
- 65 *Id.* at *11.
- 66 *Id.* (citing 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000), and 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998)).
- 67 *Id.* at *12-13.
- 68 *Id.* at *13-15.
- 69 *Id.* at *15.
- 70 *Id.* at *16.
- 71 *Id.*
- 72 *Id.*
- 73 *Id.* at *18. The court went on to consider issues arising under the state law claims and concluded that the manufacturer of an innovator drug did not owe a legal duty to consumers of a generic equivalent of its drug. *Id.* at *22.

A Rx for the Courts *continued from page 9...*

tured, a reasonable alternative design could have been used to avoid or reduce the foreseeable risks of harm presented by the product.” *Bryant*, 585 S.E. 2d at 733. Comment b under § 6(c) explicitly states, however, that whether prescription drugs and medical devices are not reasonably safe is not to be determined using § 2(b) or § 2(c).

Neither of these alternatives is workable for prescription medical products, as it ignores the unique nature of the product and the public policy concerns surrounding such products. Restatement Third § 6(c) is better suited to address the distinct issues surrounding liability for design defects in prescription medical products. Theoretically, § 6(c) should increase the availability of prescription medical products to patients at lower costs without overlooking the safety of the product.

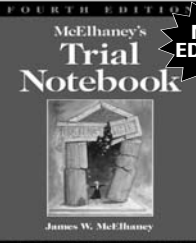
It seems that the underlying premise of § 6(c) is that most, if not all, prescription drugs and medical devices have a certain indicia of safety, stemming from years of testing followed by the rigorous scrutiny of the FDA before gaining approval to be marketed. Such an indicia of safety is important because the research and information on which the safety is based is what is relied upon and available to physicians and other health care providers who are in the best position to determine whether such products are appropriate and safe for a particular patient. Against that back drop, it makes sense to employ the reasonable physician test. Any other test ignores the critical role of the learned intermediary in the prescription of such devices.

Moreover, the reasonable physician standard will meet the demands of our aging population by giving patients more alternatives for prescription drugs and medical devices under the guidance of a qualified physician. A variety of products from which a physician can choose to treat his patients invites competition between medical and drug device manufacturers, which may curb the rising prices of such products. Controlling the rising prices of medical products will help keep them available to all patients who might benefit from their use.

Finally, § 6 (c) does not permit a fact finder to determine whether a reasonable alternative design could have been manufactured. As indicated by Judge Andrews, such a determination could not be undertaken by the fact finder without replicating the extensive testing and FDA approval process required before a product is marketed. Although § 6(c) eliminates the alternative reasonable design element, making it almost impossible for a plaintiff to prevail on a design defect claim, a plaintiff is not foreclosed from bringing a claim for inadequate warnings—a claim that can be readily addressed by the fact finder.

The adoption of § 6 (c) is most consistent with society’s desire for the safest medical products at the lowest cost. Thus, the courts should seriously consider adopting § 6 (c) for design defect claims for both prescription drugs and medical devices, as its benefits far outweigh the risks articulated by its opponents.

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UCLA
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 gradyk@ballardspahr.com
 www.ballardspahr.com

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 Tel: (213)532-2103
 amortimer@hunton.com

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Division V - Substantive Areas of Litigation - Co-Directors

Walter J. Andrews, Esq.
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 Tel: 703-714-7642 • wandrews@hunton.com

Marjory G. Basile, Esq.
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 Tel: 313-496-7596 • basile@millercanfield.com

Robert M. Craig, III, Esq.
 Waste Management
 Tel: 713-512-6228 • rcraig@wm.com

William T. Garcia, Esq.
 Tel: 202-297-8838 • billgarciaadc@aol.com

ABA Staff

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ABA Section of Litigation
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