Committee News

Winter 2013

Products Liability Committee

OPERATOR'S MANUALS ARE FOR NERDS (AND LAWYERS TOO)

By: Richard G. Norris, II[1], *Wells Marble & Hurst, PLLC*

The operator's manual; why would you not want to read it? It is filled with wonderful information about your product that you can get nowhere else. Consider the following pearls of wisdom:

"For external use only." *(On a curling iron)*

"Do not iron clothes on body." *(On a clothes iron)*

"Do not use for drying pets." *(On a microwave oven)*

"Do not attempt to stop chain with your hands." *(On a chainsaw)*

"This product not intended for use as a dental drill." *(On an electric rotary tool)*

Sadly, these product instructions likely were written after someone mis-used these products in the manner suggested by the warnings. Fortunately for the rest of us, we can now simply read the operator's manual that came with our chain saw and learn that it is not a good idea to attempt to stop the chain with our hands, or, from the manual that came with our microwaves, learn that it is not a good idea to stuff Fluffy in it to dry him off.

Yet, the fact is most people do not read the literary gems that accompany the products they buy. The few that do typically get only as far as the assembly

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MESSAGE FROM THE EDITOR

Dear Readers:

Welcome to the first Products, General Liability, and Consumer Law Committee newsletter of 2013. This issue contains four articles which we hope will provide information helpful to your practice or, at the very least, a bit of interesting reading when you need a break from your busy work day.

In the first article, Richard Norris discusses the importance of attorneys as well as experts reading the operator's manual in a products liability case. Mr. Norris describes his own experience in a case where the opposing party's expert did not read the operator's manual before testifying, with serious consequences.

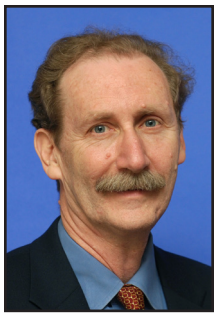
Next, James Lamb, Ph.D., DABT, and Barbara Neal, DABT of Exponent, and Clifford Zatz and Cheryl Falvey of Crowell & Moring, discuss developments in the science and regulation of endocrine disruptors, and the effects of those developments on litigation.

In the third article, Elaine Solomon summarizes the status of Pennsylvania product liability law and describes some recent cases that have created some confusion as to whether Pennsylvania courts should follow the *Second Restatement* or *Third Restatement* with regard to the liability of a commercial seller or distributor for harm caused by defective products.

Finally, David Kent provides an informative update on new rules promulgated by the Texas Supreme Court with regard to expedited resolution of "small" cases and "loser pays" litigation.

Enjoy the issue, and thank you for your continued participation in the Products, General Liability and Consumer Law Committee. ⚖⚖

Mariel Taylor
Gregory Boulos




THE STATE OF THE ART OF ENDOCRINE DISRUPTOR SCIENCE, REGULATION, AND LITIGATION

By: James C. Lamb, IV, Ph.D, DABT, Barbara H. Neal, DABT, *Exponent*, Clifford J. Zatz, Cheryl A. Falvey, *Crowell & Moring LLP*

The federal government devotes significant attention and resources to the science of endocrine disruption and possible links to certain chemicals used in consumer products or as pesticides on our foods. The popular press claims endocrine disruptors cause everything from childhood obesity to cancer. A recent radio report suggested that the lack of federal regulation of endocrine disrupting chemicals has resulted in an increased use of pesticides in food that now rivals the levels in 1962 when Rachel Carlson first released her book, "Silent Spring," about the effects of the uncontrolled use of pesticides. Human health effects allegedly caused by endocrine disruption range from the early onset of puberty to cancer, and from obesity to autism. With endocrine disruption increasingly moving from scientific circles to the popular media, this article examines current events relating to the science, regulation and litigation in the area of endocrine disruption and its relevance to toxic tort and consumer class action litigation.

What is an Endocrine Disruptor?

Endocrine disruptors have been broadly described as any substance that may affect the production, release, transport, metabolism, or elimination of hormones in the body. Hormones affect the growth, reproduction, and behavior of humans and other species in the ecosystem. To be classified as a "disruptor," a substance's effect should be more than any measurable activity in these hormonal systems, which are in a constant state of flux; it should be adverse in some manner.

The State of Endocrine Science

The developing science in this area is controversial because of strong and diverse opinions on the interpretation of the studies, particularly the science behind low-dose effects of these chemicals and the allegation that hormonally active substances may act through unusual (called "non-monotonic") dose-response curves. The scientific debate revolves around such themes as the reliability of industry-funded scientific research and government interpretations of studies. The Endocrine Society, the world's oldest and largest society dedicated to research on hormones and the clinical treatment of endocrine disorders, has issued a policy statement on endocrine disruption expressing concern that regulatory policies that fail to consider the low-dose effects of endocrine disrupting chemicals could lead to regulatory decisions that inappropriately define safe levels for these chemicals.[1] The statement argues that current policy relies too heavily on toxicological studies examining the effects of high doses, despite evidence of effects at low doses "even when high dose effects are not present." It further argues that current regulatory activity is too concentrated on certain kinds of research to the exclusion of research on hormonal disruption involved in metabolism, obesity, and brain signaling.

Others argue that tests for the endocrine activity of chemicals can be unreliable predictors of adverse health effects or disruption of the endocrine system. For example, the heavy reliance on *in vitro* (essentially test tube) studies that strip away the normal protective and adaptive systems that characterize biological and endocrine systems may skew the risk analysis as to human health effects. The scientific community cannot agree on whether evidence of changes in hormonal "activity" predicts "disruption" to the point of harm. The "low-dose" theory has also been criticized as ignoring credible scientific studies that suggest otherwise and

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1 http://www.endo-society.org/advocacy/policy/upload/Endocrine-Disrupting-Chemicals-Position-Statement.pdf

THIRD RESTATEMENT OF TORTS VERSUS SECOND RESTATEMENT OF TORTS: THE "MUDDIED WATERS" OF PRODUCT LIABILITY LAW IN PENNSYLVANIA

By: Elaine Solomon[1]

The Third Circuit Court of Appeals has once again affirmed that federal courts sitting in diversity and applying Pennsylvania law to products liability cases should look to Sections 1 and 2 of the *Restatement (Third) of Torts*, not the standards set forth in Section 402A of the *Restatement (Second) of Torts*. As a result, there continues to be uncertainty in this area of the law, and "forum shopping" between state and federal court in Pennsylvania becomes even more of a strategic decision.

By way of background, Pennsylvania state courts have followed Section 402A of the *Second Restatement* since 1966. In a 1978 decision, the Pennsylvania Supreme Court proclaimed that negligence concepts have no place in a products liability case. *Azzarello v. Black Brothers Company, Inc.*, 391 A.2d 1020 (Pa. 1978). The Court noted that Section 402A provides: "One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused…if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold." Section 402A further provides that liability is imposed even though "the seller has exercised all possible care." *Id.* at 1027. As a result, the Court held that the trial court's use of the phrase "unreasonably dangerous" in a jury charge improperly inserted negligence concepts into the case. *Id.*

Despite the *Azzarello* holding, Pennsylvania courts have "muddied the waters" by reaching inconsistent holdings with respect to certain products liability concepts under Section 402A. As an example, with respect to the defense of assumption of risk, the Pennsylvania Superior Court held that to prove that affirmative defense, a defendant must prove that the buyer knew of a defect and yet voluntarily and unreasonably proceeded to use the product. *Gaudio v. Ford Motor Co.*, 976 A.2d 524, 541 (Pa. Super. Ct. 2009). In addition, to establish a defense of misuse of the product requires evidence that "the use was 'unforeseeable or outrageous.'" With respect to a product alteration defense, the Pennsylvania Supreme Court held that a manufacturer can be held liable if the manufacturer "could have reasonably expected or foreseen such an alteration of its product." *Davis v. Berwind Corp.*, 690 A.2d 186, 190 (Pa. 1997). Regardless of *Azzarello*, as Pennsylvania Supreme Court Justice Saylor has commented, negligence concepts have actually played a central role in design defect cases. *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1012 (Pa. 2003) (Saylor, J., concurring).

Even though Pennsylvania courts have found it increasingly difficult to determine whether a product is "unreasonably dangerous" as described in the Second Restatement without examining evidence of the seller's exercise of care or the foreseeability of the risk, the Supreme Court has not to date issued a decision formally adopting the *Third Restatement of Torts*. Section 1 of the *Third Restatement* makes sellers liable only for the sale of products that are "defective" and Section 2 provides that a product may qualify as "defective" if it meets one of three sets of criteria. Specifically, Sections 1 and 2 provide:

> Section 1. Liability of Commercial Seller or Distributor For Harm Caused By Defective Products.
>
> One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.
>
> Section 2. Categories Of Product Defect
>
> A product is defective when, at the time of sale or distribution, it contains a manufacturing

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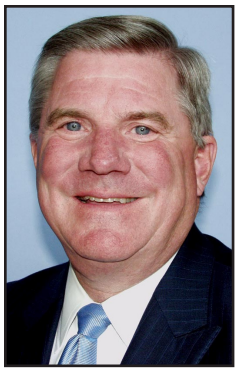

TEXAS SUPREME COURT ISSUES CONTROVERSIAL NEW RULES FOR MANDATORY EXPEDITED RESOLUTION OF "SMALL" CASES

By: David C Kent[1]

Responding to a legislative directive enacted in 2011, the Texas Supreme Court has issued controversial new rules for the expedited resolution of "small" cases involving $100,000 or less, along with "loser pays" rules for the dismissal of frivolous cases. The rules for expedited resolution are notable for their mandatory nature: defendants cannot opt out of the rules unilaterally or by agreement, and courts may remove cases only on motion for "good cause" shown. The rules apply to cases filed on or after March 1, 2013.

In 2011, the Texas Legislature enacted HB 274, which required the Texas Supreme Court to issue procedural rules concerning four subjects. In relatively short order, the court issued rules concerning two of those subjects—permissive interlocutory appeals and offers of judgment. The other two subjects—expedited resolution of small cases and dismissal of frivolous cases—took longer. Those topics were the focus of a great deal of study, comment and debate for more than a year, with input from committees appointed by the court, as well as outside groups, including the State Bar of Texas, a coalition group formed by ABOTA and the plaintiff and defense bar, and a private tort reform group. The Supreme Court issued draft rules on November 13, 2012 and invited public comments. After receiving extensive—and often critical—comments from numerous organizations, including three Sections of the State Bar of Texas and plaintiff and defense bar organizations, the supreme court made some revisions to the draft rules, but retained their critical mandatory provisions.

Expedited resolution of "small" cases. The principal rule governing "expedited actions" is new Rule 169. It governs cases, other than healthcare liability, Family Code or Property Code cases, in which the claimant seeks only monetary relief , which in the aggregate does not exceed $100,000, including "damages of any kind, penalties, costs, expenses, pre-judgment interest, and attorneys fees." Although some have suggested the $100,000 ceiling will capture a large number of cases, its scope may be limited by including in the $100,000 figure certain items that in some cases are excluded when calculating jurisdictional limits, such as court costs, expenses, pre-judgment interest and attorneys' fees. It also may be limited by excluding cases seeking a combination of monetary and non-monetary relief.

The binding nature of the $100,000 ceiling is reinforced by a provision that a party pursuing relief under this rule may "in no event" recover a judgment exceeding $100,000, excluding post-judgment interest. This contrasts with other jurisdictional limits in Texas, which allow a final judgment to exceed a court's jurisdictional limit so long as the court's limited jurisdiction was originally invoked in good faith and without fraud. It also avoids the occasional anomaly of a jury's verdict exceeding the amount of damages sought in the complaint, which normally is cured by a post-verdict amendment increasing the complaint's ad damnum clause to match the jury's verdict. Under these rules, the $100,000 cap is absolute.

In an apparent nationwide first among states with rules for expedited resolution of small cases, and despite virtually unanimous opposition from all interested parties, the Texas rules are mandatory. Unlike other states where parties can jointly opt out or a defendant can unilaterally do so, the Texas system is difficult to escape once invoked. In its November order publishing the draft rules, the Supreme Court acknowledged the opposition to this feature of the rules, but concluded that the objectives of the statute and the benefits to the judicial system could not be realized "without rules that compel expedited procedures in smaller cases."

The new rules contain several features designed to enforce their mandatory nature and yet prevent parties from "gaming the system" for unfair advantage. For example, Rule 47 now requires claimants to state in

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their pleading the amount of damages sought, including a specific allegation for invoking the $100,000 ceiling. A party who fails to specify the damages sought is prohibited from conducting discovery until a compliant amended pleading is filed. A party that initially invokes the expedited resolution system can leave the system if it timely files an amended pleading seeking damages beyond the $100,000 limit, but must obtain leave of court for "good cause" shown if it waits too long to do so (i.e., more than 30 days after discovery has closed or less than 30 days before trial). Additionally, any party may file a "good cause" motion to leave the expedited actions process. If the trial court grants the motion, it must reopen discovery, but has discretion about continuing trial of the case.

Neither the new rules themselves nor the court's enabling order define "good cause," although Rule 169 does say that good cause must "outweigh any prejudice to an opposing party." The official comments give examples of factors that may be considered in determining "good cause," including whether the damages sought by multiple claimants against the same defendant exceed $100,000 in the aggregate, whether a defendant has filed a compulsory counterclaim that exceeds $100,000 or seeks non-monetary relief, the number of parties and witnesses, the complexity of the legal and factual issues, and whether an interpreter is necessary. The new rules do not include any provision for interlocutory appellate review of a ruling on a "good cause" motion.

The mechanism for promoting expedited resolution of these cases is a severe restriction on the time afforded for discovery and trial. All discovery must be completed within 180 days after the date the first request for discovery of any kind is served on a party. Parties are basically limited to 15 interrogatories, 15 requests for production, 15 requests for admissions, and a request for disclosure (a special Texas rule identifying 12 categories of discovery to which no objection can be made). Additionally, upon request, a party must disclose all "documents, electronic information and tangible items" in its possession, custody or control that it "may use to support its claims or defenses." Depositions are limited to a total of six hours per party for examination and cross-examination of all witnesses, although the parties can agree to expand this limit to 10 hours and the trial court may modify the limits to avoid "unfair advantage" to a party. Pre-trial Daubert challenges to experts are prohibited unless raised as an objection to summary judgment evidence or requested by the party sponsoring the expert.

The November 2012 draft rules prohibited the trial court from sending the case to alternative dispute resolution (ADR) absent contractual agreement or consent of the parties. In the face of significant public criticism, the final rules were changed to permit the trial court to order no more than one half-day ADR session (although the parties can voluntarily agree to more).

Once discovery closes, the Rules provide a means for quickly moving the case to trial. Upon any party's request, the trial court "must" set the case for trial within 90 days after the close of the discovery period. The court may grant up to two continuances, which collectively cannot total more than 60 days. At trial, each "side" (not party) is allotted eight hours to present all parts of its case, from jury selection through closing arguments (not including time spent on objections, bench conferences and challenges for cause to a juror). On motion and for "good cause" shown (again, an undefined term), the court may expand these time limits to 12 hours per side.

The new rules' mandatory nature promises to be controversial. One defense organization has already suggested that counsel should include a constitutional challenge to the rules' mandatory provision as a standard part of their answers. Nevertheless, if the rules work as intended, they will produce a system that resolves "small" cases in a reasonable time (typically less than a year) at a cost commensurate with the amount in controversy.

"Loser pays" motions to dismiss frivolous claims. As directed by HB 274, the Texas Supreme Court also promulgated new Rule 91a, dealing with the dismissal of frivolous claims, which Rule 91a labels "baseless" claims. This Rule introduces to Texas state court practice a form of the federal system's 12(b)(6) motion to dismiss. A party may move to dismiss "a cause of action" that has "no basis in law or fact." A cause of action has no basis in law if "the allegations, taken as true, together with inferences reasonably drawn from them, do not entitle the claimant to the relief sought." It has no basis in fact "if no reasonable person could believe the facts pleaded."

The rule is intended to provide a tool for dismissing frivolous claims at an early stage of the proceedings. To achieve this goal, a motion to dismiss must be filed within 60 days after service on the movant of the first pleading containing the challenged cause of action, and the court must grant or deny the motion within 45 days after it is filed. The responding party must receive

twenty-one days' notice of hearing and must file any response at least seven days before the hearing.

The trial court may not consider evidence in ruling on the motion and must base its rulings solely on the pleadings, although it may take into account pleading exhibits permitted by Texas Rule of Civil Procedure 59. Under Rule 59, only documents "constituting, in whole or in part, the claim sued on, or the matter set up in defense" are permissible exhibits. Examples listed in Rule 59 include "notes, accounts, bonds, mortgages, [and] records." If new Rule 91a is enforced, this will prevent parties from attempting to defeat a motion to dismiss by attaching as exhibits documents that are merely evidentiary.

Except for cases by or against a governmental entity or official, the new rule also requires the trial court to award "the prevailing party" its attorney's fees and costs incurred with respect to the challenged cause of action. This provision differs somewhat from the directive of HB 274, which stated that attorneys' fees must go to the party that prevails "in whole or in part" on the motion. Perhaps the distinction is that Rule 91a speaks of challenges to a "cause of action," as to which there presumably can be no partial victory: the trial court either does or does not dismiss the challenged cause of action.

Because the new rule awards attorneys' fees to the prevailing party (which can be either plaintiff or defendant), defendants may hesitate to file a motion to dismiss unless they feel strongly about its chances of success. The rule allows parties to avoid the possibility of losing and paying their opponent's fees by either voluntarily dismissing the challenged cause of action or withdrawing the motion at least three days before the date of hearing. If the respondent amends the challenged cause of action at least three days before the hearing date, then the movant can either withdraw the motion to dismiss or file an amended motion directed to the amended cause of action. An amended motion restarts all of the hearing and response deadlines. The rule requires strict compliance with the three-day deadline for withdrawal and amendment. If either party misses that deadline, the court must rule on the motion (and award fees to the prevailing party), unless the parties agree otherwise.

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OPERATOR'S MANUALS ARE...

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instructions. The rest they can figure out by themselves, or so they believe. It is somewhat understandable. They just bought a new "toy" and want to play with it. Who wants to take the time to read through all the boring and, often, common sense instructions that fill the manual that came with that new toy ?

As an attorney handling a product liability case, reading the operator's manual is not optional.

As an attorney handling a product liability case, reading the operator's manual is not optional. It is a given that "knowing your case" means, in part, knowing about the product at issue. Not simply being generally familiar with the product, but being intimately familiar with it. Not simply knowing what the product is and what it is used for, but knowing how it works and how it is properly used. This means, among other things, doing what few others do – reading the operator's manual. Reading all the silly warnings, the serious warnings, the assembly instructions and the instructions on how the product should and should not be used. It means reading the operator's manual cover to cover.

Several years ago I defended a case where the plaintiff admitted to not having read the operator's manual. This resulted in plaintiff being seriously injured. Making matters worse, his expert had not read the operator's manual. This resulted in plaintiff's case being seriously damaged.

The case involved an allegedly defective blade on a table saw. The blade was equipped with carbide tips which, according to the plaintiff and his expert, had not been properly affixed to the teeth of the blade. One of those tips broke off the blade while the saw was in use, injuring the plaintiff.

The plaintiff's attorney did his homework and hired the precise kind of expert needed to opine about the bonds between the carbide tips and the steel of the blade and the problems he believed existed in that blade. Not only did the plaintiff's attorney hire the right kind of expert, he hired one who was extremely well-respected. His credentials were impeccable and his examination of the blade, painstaking.

Upon examination of the saw, our experts discovered that the blade had hit the throat plate. Given the clearance between the blade and the edge of throat plate, it was clear that there had to have been substantial pressure applied to the side of the blade. It was obvious that the cause of that pressure was a fairly substantial kickback that put the blade into a harmonic.

Plaintiff's expert knew it was the contact with the throat plate that caused the carbide tip to break free. He even did his homework and knew the blade contacted the throat plate because of a kickback. He owned a table saw made by a different manufacturer. He had used it multiple times and knew about kickbacks. He, however, was not an expert on table saws, let alone the specific model of table saw at issue in our case. Nor was he an expert on how a table saw should properly be used or, more importantly, not used. And, as stated, he never bothered to read the operator's manual for the saw.

Without knowing how to properly use the saw, the expert volunteered why "in his expert opinion" the accident happened. He even couched his testimony in terms of proximate cause.

The expert pointed out that plaintiff had the rip fence on the saw only a few inches away from the blade, but that he was not making a rip-cut (a cut along the grain of the wood). Rather, he was making a cross-cut (a cut across the grain of the wood). He also pointed out the plaintiff's testimony that he rested his hand on the rip fence as he pushed his work piece across the table. According to plaintiff's expert, the plaintiff did not push the board straight across; he inadvertently pushed it into the blade at an angle with the end of the work piece against the rip fence, binding the blade. As the work piece was against the rip fence, it was unable to correct itself and the saw kicked back.

Plaintiff's expert was absolutely correct.

When the accident happened, the plaintiff was making a cross cut. Moreover, he had the rip fence installed on the saw immediately adjacent to the blade and he was using it as a guide. That is what caused the kickback and, ultimately, the carbide tip to break and injure plaintiff. Unbeknownst to plaintiff, however, this was the defense theory all along. Yet, the defense did not even have to disclose its theory, or even introduce the issue, at the deposition. The expert volunteered it.

If the expert had read the operator's manual, he would have seen numerous instructions and warnings, in multiple locations throughout the manual, stating:

"Move the rip fence out of the way when crosscutting."

"Never use rip fence as cutoff gauge when crosscutting."

Indeed, the operator's manual made clear that improper use of the saw – like using the rip fence as a gauge when crosscutting – could result in a kickback and serious injury to the user.

After a few follow up questions, the expert fully agreed that the proximity of the rip fence to the blade was the proximate cause of the accident and the plaintiff's injuries. He had no idea what had just happened, as he had no idea what the operator's manual said.

In fact, the plaintiff's attorney, intrigued by the line of questioning, explored it again on direct, clarifying the expert's opinion even further. In the end, the plaintiff's expert – with no one on that side of the table being any the wiser – had inadvertently testified that the proximate cause of the accident was the plaintiff's improper use of the saw in direct contravention of the directions in the Operator's Manual. That but for that improper use, the accident would never have happened.

If the plaintiff read the operator's manual on the front end, perhaps he would not have misused the saw and the accident would never have happened. If the plaintiff's attorney had read the operator's manual more closely, he could have cautioned his expert about offering opinions on causation. If the plaintiff's expert had read the operator's manual, he would have not offered his opinion on the cause of the accident.

The point of the story is simple. Read the operator's manual that comes with the product. Then read it again. Then make sure any experts you hire read it. Then make sure they read it again. Operator's manuals are not just for nerds. They offer a lot more than "Do not attempt to stop chain with your hands" and "Do not iron clothes on body." You must know what they say about the product at issues because - what you do not know, may hurt you or your case.

THE STATE OF THE ART...

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ignoring traditional toxicological concepts that require the extrapolation of animal data to humans.[2] Critics of the low-dose theory cite an overreliance on studies by certain authors and an unbalanced interpretation that ignores the strong negatives of some studies and dismisses others based on their funding source, despite sound research methods underlying that industry-and government-funded research.

Current Regulatory Activity: EPA Endocrine Screening and Testing

In 1996, Congress focused on endocrine issues in passing the Food Quality Protection Act (FQPA) and amendments to the Safe Drinking Water Act. This legislation mandated screening of pesticide chemicals and certain safe drinking water contaminants and required the Environmental Protection Agency (EPA) to "take action," as appropriate, on substances found to have adverse effects on humans. Pursuant to this directive, the EPA established the Endocrine Disruptor Screening Program (EDSP), and devoted years to developing a formal screening system to identify chemicals with potential endocrine effects. Tier 1 screening has initially focused on estrogen, androgen and thyroid interactions. Tier 1 tests specify high dose exposures and results are not intended for use in risk assessment. Currently, the Tier 1 EDSP screen costs around $1 million per chemical. Tier 1 results will be evaluated together to determine whether there are potential endocrine pathway interactions and whether Tier 2 testing for use in risk assessment is warranted. A set of all Tier 2 tests that may follow is projected to cost millions per substance and will take years to complete.

The CPSC's Phthalates Regulatory Example

Congress' mandate to the Consumer Product Safety Commission (CPSC) on phthalates provides a striking legislative example of the trend toward cumulative risk assessment. In the Consumer Product Safety Improvement Act of 2008 (CPSIA), Congress directed the CPSC to appoint a Chronic Hazard Advisory Panel (CHAP), a group of seven scientists selected from nominations made by the National Academy of Sciences, to examine the endocrine effects of the full range of phthalates. Phthalates are plasticizers used in a variety of household products, such as toys, cosmetics, and food packaging. In recognition of the dynamic nature of multiple chemical exposures, the statute requires the CHAP to assess phthalate risks in a cumulative manner, rather than in isolation, and consider the effect of total exposure to phthalates, both from the children's products and other sources, such as personal care products and food. Congress did not tell the CHAP how to handle industry-funded studies but required that the scientists rely upon "the most, recent, best available, peer-reviewed, scientific studies . . . that employ objective data collection practices and employ other objective methods." Congress focused on the scientific validity and objectivity of the data collection and scientific method, not the funding source.

The CPSC's regulatory agenda schedules this groundbreaking phthalates risk assessment for completion in 2013. It will have ramifications beyond consumer product regulation, and the science will be relevant to work at both the Food and Drug Administration (FDA) and the EPA.

Will Obesogens be the Next Toxic Tort?

The emotional rhetoric in the press about the "stolen future" of children exposed to pesticides with "gender bending" effects that may cross generations or affect vulnerable fetuses presents significant tort litigation challenges. A recent opinion column in the New York Times used language suggestive of product litigation:

- "… following the script of Big Tobacco …"
- "…BPA. The failure to regulate it means that it is unavoidable..."
- "It's scary," said Jennifer T. Wolstenholme … "found behaviors … that may parallel autism … or attention deficit disorder in humans."[3]

Tort claims involving chemical causation have already been affected, with plaintiffs increasingly alleging health complaints such as diabetes, thyroid disease, and endometriosis caused by exposures to chemicals. Complaints can arise in the consumer, occupational or environmental area, with juries determining whether chemicals played a role in complex medical issues of hormonal variability. The burden of proof in a tort case is only a "preponderance of the evidence," and in many jurisdictions, the plaintiff need only prove that an exposure was a "substantial contributing factor" in the disease process. As if that challenge in the courtroom

2 http://www.americanchemistry.com/ACC-Letter-Endocrine-Disruption-Hearing

3 Nicholas D. Kristof, *Big Chem, Big Harm*, N.Y. Times, August 25, 2012, at SR11.

were not enough, the jury will face a scientific community divided on fundamental principles of toxicology, such as dose-response theories and extrapolation from animal studies. As a practical matter, how will juries perceive cross-examination into the diet and lifestyle of a plaintiff claiming obesity caused by exposure to pesticides?

The challenge of endocrine disruption science in the courtroom will not fall to the jury alone. The question of what effects on the endocrine system make a product "defective and unreasonably dangerous" presents an interesting legal issue for summary judgment. Courts will need to define injury, deciding whether endocrine "disruption" alone will suffice. Judges will also have to grapple with whether the low-dose endocrine theory is *Daubert*-worthy. Theories of causation resting on science developed to support regulatory policymaking may not meet the criteria for what constitutes legally sufficient causation evidence in the courtroom.

Given the health costs associated with obesity, "obesogens" may become the next tort litigation challenge arising from endocrine disruption science. This will depend on whether the science develops in a manner that supports the "obesogen" theory. Claims related to obesity raise a host of questions about how obesity will be defined for purposes of tort liability, what "mitigation of damages" might mean, how the substantial contributing factor test would be applied to this multi-factorial condition, even how the statute of limitations would work. In light of the uncertainty, lawyers serving companies that manufacture chemical products must recognize that regulatory compliance is not necessarily a defense in tort cases, and would be well served by proactively monitoring the developing science. ⚖

THIRD RESTATEMENT OF…

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> defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:
>
> 1. contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
>
> 2. is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
>
> 3. is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

The Third Circuit Court of Appeals has recognized that negligence concepts have been applied in products liability cases by Pennsylvania state courts, and further commented that they have "muddied the waters at times with the careless use of negligence terms in the strict liability arena." *See* Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 53 (3d Cir. 2009). To date, three Third Circuit decisions have now predicted that if the Pennsylvania Supreme Court were confronted with the issue, it would adopt the *Third Restatement of Torts* with respect to products liability actions, rather than continue to apply the *Second Restatement*. At the federal district court level, there has been a split among the judiciary – some holding that the *Second Restatement* should apply because the state Supreme Court has not affirmatively adopted the *Third Restatement*, and others holding that the *Third Restatement* must apply because the Third Circuit's prediction that the Supreme Court would adopt the *Third Restatement* is binding upon federal district courts sitting in diversity.

The rationale for the latter pronouncements is that the Pennsylvania Supreme Court has not issued a definitive opinion as to whether the *Third Restatement of Torts* or the *Second Restatement of Torts* applies to strict liability and product defect cases. Therefore, federal courts applying substantive law must predict how the Commonwealth of Pennsylvania's highest court would decide the case. In a 2011 decision, the Third Circuit affirmed the district court's application of the *Third Restatement*, and allowed the defendant to rely on evidence of compliance with industry and governmental standards on the issue of whether a

product was "defective" or not. *Covell v. Bell Sports, Inc.*, 651 F.3d 357 (3d Cir. 2011). The *Covell* decision reaffirmed the Third Circuit's 2009 decision in *Berrier v. Simplicity Manufacturing, Inc.*, in which the Court also predicted that the Pennsylvania Supreme Court would not continue to apply the *Second Restatement*, but rather, would adopt the *Third Restatement of Torts* for product liability actions. The most recent discussion of this topic was an Order issued on a petition for rehearing in *Sikkelee v. Precision Airmotive Corp, et al*, 876 F.Supp.2d 479 (M.D.Pa. July 3, 2012, Jones, J.) and 2012 WL 5077571, Case No. 12-8081 (3d Cir. Oct. 17, 2012) where, although the Third Circuit refused to accept an interlocutory appeal on the issue or grant rehearing, it did hand down an Order in which it once again stated that because the Pennsylvania Supreme Court has not yet held which Restatement applies, it would follow its own Third Circuit precedent in *Berrier* and *Covell* that the *Third Restatement* should apply.

These decisions serve to highlight the dichotomy between a products liability analysis under the *Second Restatement* versus the *Third Restatement*. Pennsylvania state courts' use of negligence concepts despite their statements that negligence concepts have no place in a product liability analysis (following the *Second Restatement*) has resulted in confusion and inconsistency. Therefore, an argument can be made that the Pennsylvania Supreme Court should adopt the *Third Restatement* so that a clear standard can be consistently applied. The *Third Restatement*'s approach to strict liability design defect law includes a balancing of a product's risk and utility, as well as a much more flexible approach than the *Second Restatement*. In addition, the *Third Restatement* applies a broader post-sale duty to warn, and injects "comparative fault" and negligence concepts (such as "foreseeable risk" of harm and "care" exercised by the defendant) into products liability law – something that has been precluded in state courts.

The Third Circuit's prediction that the *Third Restatement* should apply to product liability actions in Pennsylvania should be binding on federal district courts sitting in diversity absent an affirmative indication from the Pennsylvania Supreme Court that the *Restatement Second* remains the law of Pennsylvania. Therefore, the *Third Restatement*'s "reasonableness" and "balancing" approach to strict liability will be utilized in federal diversity actions. As a result, federal court will be a more favorable forum than state courts for manufacturers and other products liability defendants, and the strategic decision of whether to remove an action to federal court will be much more important at the outset of a product case in Pennsylvania.

2013 TIPS CALENDAR

April 2013

4-5 **Emerging Issues in Motor Vehicle Product Liability Litigation National Program** — **Arizona Biltmore Resort & Spa, Phoenix, AZ**
Contact: Donald Quarles – 312/988-5708

5-6 **Toxic Torts Committee Midyear Meeting** — **Arizona Biltmore Resort & Spa, Phoenix, AZ**
Contact: Felisha A. Stewart- 312/988-5672

13-17 **TIPS National Trial Academy** — **Grand Sierra Resort, Reno, NV**
Contact: Donald Quarles – 312/988-5708

23-28 **TIPS Section Spring Leadership Meeting** — **JW Marriott Washington, DC**
Contact: Felisha A. Stewart- 312/988-5672
Speaker Contact: Donald Quarles – 312/988-5708

May 2013

2- 4 **Fidelity & Surety Committee Spring Meeting** — **Walt Disney World Swan Orlando, FL**
Contact: Donald Quarles – 312/988-5708

16-18 **Property Insurance Law Committee Spring CLE Meeting** — **PGA National Resort & Spa, Palm Beach Gardens, FL**
Contact: Ninah F. Moore- 312/988-5498

August 2013

8-13 **ABA Annual Meeting** — **San Francisco Marriott San Francisco, CA**
Contact: Felisha A. Stewart- 312/988-5672
Contact: Donald Quarles – 312/988-5708

October 2013

8-13 **TIPS Fall Leadership Meeting** — **Minneapolis Marriott Hotel Minneapolis, MN**
Contact: Felisha A. Stewart- 312/988-5672
Speaker Contact: Donald Quarles – 312/988-5708