OREGON STATE BAR SECTION Products Liability

Products Liability NEWSLETTER

A section newsletter of the Oregon State Bar

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Notes from the Chair

By Meagan Flynn, Preston Bunnell & Flynn LLP

The section's annual CLE Seminar will be held the afternoon of Friday, October 26, 2007.

We will continue last year's tradition of holding it at the Governor Hotel in downtown Portland and starting off with a reception at noon. The reception offers a good opportunity to mingle with colleagues and enough food that you don't need to worry about getting lunch before the CLE.

Each year, the planning committee strives to find topics that are interesting and relevant to both those section members with significant experience litigating product liability cases and those who joined to the section only to receive this fabulous newsletter on a semi-regular basis.

This year's program will emphasize the fundamental issues that every practitioner wants to be aware of, including new developments and issues on the horizon that even the most experienced product lawyers may not yet have heard about. Jay Beattie, the section's past-chair, will talk about fundamentals and recent developments in deciding what is and isn't plead as a product claim and about the many ways that determination can alter the course of your case. Next, an experienced panel of plaintiff and defense counsel – Jane Paulson, John Coletti, Molly Mullen and Dan Reising – will discuss important considerations and strategies from the moment the client first calls through the pleading and motion stage. To wrap everything up, Jim Coon and Heather Van Meter will bring you up to date on recent developments in product liability law and even offer a heads-up on pending appellate cases with issues to watch for.

All this plus food and a 4:15 ending time for a mere $45 for section members ($65 for non-members). What a great way to spend a Friday afternoon. Just fill out and return the registration form printed at the back of this newsletter.

Food Allergies Litigation

By Heather J. Van Meter, Williams, Kastner & Gibbs PLLC

Food is the sustenance of human life, health and development. Food gives us energy to get through each day, but can also put us to sleep after Thanksgiving. Food can help keep us thin, but can contribute to obesity. Food can even be the subject of entire cable television channels.

Food Is A "Product"

For litigation purposes, food is simply a "product." Food is subject to products liability laws just like cars, hairdryers and widgets.

Continued next page

As a product, food has some unique characteristics. Some people, especially children, have allergic reactions to food. Statistically speaking, two to four percent of adults have food allergies, and six to eight percent of children have food allergies.[1] Readers may be surprised by the low incident rate – especially because 20-25% of Americans *believe* they have food allergies.[2] Some plaintiff attorneys argue that the known incident rate of food allergies, especially connected to certain products, makes all food allergy claims for those products foreseeable.

Food Allergies – The Basics

Allergic reactions to food involve an *immune* system response to a food product, specifically a food protein. The presence of the food protein triggers the abnormal immune response.

The first exposure to a food allergen will *not* produce an allergic reaction. It will produce a "sensitization," incorrectly programming the immune system to produce a certain antibody the next time the food allergen is presented. This is important because if a person has a peanut or other food item one time without incident, this does not mean that the person has no allergy to the food. This also means that a person cannot claim that upon *first* exposure to a food an allergic reaction resulted.

When a food is consumed the second time, if a person is allergic, antibody is produced, attaches to mast cells, then causes allergic reaction. The reaction can range from barely noticeable to life-threatening. Oral allergic reactions include an itchy mouth, itchy throat, or swollen lips. The respiratory system may also react, including asthma or laryngeal swelling. The dermal system can react, and skin may become itchy or break out in hives or eczema. Hives is the most common allergic reaction, although only 20% of acute hives are related to food allergies.

More severe allergic reactions can include nausea, vomiting, diarrhea or anaphylaxis. An anaphylactic reaction is characterized by rapid onset with multiple organ involvement, and is potentially fatal. Anaphylactic reaction to food accounts for 30,000 emergency room visits, 2,000 hospitalizations,[3] and 150 to 200 deaths per year.[4] The foods at highest risk for anaphylactic reaction are peanuts, tree nuts, fish and shellfish, and peanuts and tree nuts typically cause the most severe reactions.[5] It is uncommon for adults to have multiple food allergies. Epinephrine is the most common treatment for anaphylaxis, and the most common reason for food allergy fatalities is delayed administration of epinephrine. Delayed administration of epinephrine may be the basis for medical negligence claims as well as food allergy product liability claims.

Presently, there is inadequate published data establishing a link between allergic reactions to food and migraines, behavioral/development disorders, arthritis, seizures, inflammatory bowel disease, or other similar conditions.

A true allergic reaction to a food will begin within two hours of ingesting the food, except diarrhea may require four to six hours to develop. The most severe reactions, including anaphylaxis, will occur within a few minutes of ingesting the food.

Food Intolerance Versus Food Allergy

It is important to note the difference between food intolerance and food allergy. Food intolerance or digestion difficulties involve a clinically abnormal response to an ingested food or additive. Food intolerance does not implicate the *immune* system. Examples of food intolerance include lactose intolerance, food poisoning, acid reflux disorder, and pharmacologic reactions to caffeine, MSG or nitrates (as in wine).

Food Allergies and Children

It is a fact that children have more food allergies than adults. For children, food allergies most commonly begin at ages one to three years, although medically speaking allergies can start at any age. Most children "outgrow" their food allergies. The most common food allergies for children are milk, soy, egg or wheat products. Most children develop a tolerance to these foods by age three. However, peanuts are different, only 20% of children allergic to peanuts will develop a tolerance by adulthood.

There has been a recent increase in awareness and diagnosis of childhood food allergies. Schools are becoming more sensitive to childhood food allergies, perhaps too sensitive, with some schools banning peanut butter in any form due to allergy concerns. Some people speculate that a recent increase in childhood food allergies is related to lack of childhood exposure to food allergens. Others speculate that any increase is due to doctors advising parents *not* to expose young children to food allergens, or alternatively an increase in physician awareness and diagnosis of food allergies. Presently, there is inadequate published data establishing a link between childhood food allergies and any of these events.

Food Allergen Labeling and Consumer Protection Act

Overall, the most common allergenic foods are milk, eggs, peanuts, tree nuts, soy, fish and some shellfish, but it was difficult for people with these allergies to know when the allergens were present in packaged foods. For this reason, the Food Allergen Labeling and Consumer Protection Act was added to the Federal Food, Drug and Cosmetic Act and became effective in 2006. 21 U.S.C. § 321. FALCPA requires food allergen labeling of manufactured and packaged foods only. It does *not* regulate or require food allergen labeling on raw food products, restaurants, grocery stores or other establishments serving prepared foods. At the time FALCPA was debated, some commentators sought food labeling regulation on restaurants, prepared foods, grocery stores, delis and schools. There are still some organizations pushing to add these entities to FALCPA's regulatory scheme. Additionally, some states and municipalities may extend FALCPA-type labeling requirements to these entities.

In addition to labeling requirements, FALCPA also established food process-

ing protocols to help prevent inadvertent contamination of foods by allergens. The Center for Food Safety and Applied Nutrition, within the Food and Drug Administration, principally regulates allergen information requirements. www.cfsan.fda.gov.

Food Allergy Claims Analysis

Food allergy claims come in a variety of forms ranging from inadvertent contamination of food products to improper labeling claims. Both manufacturing defect and failure to warn claims are possible. Food allergy claims may be based on any foods, although the most common are milk, eggs, peanuts, tree nuts, soy, fish and shellfish. It is important to note that if a claimant alleges allergic reaction to something other than the most common food allergens, lack of foreseeability may exist.

Potential defendants to food allergy claims include food processors and manufacturers, food distributors, grocery stores, schools, restaurants, and even homeowners. FALCPA does not extend to all of these potential defendants, but restaurants and schools have already been sued for food allergy claims.

For initial case screening purposes, it is important to be familiar with the conditions caused and not caused by allergic reactions to food. For instance, if a potential client claims migraines or arthritis resulting from a food allergy, the claim is suspect. Additionally, allergic reaction timing is important. If a potential client claims that an anaphylactic response developed 24 hours after ingestion, the claim is suspect.

If a food allergy case is presented, the plaintiff's first order of business is to immediately collect and preserve the food item and any packaging. If the food item is not available, a spoliation defense may be raised, especially on a food allergen contamination claim. The food item should then be tested to determine whether there is evidence of a food allergen, and/or the packaging should be inspected for warnings. The claimants' medical history should also be investigated.

If a claim is based on improper labeling or failure to disclose a food allergen regulated by FALCPA, any analysis should include whether the claim is preempted. If the claim conflicts with or is inconsistent with the purposes of FALCPA, it may be subject to removal to federal court (if originally filed in state court), and/or defendant may file a motion for summary judgment based on alleged violation of the supremacy clause and federal preemption. FALCPA preemption challenges would likely only apply to those allergens regulated by FALCPA.

Last but not least, damages. Damages in most food allergy cases will either be extremely high or extremely low. In low damage cases, a claimant will have had minimal symptoms requiring little or no medical treatment and perhaps one day of work lost. In high damages cases, the claimant will have had a severe or anaphylactic reaction requiring an emergency room visit or hospitalization with several days' treatment and lost work, possibly including long-term impairment. The worst case scenario is food allergy wrongful death, of course. But with only 150 to 200 deaths per year nationwide, these cases are thankfully rare.

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Don't Know Much About Epidemiology?

By Steven Rotman, Reprinted with permission of TRIAL (September 2007)

Epidemiology plays an important but complicated role in pharmaceutical and toxic tort litigation. Courts and scientists place greater value on epidemiologic evidence than on animal studies or human case reports and view epidemiological studies as the preferred evidence for determining the cause of disease in humans.

Epidemiology applies the scientific method to the study and comparison of groups of people, using the principles of medicine, public health, and biostatistics. Simply put, epidemiology can illuminate whether drugs cause, or are associated with, injuries.

For instance, some diseases, such as mesothelioma, occur only with exposure to a harmful agent (in that case, asbestos). More often, however, the disease or injury is not uniquely linked to the exposure. People not exposed to cigarettes still can get lung cancer, and not all cigarette smokers get lung cancer—yet we know that lung cancer is caused by cigarette smoking from multiple lines of evidence (animal studies, human case reports, experimental studies, toxicology data). Epidemiologic studies constitute the best evidence, providing a valid statistical association between exposure to cigarettes and lung cancer.

In pretrial *Daubert* proceedings, epidemiological studies often come under intense scrutiny, and if the results are negative (that is, not finding a valid association between exposure to the agent under study and an increased risk of the disease) or deemed unreliable, they can lead to case dismissal.[1] Even when epidemiological studies provide strong evidence in support of causation, defense lawyers and their retained experts will point out the studies' limitations—and all studies have limitations.

Jurors tend to find these studies confusing because of their complexity, and defense experts can make them more so. Many judges also misunderstand them. For these reasons, a civil jury trial is a challenging forum for presenting this type of evidence.[2]

General and specific causation

The ultimate issue in pharmaceutical litigation is causation, and a single epidemiological study does not establish causation. A study can, however, answer whether exposure to a drug is associated with an increased risk of the disease or condition under study.

Scientistss recognize that causation is a judgment about the totality of experimental or epidemiological data.[3] As an amicus brief in the *Daubert* case noted, "By its nature, scientific evidence is cumulative: the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion."[4] Only through the accumulation of scientific evidence may a scientist infer causation.[5]

Proving causation in pharmaceutical cases requires showing that the drug is capable of causing the alleged injury (general causation) and that it was a substantial contributing cause of the plaintiff's injury (specific causation). Epidemiology is primarily used for addressing general causation but can also provide useful evidence in support of specific causation.[6]

Other evidence can help prove general causation. Case reports of the injury occurring after drug exposure provide good foundation evidence and, depending on their quality and content, can be persuasive.

Defendants downplay the value of case reports, claiming that they are merely anecdotal because there is no control group. However, if the injury has no other plausible explanation, if the timing of the injury in relation to drug exposure is striking, if the report concludes that the exposure was a likely cause of the injury based on differential diagnosis, or if the case report includes a challenge/rechallenge (where one takes a drug; watches for reactions; stops the drug; and then resumes taking it, watching for the same reactions as before), these facts can provide persuasive general causation evidence.

Other evidence that contributes to proving general causation includes animal studies and human pharmacology and toxicology experimental evidence, which provide insight into the mechanism of action (how a drug causes an injury) and biological plausibility (a causal connection that is consistent with medical knowledge). Proving the mechanism of action, although certainly helpful, is not required, and this mechanism is often, at best, only partially understood. Indeed, the manufacturers of many drugs admit they do not know how the drugs work.[7]

In 1965, scientist Austin Bradford Hill suggested various factors scientists could consider when determining whether to infer causation.[8] Each element of the so-called Hill guidelines does not have to be established to distinguish causal from noncausal associations; causation can be inferred even if some of the criteria are not met.[9]

The Hill guidelines are strength (of the association); consistency (that is, a repeated observation in different populations); specificity; temporality; biological gradient (that is, dose response); biologic plausibility; coherence (that is, the findings are consistent with other knowledge); experiment (that is, supporting animal and clinical evidence); and analogy (to similar drugs and disease).

Study types

Epidemiological studies generally fall into one of several categories, depending

on the methods used to study the groups.

Cohort studies. Cohort studies are observational studies used when a large population exposed to a substance can be followed over time and compared with a large, unexposed population. Cohort studies can be used to measure the effects of environmental and toxic chemical exposures as well as the occurrence of adverse health effects in people who have used particular pharmaceutical products.

The largest cohort study ever conducted, the Million Women Study in the United Kingdom, showed a doubling of breast cancer risk among current users of combined hormone replacement therapy and increasing risk with increased duration of exposure.[10]

Case-control studies. These are a type of observational epidemiological study often used to evaluate the association between exposure to a drug and a rare or unexpected outcome of that exposure (such as hemorrhagic stroke or primary pulmonary hypertension). Case-control studies assess the effect of a drug by comparing users who have a disease or injury of interest (the "cases") to users without that disease or injury (the "controls").

By contrast, cohort studies start with a group of people exposed to a particular drug or agent and compare them with a group of people who were not exposed. Case-control studies usually are smaller (that is, fewer subjects are required), their duration is shorter, and costs are lower.

A case-control study starts with ascertaining a case group that has the disease or injury of interest, and a matched control group. Controls are matched to the case group on the basis of specified criteria, such as age, gender, race, and various socioeconomic characteristics.

Members of these two groups are then questioned extensively concerning lifestyle and health issues, medication use, and education level. If the question under investigation is whether Drug X causes Disease A, all cases and controls are asked to provide details about their exposure to Drug X. Preferably, the study should be "blind" to minimize bias—that is, study participants should be unaware of the study's hypothesis (that Drug X does (or does not) cause Disease A).

After statistical adjustments are made to account for differences between the groups with respect to known Disease A risk factors, a statistician can calculate whether there is a statistically meaningful difference of outcome between the cases and the controls, measure the magnitude of that difference, and calculate the degree to which the perceived difference could be due to chance.

Generally speaking, if the rate of exposure in the case group is greater than that in the control group (after adjustments for confounding factors), an association exists between the exposure and an increased risk of the disease. That association can be quantified, and the result is expressed as an odds ratio with a "P value" and/or a confidence interval. [See box on page 34 for definitions of common epidemiology terms.] Exposure data can be collected to allow for assessments of dose, duration of exposure, how recent the exposure was, and other variables.

Randomized controlled trials (RCTs). These are interventional clinical trials that test the efficacy of a drug or procedure. The random assignment of the drug exposure in RCTs by the scientists conducting the study distributes potentially confounding factors equally among comparison groups. One group includes users of the drug under study; the other includes users of an alternative drug for treatment of the same medical condition or users of a placebo.[11]

RCTs are considered the strongest type of epidemiologic study for evaluating drugs: They have confirmed and quantified the cardiac risks from Vioxx and the breast cancer risks from hormone replacement therapy.[12]

The Women's Health Initiative was a 15-year RCT involving 161,808 postmenopausal women designed primarily to determine if hormone replacement therapy conferred a cardioprotective effect. It also tracked, as part of an observational cohort study, fractures and the incidence of breast and colon cancer. A total of 16,608 women were involved in the Prempro arm of this study, which was halted because it detected increased numbers of adverse health events, including invasive breast cancer, among women who took the drug.[13]

In the Vioxx litigation, RCTs have provided strong evidence of causation. The VIGOR study was designed to show that Vioxx caused less gastrointestinal toxicity than traditional nonsteroidal anti-inflammatory drugs (in this case, naproxen).

ADVANTAGE was an even larger study of 5,557 patients with osteoarthritis who were randomly assigned either Vioxx or naproxen. The APPROVe study (which resulted in the eventual withdrawal of Vioxx from the market) was designed to test whether Vioxx slowed the progression of colonic polyps.

All three RCTs provided evidence that Vioxx increases the risk of heart attacks, and APPROVe revealed a doubling of risk of heart attack or stroke even in a healthy population.

Size matters – and other concerns

Underpowered studies may miss an association, so effective studies must have adequate sample size to detect a difference between exposed and unexposed groups—if a difference really exists. Detection of rare events can require substantial numbers of study subjects.

Considerations such as time and cost may influence decisions about sample size and power. As a general rule, the greater the power, the more likely a study result will have a low P value and meet the conventional definition of statistical significance. When designing the study, the researcher will use statistics to calculate the minimum size of the study that will be needed to ensure that it answers specified questions within a specified range of confidence that the results will be valid, based on certain assumptions about exposure prevalence.

Often, a defendant will point out that although a study may associate a drug with a disease, it does not answer

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many necessary questions: For example, is the drug associated with the disease in subpopulations that were not studied, or at low doses, or after short-term use? A study usually will not generate enough data to answer these detailed questions, allowing defendants to argue that the plaintiff cannot meet his or her burden.

However, in cases where the defendant sponsored the study, the plaintiff can argue that the defendant chose to keep the study small enough to avoid answering those questions.[14] In addition, when pharmaceutical companies sponsor case-control studies to investigate whether their drug causes a disease or injury, they often do so under pressure from the FDA and usually design the studies to be marginal on power.

By doing this, they save money and, more important, are more likely to miss detecting a result associating their drug with the disease (that is, the study more likely will have a false negative result, called a "Type II" error). Moreover, in a study that does not have a lot of power, if there is a result that associates a drug with a disease, defendants will be able to argue that the results are not statistically significant or that the numbers are small or "fragile."

When there is a clear association of a drug with a disease, but the study results do not meet the conventional definition of statistical significance (with a P value less than .05, meaning there is less than a 5 percent probability that the association is due to chance), defendants often point out that the finding should be disregarded—even if the odds ratio is high, indicating some association between the drug and the condition. They treat a P value of .05 as a bright line.

This approach has been criticized by epidemiologists:

The notion that only when data demonstrate "statistical significance" do epidemiologists draw inferences about observed associations between suspected risk factors and medical conditions is mistaken. . . . Indeed, the term "statistical significance" could be expunged from the lexicon of the epidemiologist with no loss; accordingly it should not be allowed to assume an importance or role in law beyond its use as an epidemiological tool.[15]

In civil litigation, the burden of proof does not require a .05 P value as a standard for admissible evidence. Several noted epidemiologists have cautioned against using a P value greater than .05 to reject a study's results, noting that this practice transforms information about an association into a simple dichotomy of "significant" versus "not significant," which can be misleading.[16]

Observational studies, particularly case-control studies, are subject to a number of biases. The design and analysis of good case-control studies minimize biases to the greatest extent possible. Strict diagnostic criteria should be developed to ensure accurate identification of cases in the target population.

For instance, to minimize misclassification bias, investigators can confirm the disease by reviewing the medical records of suspected cases, without knowledge of their exposure status. Where timing of ingestion in relation to onset of symptoms is critical, extra care must be taken to ensure accurate data about when each person took the drug.

Inclusion and exclusion criteria should be clearly defined for both cases and controls before they are enrolled in the study. Exposure should be clearly defined, and an exposure window should be identified. Interviewers should be randomly assigned to cases or controls, and questions should be asked about multiple medications—this blinds subjects to the exact exposure under study. If possible, the interviews should be structured and scripted to protect against interviewer bias.

Working with experts

That an exposure may be associated with a disease does not mean that the exposure is the cause of the disease. At deposition, most epidemiologists will agree that there are only four possible explanations for a finding that A is associated with B: causation, chance, bias, and confounding factors. The researchers must therefore consider whether chance, bias, or confounding factors are likely explanations for the finding by reviewing the study critically.

In the end, researchers must make a judgment about whether an association indicates that a drug causes a condition. Chance, bias, and confounding factors cannot be eliminated completely, but they can be minimized. Experts should be questioned so that the opinion that causation is the most likely explanation for the results of the study can be critically explored. And all experts can be questioned on the roles of chance, bias, and confounding.

It is important not to get bogged down in a minitrial of the study itself. An expert, on direct examination, should be able to fully describe a study in about 30 minutes, explaining that all studies have limitations and biases and that, while chance can never be eliminated, it can be reduced to an acceptable level.

The use of visual aids at trial can be very helpful. For example, when the tables that appear in a published study are projected on a screen in the courtroom, jurors can see the data as the expert interprets it.

A case study

The litigation surrounding the drug phenylpropanolamine (PPA)—an ingredient in decongestants and appetite suppressants—and its role in causing hemorrhagic stroke in users featured a large, industry-funded, case-control study conducted by Yale researchers working with top stroke neurologists.[17] FDA reviewers concluded that the study was "one of the best planned, conducted, and most thoroughly analyzed studies reviewed in the last ten years"[18] and that it "demonstrated an increased risk of hemorrhagic stroke associated with PPA use."[19] Subsequently, PPA was removed from the market.

This study looked like a plaintiff's dream come true, and defense lawyers and their experts set out to destroy its credibility. The defendants took multiday depositions of the study's lead investigators and obtained by subpoena about 60 boxes of study documents, includ-

ing e-mail and medical records from all patients who participated.

Internal records revealed that the PPA manufacturers had developed a strategy to attack the study before they even read it. The defendants unveiled a massive assault on the study in a *Daubert* brief filed in the multidistrict litigation (MDL), claiming that the study was fatally flawed in several ways, including its design, which industry sponsors had approved. According to the defendants:

- The study results were "fragile" due to small numbers, and the participation rate was too low.
- Cases were misclassified based on the timing of PPA exposure.
- Investigators (whom the industry sponsors had selected) had manipulated the data to find a positive association between PPA and hemorrhagic stroke.
- The control selection process was flawed.
- Investigators failed to account properly for the possibility that the stroke started before PPA ingestion.
- The results were not statistically significant.
- The study did not address (and thus did not answer) questions about every conceivable subpopulation (men, women, children, elderly) and every stroke subtype.

In rejecting this *Daubert* challenge, the PPA court made no attempt to resolve the many disputed issues concerning the study. Instead, it criticized the defense approach as an "ex post facto dissection" of the study. The court concluded that the defense "fail[ed] to undermine [the study's] reliability,"[20] recognizing that scientific studies almost invariably contain flaws.

The court also noted that researchers commonly extrapolate from the subpopulations studied to subpopulations not studied, if certain conditions are met: for instance, if there is no biological reason why they should not apply and if there is a good reason why only select subpopulations are studied. (For example, children are commonly not studied due to difficulties with informed consent—yet, extrapolation from the results of adult studies is common.) Had there been several studies—as there were linking Vioxx and heart attacks—it would have been less likely that the defense would have taken this attack strategy because the defense loses credibility if its strategy is predicated on attacking all the studies.

The plaintiff attorneys had to defend the study against these attacks. Any scientist would understand that limiting a study's application to specific subpopulations is rarely a concern in the real world; however, it became an issue in this litigation and will become one in future cases if the defense believes it can succeed with a lay jury or some judges in making arguments that would never fly with scientists.

To avoid having an entire trial dedicated to proving whether a study is valid and its results reliable, plaintiff attorneys should plan to address these issues quickly and thoroughly. They should counter such criticisms primarily in cross-examination of defense experts, and leave an option for rebuttal expert testimony if needed.[21]

When a single study, no matter how worthy, is the main support for an argument, and the defense proceeds to tear it apart, the best strategy is to expose the defense effort as a litigation tactic and show how it is misleading. Make the credibility of the defense lawyers and experts the issue.

To make sure the study results are in your grasp, have an epidemiologist or a biostatistician available to consult in advance of trial; use basic epidemiology textbooks to gain familiarity with epidemiological terms and concepts; and aim to master the pertinent study-related documents, including the protocol, minutes of meetings, draft reports, and data summaries.

Proving causation in pharmaceutical cases with evidence from epidemiologic studies can make or break a case. Lawyers must understand the basics of epidemiology and develop a strategy for using epidemiological evidence effectively. This evidence can be spun by experts, so that even adverse study results can be presented in a light that advances the defendant's litigation interests. The best way to handle these challenges is to learn and understand the science, present it in a simple and straightforward manner, and identify and expose the spin for what it is.

Steven Rotman practices pharmaceutical litigation at Bubalo, Hiestand & Rotman in Louisville and Lexington, Kentucky.

Endnotes

1. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).
2. Lawyers handling pharmaceutical cases should work closely with their epidemiology expert witness and purchase several epidemiology textbooks for easy reference, such as Leon Gordis, *Epidemiology* (3d ed., Saunders 2005); Charles H. Hennekens & Julie E. Buring, *Epidemiology in Medicine* (Lippincott, Williams & Wilkins 1987); *Modern Epidemiology* (Kenneth J. Rothman & Sander Greenland eds., 2d ed., Lippincott, Williams & Wilkins 1998); Kenneth J. Rothman, *Epidemiology: An Introduction* (Oxford U. Press 2002); *Reference Manual on Scientific Evidence* (2d ed., Fed. Jud. Ctr. 2000).
3. *See Reference Manual on Scientific Evidence*, *supra* n. 2, at 374; *see also* Hennekens & Buring, *supra* n. 2, at 4.
4. Br. of Profs. Kenneth J. Rothman et al., in Support of Petrs., 1992 WL 12006438 at *11 (Dec. 2, 1992); *Daubert*, 509 U.S. 579.
5. *Id.*
6. The use of epidemiology and the concept of attributable risk for case-specific evidence in the context of a Vioxx case was discussed in J. Paul Sizemore, *Embracing Risk Factors in Pharmaceutical Litigation*, TRIAL 44 (Nov. 2006).
7. Many drug manufacturers admit in product labels that they do not know how the drugs work—take,

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Jury Instructions Every Defendant Should Request in a Punitive Damages Case

By George Pitcher and Adam Clanton, Williams, Kastner & Gibbs PLLC, Portland

Lawyers defending punitives claims have much to consider in drafting jury instructions given recent, substantial rulings from the United States Supreme Court regarding constitutional limits on punitive damage awards.[1] U.S. Supreme Court cases examining the appropriate calculation of punitive damages have been helpful in rooting out jury excess *after* a verdict is rendered, but there is little guidance in Oregon law regarding what instructions a jury should receive on excessive awards and their constitutional limits at the time of deliberations.

Juries make the first decision as to what amount of punitive damages to award, if any. Therefore defendants should pursue every opportunity to instruct juries on the limits that apply to punitive damages awards. Defendants should seek to maximize the benefit of their constitutional protections by requesting jury instructions regarding, at a minimum, three concepts:

(1) do not punish for harm caused to others;

(2) do not punish for extra-territorial conduct; and

(3) there must be a reasonable ratio between compensatory and punitive damages.

Oregon's Uniform Civil Jury Instructions presently do not address these issues, therefore defense lawyers must draft and request their own special instructions. Jury instructions and motions in limine provide two battlefields where trial lawyers will be attempting to flesh out the full meaning of the Supreme Court's edicts on punitive damages, and this article addresses some of the jury instructions defendants should be requesting.

Oregon's Uniform Jury Instructions Are Insufficient

In its recent decision in *Philip Morris USA v. Williams*, the U.S. Supreme Court cautioned that "[u]nless a State insists upon proper standards that will cabin the jury's discretionary authority, its punitive damages system may deprive a defendant of fair notice of the severity of the penalty that a State may impose" and result in "an arbitrary determination of an award's amount."[2]

Oregon's Uniform Civil Jury Instructions currently do *not* contain any instructions regarding limitations on a jury's ability to award punitive damages. UCJI 75.02 states only that in awarding punitive damages a jury may consider "(1) the character of the defendant's conduct; (2) the defendant's motive; (3) the sum of money that would be required to discourage defendant and others from engaging in such conduct in the future; and (4) the income and assets of the defendant."[3] Although, the "caveat" following the instructions suggests that "[i]t may be necessary to instruct the jury on certain federal constitutional limitations on punitive damages," the instructions themselves are silent as to what a jury may *not* consider, leaving a jury to settle on an amount without any true guidelines or limitations, despite the U.S. Supreme Court's warnings against this arbitrariness.[4]

1. Do Not Punish For Harm Caused to Others

A punitive damage award is, of course, designed not to compensate but to punish unlawful conduct and to deter its repetition.[5] The Supreme Court has acknowledged that in calculating a figure appropriate to effectively punish a defendant, a jury may take into account whether the conduct "posed a substantial risk of harm to the general public" as evidence of the defendant's "reprehensible" state of mind. While a jury may indirectly consider harm to others in order to assess a defendant's indifferent mental state when punishing for conduct against the named plaintiff, the *Philip Morris* court declared that "a jury may not go further than this and use a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties."[6] The post-*Philip Morris* case *Moody v. Ford Motor Company* emphasizes this point, noting that where a jury was invited to consider the harm caused by rollovers in all types of vehicles, not just the Ford Explorer, plaintiffs' attorney opened the door to a "veritable supernova of prejudice."[7] Based on *Philip Morris*, *State Farm*, and *Moody*, defense attorneys should request limiting instructions emphasizing this "state of mind" distinction and the prohibition against punishment for harm to non-parties.[8] Simple examples may include:

> *You may only consider evidence of defendant's alleged conduct toward others to show defendant's state of mind at the time plaintiff was allegedly harmed. In other words, you may only consider whether defendant's alleged conduct toward others showed reprehensibility or indifference to harm that may have been suffered by plaintiff in this case. You may not, however, directly punish defendant for alleged harm to others who may choose to bring lawsuits of their own, in which other juries can resolve their claims.*

Defendant in the *Phillip Morris* case requested an instruction attempting to communicate this concept, which was criticized by some justices at oral argument:

> *You may consider the extent of harm suffered by others in determining what the reasonable relationship is between any punitive award and the harm caused to plaintiff by the defendant's misconduct, but you are not to punish the defendant for the impact of its alleged misconduct on other persons, who may bring lawsuits of their own in which other juries can resolve their claims.*

Justices commented during oral argument that this proposed instruction was less than a model of clarity. Put in simplest terms, the following instruction regarding the *Phillip Morris* holding would be appropriate:

"A jury may not punish for the harm caused to others."[9]

Oregon courts should be receptive to these types of instructions based on the *Philip Morris* court's express holding that "the Due Process Clause requires States to provide assurance that juries are not asking the wrong question, *i.e.* seeking not simply to determine reprehensibility, but also to punish for harm caused to strangers."[10]

2. Do Not Punish For Extra-Territorial Conduct

Philip Morris stands for the broad proposition that a jury may not punish a defendant for conduct against *any* party, regardless the jurisdiction where the harm occurred. *State Farm* then expressly states that "[a] jury *must be instructed* . . . that it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred."[11] For instance, the Utah trial court in *State Farm* twice denied State Farm's motion to exclude evidence of admittedly legal out-of-state business practices that plaintiff used to bolster its arguments regarding practices that were allegedly unlawful in Utah.[12] To address this concern, and to insure that jury consideration of defendant's state of mind bears only on unlawful, in-state conduct, an additional jury instruction may be proposed as follows:

You may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the state where it occurred. A state court does not have the power to punish a defendant for conduct that was lawful where it occurred and that had no impact on this state or its residents. [13]

3. There Must Be a Reasonable Ratio Between Compensatory and Punitive Damages

Although the U.S. Supreme Court has declined to set a bright-line test defining the permissible ratio between compensatory and punitive damage awards, the Court observed in *State Farm* that "few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process" and that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety."[14] The Supreme Court has expressed a non-binding but informative policy that "[s]ingle-digit multipliers are more likely to comport with due process"[15] and that it will "raise a suspicious judicial eyebrow" at disproportionately large punitive damage awards.[16] To give these protections their full meaning at the trial court level, the people determining the amount of punitive damages to award—the jury—needs to hear about them. Defendants should request special instructions on the relationship between compensatory and punitive damages to avoid unpredictable and potentially unconstitutional awards. Ranging from the general to the specific, jury instructions could include:

The amount of punitive damages you award, if any, must be reasonable and proportionate to the amount of harm to the plaintiff and the amount of economic and/or non-economic damages you award.

A punitive damages award is generally not reasonable and not proportionate if it exceeds four times the amount of your award of actual damages.

There is no fixed formula as to the size of a punitive damages award. However, awards exceeding a single-digit ratio between punitive and compensatory damages may be impermissible. Where your award of compensatory damages is substantial, then any punitive damages award should be approximately equal to compensatory damages. Where your compensatory damages award is small, and the defendant's conduct is particularly egregious, a punitive damages award of more than four times the amount of compensatory damages may be appropriate.

While a court should be willing to instruct on the concept of proportionality, getting a court to instruct a jury regarding the actual numbers discussed by the Supreme Court may only be aspirational unless and until the Supreme Court adopts a bright-line rule. These instructions are nevertheless worth pressing at the trial court level as the law on punitive damages jury instructions develops in the coming years.

Conclusion

The *Philip Morris* court stated that "it is constitutionally important for a court to provide assurance that the jury will ask the right question, not the wrong one."[17] In response, state courts should make efforts to improve punitive damage jury instructions to reflect the constitutional parameters of a permissible award and avoid "punishments that reflect not an application of law but a decisionmaker's caprice."[18] This is particularly true in Oregon, where the uniform jury instructions are completely silent on *Philip Morris* and *Campbell*. Defense lawyers must consider and draft special instructions that incorporate the U.S. Supreme Court's full protections limiting punitive damages awards based on harm to others, extra-territorial conduct, and the ratio between compensatory and punitive damages.

Endnotes

1 The United States Supreme Court has directed courts to identify constitutionally excessive punitive damage awards by balancing "(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003) (citing *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 575 (1996)).

2 549 U.S. __, 127 S.Ct. 1057, 1062 (2007) (internal quotations omitted) (citing *BMW*, 517 U.S. at 574).

3 *See also* ORS § 30.925 (discussing additional factors to consider award-

Continued next page

ing punitive damages in a products liability action).

4 *See* "Caveat," UCJI No. 75.02. The 2006 comments following this instruction state that the UCJI Committee "decided not to make substantive changes to this instruction to incorporate the federal constitutional limitations on punitive damages" because it was awaiting the U.S. Supreme Court's decision in *Philip Morris*. The comment suggests, however, that such changes may be forthcoming.

5 *Phillip Morris*, 127 S.Ct. at 1062; *BMW*, 517 U.S. at 568.

6 *Philip Morris*, 127 S.Ct. at 1064.

7 2007 U.S. Dist. LEXIS 19883, at *77 (N.D. Okla. 2007).

8 For an interesting discussion of model jury instructions, see also Andrew L. Frey, "*No More Blind Man's Bluff on Punitive Damages: A Plea to the Drafters of Pattern Jury Instructions*," LITIGATION, 24 (Summer 2003)

9 *Phillip Morris*, 127 S.Ct. at 1065.

10 *Id.* at 1064.

11 *State Farm*, 538 U.S. at 422 (citing *BMW*, 517 U.S. at 572-73).

12 *Id.*

13 *Id.*

14 *Id.* at 425.

15 *Id.*

16 *BMW*, 517 U.S. at 583.

17 *Philip Morris*, 127 S.Ct. at 1064.

18 *Id.* at 1062; *see also State Farm*, 538 U.S. at 416.

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for example, the labels as shown in the *Physicans' Desk Reference* (Thomson 2007) for the following widely used drugs: Ativan, Effexor, Fluothane, Inderal, Lodine, Neurontin, and Risperdal.

8. Austin Bradford Hill, *The Environment and Disease: Association or*

Continued from page 7

Don't Know Much About Epidemiology?

Causation?, 58 Procs. Royal Socy. Med. 295 (1965). The standards of epidemiological evidence offered by Hill are saddled with reservations and exceptions. Hill was ambivalent about their utility. *See Modern Epidemiology*, *supra* n. 2, at 24-25.

9. Hill, 58 Procs. Royal Socy. Med., at 295.

10. Million Women Study Collaborators (Beral), *Breast Cancer and Hormone-Replacement Therapy in the Million Women Study*, 362 Lancet 419 (2003).

11. For a detailed discussion of clinical trials, see Gale Pearson, *Uncover Bias in Clinical Trials*, on page 22.

12. *See e.g.* Claire Bombardier et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis: VIGOR Study Group*, 343 New Eng. J. Med. 1520 (2000); Robert S. Bresalier et al., *Cardiovascular Events Associated with Rofecoxib in a Colorectal Adenoma Chemoprevention Trial* (APPROVe), 352 New Eng. J. Med. 1092 (2005) (Erratum, 355 New Eng. J. Med. 221 (2006)); Jeffrey R. Lisse et al., *Gastrointestinal Tolerability and Effectiveness of Rofecoxib Versus Naproxen in the Treatment of Osteoarthritis: A Randomized, Controlled Trial* (ADVANTAGE), 139 Annals Internal Med. 539 (2003).

13. Jacques E. Rossouw et al., *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results from the Women's Health Initiative Randomized Controlled Trial*, 288 JAMA 321 (2002).

14. Most courts will allow a plaintiff to address issues of dose and duration and how recent the study was, as well as questions about subpopulations, with evidence from other sources, such as case reports.

15. *See* Br. of Profs. Kenneth J. Rothman et al., *supra* n. 4, at **3, 4.

16. *See e.g.* Clarice Weinberg, *It's Time to Rehabilitate the P-Value*, 12 Epidemiology 288 (2001); *see also* Richard Lempert, *Statistics in the Courtroom: Building on Rubinfield*, 85 Colum. L. Rev. 1098 (1985).

17. *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1235-36 (W.D. Wash. 2003); Walter N. Kernan et al., *Phenylpropanolamine and the Risk of Hemorrhagic Stroke*, 343 New Eng. J. Med. 1826 (2000).

18. Yi Tsong, *Statistical Review of Epidemiological Report of the Final Report of the Yale Hemorrhagic Stroke Project* App. B 16, at www.fda.gov/ohrms/dockets/ac/00/backgrd/3647b1b_tab02.doc (Sept. 26, 2000).

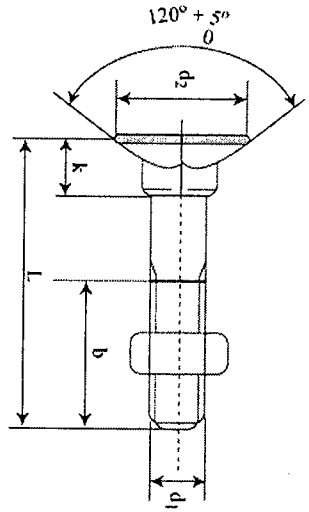
19. Memo from Lois La Grenade & Parivash Nourjah, Div. of Risk Assessment I, FDA, to Charles Ganley, Div. of OTC Drug Prods., FDA, *Review of Study Protocol, Final Study Report and Raw Data Regarding the Incidence of Hemorrhagic Stroke Associated with the Use of Phenylpropanolamine* 2, at www.fda.gov/ohrms/dockets/dailys/00/oct00/102400/c000234.pdf (Sept. 27, 2000).

20. *See In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d at 1240.

21. Rebuttal expert testimony must be disclosed in advance. *See* Fed. R. Civ. P. 26(a)(2)(C).

THE NUTS AND BOLTS OF PRODUCTS LIABILITY LITIGATION:

PRE-FILING TO SUMMARY JUDGMENT



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1:00 pm - 1:30 pm

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Jay Beattie,
Lindsay Hart Neil & Weigler LLP

A discussion about what makes a products liability claim and why it matters.

1:30 pm - 3:00 pm

What Do I Do With A Products Case?

Jane Paulson and John Coletti,
Paulson Coletti Trial Lawyers PC

Molly Jo Mullen,
Bodyfelt Mount Stroup & Chamberlain LLP

Daniel Reising,
Fucile & Reising LLP

A panel discussion from the plaintiff and defense perspective on case evaluation, pre-filing issues, pleading your case, answering the complaint and motion practice.

3:00 pm - 3:15 pm

Refreshment Break

3:15 pm - 4:15 pm

What's On The Horizon

Heather Van Meter,
Williams Kastner & Gibbs PLLC

James Coon,
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Recent developments in products liability and pending legal issues

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CLE Seminar Speakers

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Heather Van Meter's practice focuses on litigation with an emphasis on drug and medical device, product liability, and other complex cases. She has also handled cases involving wrongful death, catastrophic injury, environmental remediation, medical malpractice, and sex abuse, as well as commercial and insurance coverage litigation.

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