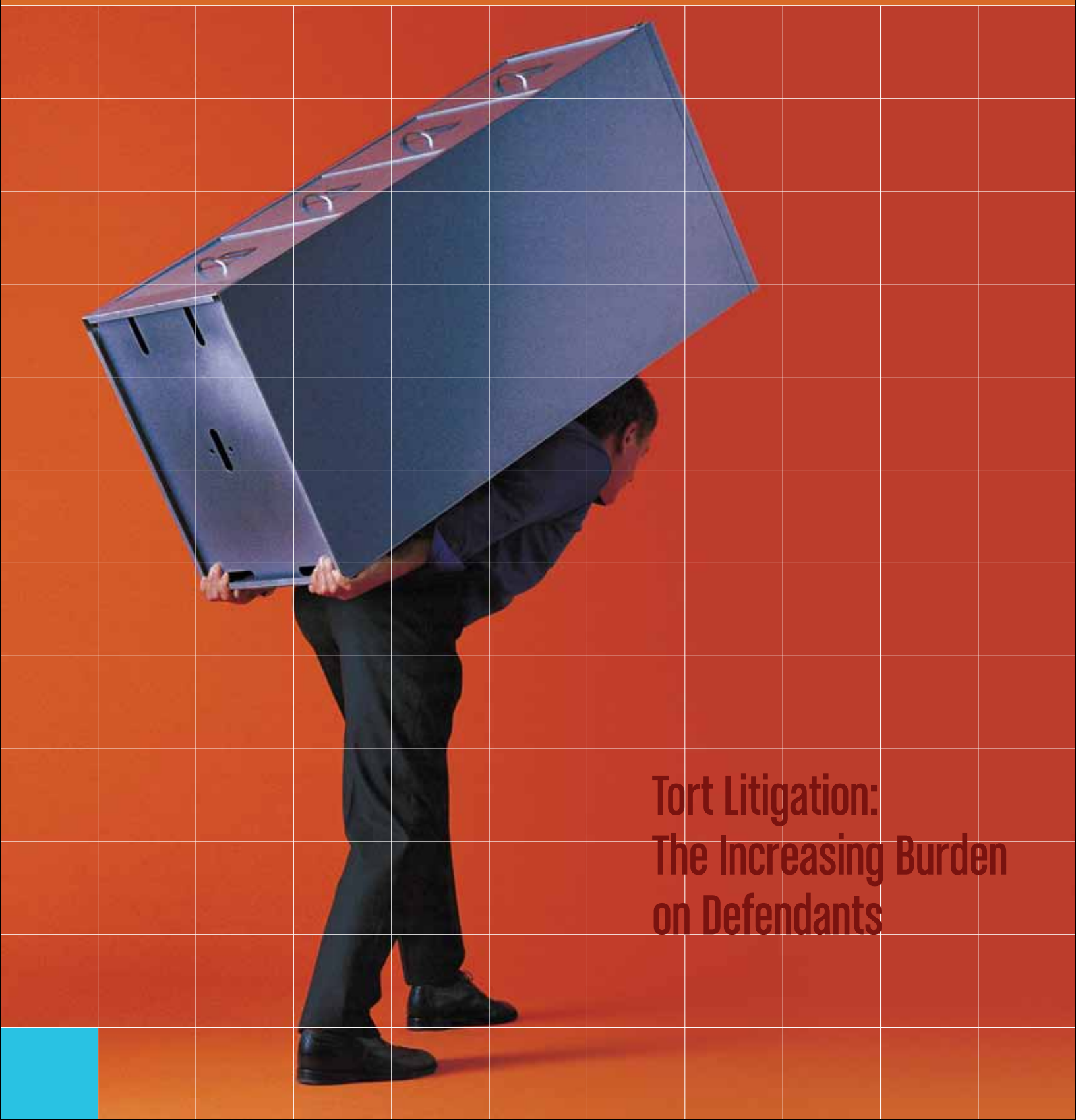
JONES DAY

PRACTICE PERSPECTIVES: PRODUCT LIABILITY & TORT LITIGATION



Tort Litigation: The Increasing Burden on Defendants

letter from the practice chair

TIME FOR AMERICA TO HAVE CLEAR AND FAIR E-DISCOVERY RULES

In the last issue of this publication, I wrote a rather sharp criticism of the tort system. I opined that the tort system had "deteriorated significantly since I was admitted to practice 35 years ago." I said, among other things, that "the [tort litigation] system should not exist primarily to enrich lawyers, redistribute wealth, or achieve by litigation what is not being done by legislation or proper regulation."

I was pleased by the number of comments I received about that column, showing that many busy lawyers and executives read our publication. Even knowing that many readers share my pro-business, economic, and job-creation bias, it is nonetheless gratifying to find bright people in rabid agreement with the views I expressed. Perhaps the most notable comment came from the CEO of a *Fortune* 100 industrial company that is one of the biggest employers in its region. He said, "When my neighbor who is a plaintiff's attorney has a much bigger house than I do, and a fleet of luxury cars that I could not afford, it tells me something about the litigation system." Enough said.

* * *

Continuing again to use this column to flag areas where it seems that the litigation system is failing us, as lawyers and as a nation, my target now is e-discovery. The burdens being placed on defendants by overly broad e-discovery demands are excessive and unfair. State and federal courts have not yet adopted uniform and fair rules, by decision or rulemaking. E-discovery too often has become an extortion tool, whereby a plaintiff with a case of questionable merit and limited damages can impose huge discovery costs on a corporate defendant—costs that are disproportionate to the size of the case and generally not recoverable even if the defendant prevails in the action.

Consider this all too typical scenario: A person is injured while conspicuously misusing a consumer product or vehicle. The injured person fortunately makes a full recovery after surgery but brings a product liability claim seeking recovery for medical expenses, lost wages, a surgical scar, and pain and suffering—and, of course, his counsel throws in a claim for punitive damages. All things considered in the venue where it is filed, absent something highly unusual, the hypothetical injury would have a jury verdict potential of less than $150,000, and many lawyers would consider and accept a settlement of much less.

Immediately after the complaint is served and before an answer or motion to dismiss is filed, the plaintiff sends a letter notifying the corporation that it must put a "litigation hold" on all emails and stored data relating to every aspect of the

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FOREIGN-MADE PRODUCT CLAIMS: HANDLING THE CRISIS

By Thomas E. Fennell and W. Kelly Stewart

It's Friday afternoon. It's been a long week—a very long week! But things have finally calmed down. It's going to be a great weekend.

Then you get the call.

A reporter asks for your comments about newly discovered purported defects in your company's products manufactured overseas. The reporter claims that the products violate state and federal regulations, create potential toxic exposures, and pose related health risks to product users in the U.S. and abroad. The story will be posted on the paper's web site later today and run in tomorrow's hard-copy edition.

So much for that relaxing weekend.

Your instincts tell you this could be bad. They're right. The fallout from these allegations and the related adverse publicity may well include expensive and risky class-action lawsuits, aggressive U.S. and foreign government investigations and actions, adverse state attorney general and state regulatory actions, and business injury claims by vendors and others—not to mention the risks of monetary damages, penalties, fines, and onerous injunctive relief. Protecting your company from these potential consequences will require careful planning and prompt and coordinated action. While every case differs, and there certainly is no one approach applicable in all circumstances, many of the issues and steps that may need to be considered in any significant product crisis involving foreign-made products are discussed below.

ASSEMBLING THE TEAM

Your first order of business should be to put in place a command structure that can quickly identify and respond to expected threats and do so in a coordinated manner consistent with an overarching and well-thought-out strategy. Think war and war room. The central body of your command structure should be a relatively small Steering Committee, the size and composition of which will turn, in part, on your assessment of the potential magnitude of the crisis. Keep in mind that denial is frequently an initial reaction to these situations, so the tendency is to underestimate the threat.

How you structure the Steering Committee and the various teams reporting to it—and the quality of those you choose to

populate them—will likely determine your success or failure. The Steering Committee must have real power and authority. Participation of one or two key company executives, even the CEO (in truly serious cases), will be helpful. The Steering Committee must include those who, by reason of their constituencies and objectives, will bring different points of view to the table: for example, a senior QA/QC executive or engineer; key marketing, public relations, and operating executives; the general counsel; a lobbyist; a PR consultant; and, of course, high-quality lead counsel. How and by whom final decisions are made must be clear, and those involved must understand that once the Steering Committee makes a decision, all must follow the course set.

The Steering Committee must delegate authority to various teams that can focus on specific threats and issues, *e.g.*, a fact investigation team, a U.S. regulatory response team, a congressional response team, an insurance coverage team, a foreign government relations team, a state attorneys general team, and U.S. and foreign litigation teams. Choose your best people, delegate wisely, and establish clear lines of communication and responsibility. The demands on each of the teams will be different, so choose the members of each team carefully, matching individual strengths to the expected tasks of the team to which they are assigned.

THE FACT INVESTIGATION

"What actually happened here?" is the first question that must be answered—and fast. Thus, one of the first teams needed is a fact investigation team. The team should be dogged, aggressive, and unrelenting in obtaining facts, while sensitive enough to political issues to know the proper channels to be used and when to raise issues with the Steering Committee.

When investigating facts in foreign countries, time and language differences may pose challenges, of course. But the team also must be aware of cultural and legal differences that can affect the ability to obtain complete and objective information, as well as worker protection laws in certain countries that may impede employee interviews. For all of these reasons, the fact investigation team must carefully plan its "attack," identifying potential contingencies and preemptive actions.

For example, to conduct face-to-face interviews, U.S. team members must secure necessary visas and other appropriate travel documents, which can take longer than anticipated. For effective interviews, relevant documents should be reviewed in advance so as to prompt more complete responses and test the accuracy of the information obtained.[1] Yet obtaining relevant documents overseas and transporting copies to the U.S. may implicate thorny data privacy laws not applicable in the U.S. or prompt punitive action by a foreign government.

The fact investigation must be designed and conducted to obtain information to: (1) respond to any resulting government investigation and/or litigation, (2) prepare necessary regulatory and government notices, (3) prepare necessary corporate and securities disclosures (*e.g.*, SEC Form 8-K and similar filings) and any other required regulatory public disclosures, and (4) otherwise address the public, company executives and employees, the company's business partners, and financial markets. For example, where the product is covered by the Consumer Product Safety Act and Consumer Product Safety Commission ("CPSC"), the company must "immediately" report to the CPSC if it obtains information that "reasonably supports," among other things, the conclusion that a product fails to meet applicable product safety rules or contains a defect that could create a "substantial product hazard" or "creates an unreasonable risk of serious injury or death."[2] While federal regulations offer some guidance as to what "immediately" may mean in that situation,[3] there is much controversy surrounding its interpretation. In any event, the deadlines will likely seem too short, given the complexity of the situation. Moreover, claims of reporting violations (and the imposition of fines for late or nonreporting) are common and have been used in later litigation and by the media to enhance claims or cast the company in a bad light. Other countries where the product was sold may likewise have similar reporting, disclosure, or regulatory oversight requirements.

DATA AND PRODUCT PRESERVATION

U.S. litigators know that one of the first issues to address when a company reasonably anticipates litigation is the preservation and collection of relevant data and tangible items.[4] This obligation applies even when the data or product exists only in another country.[5] Preserving (and collecting) data and items in other countries pose unique challenges. For example, moving data or products in and out of various countries, even when the title is in the company's name, may be problematic due to data privacy or other host-country laws. Even taking actions merely to preserve certain types of data can trigger

laws not necessarily familiar to U.S. litigators. All potentially applicable laws must be considered, and preservation and collection actions undertaken, with those laws in mind.

In U.S. litigation, the company must preserve data and tangible items—even in the possession of a third party—when that information is "in the possession, custody or control" of the company. For purposes of control, however, it does not matter that the data or product may be located abroad. Carrying out the company's obligation to preserve information often can be dicey with respect to foreign third parties, given that such requests may be met with little cooperation by foreign companies and by certain foreign governments. Obtaining and reviewing vendor contracts may be necessary, among other things, in determining whether the company has "control" over data or products in the hands of foreign third parties. Despite the obvious difficulties, reasonable efforts to preserve relevant data or items are imperative.

U.S. GOVERNMENT INVESTIGATIONS AND LITIGATION

Numerous federal, state, and local entities may become involved when the safety of a foreign-made product is at issue. The company could face multiple civil and criminal investigations—and simultaneous data and testimony demands. Whether it is an "invitation" by a U.S. congressional committee for the CEO to testify and provide documents, a request from a congressional investigative staff to interview a plant manager, or a formal document and data demand from a state attorney general, the company will likely receive urgent, competing demands for documents, data, interviews, and testimony. Working with each requesting party must be closely coordinated to ensure accurate, timely, and consistent responses. Inaccurate or inconsistent responses may prove more harmful than any damages resulting from the alleged product defect, particularly since communication—and, in some cases, coordination—among these various entities is common.

Purported class actions and individual and shareholder lawsuits also often follow product recalls or claimed product defects. The number and nature of the cases will depend on various factors, including the extent to which health issues or injuries have been reported, the extent of adverse publicity, whether government entities allege regulatory violations, and the company's perceived performance in handling allegations with respect to the product. Lawsuits may assert claims ranging from the typical strict liability and negligence allegations to less typical but "trendy" theories, such as public nuisance.

Given the interrelationships of the multiple investigations and litigation, it is important to develop an overall strategy to coordinate their successful resolution. For example, promptly resolving a government or regulatory investigation may or may not help ease the litigation threat or even be in the company's best interest. With respect to litigation, it is important to consider its different potential directions and inevitable evolutions when making overall strategy calls, including the timing of any trials or resolution. For these reasons, the company will be better served if one highly experienced law firm develops and coordinates overall strategy to minimize legal exposure, adverse government actions, and negative public relations.

Key litigation decisions must be made early on. For example, a federal forum may be more beneficial than a state forum—mandating that any issues under the Class Action Fairness Act or other removal options be immediately addressed. The company must also quickly analyze whether certain defenses, such as jurisdiction, are viable; if so, it must act to preserve and adequately develop them. In addition, the company must use all effective case-management tools and strategies, including appropriately bifurcated discovery and targeted motion practice.

Another question that must be answered is whether it is in the company's best interest to seek coordination of pretrial proceedings under federal multidistrict litigation ("MDL") laws and rules or state-law equivalents, as there are risks and benefits to MDL coordination. For example, in many cases, MDL treatment results in the filing of additional lawsuits because plaintiff's counsel frequently believe that a global settlement will eventually occur, with relatively little or no work required by them. Moreover, where lawsuits proceed separately, appropriate strategy decisions can capitalize on the differential progress of various of the active lawsuits, including targeted motion practice. MDLs, on the other hand, may save a defendant significant litigation expense because there typically is less repetitive discovery, along with consistent discovery and pretrial rulings that are applicable to all federal cases. Federal MDL proceedings may be informally coordinated with or serve as guidance for any applicable state MDL counterparts or individual state cases. The MDL

forum and judge, of course, are significant factors in measuring the benefits or disadvantages of MDL treatment, and typically they are not determinable in advance of action by the Judicial Panel on Multidistrict Litigation.

FOREIGN GOVERNMENT INVESTIGATIONS AND LITIGATION

Depending on the geographic distribution of the product, the company may face government investigations and litigation in one or more other countries. Early in the process, the company will likely need to respond to data demands and requests for information from involved foreign governments. You must develop a country-specific litigation strategy that complements the U.S. litigation and public-relations strategies. Where a single firm has offices in the countries affected, a cohesive response is usually easier to achieve.

Another potential issue to consider is the impact on the company's import/export licenses and other international trade requirements. Having a foreign country shut down the company's operations within its borders or quarantine products because of an alleged product safety issue is entirely possible. U.S. due process procedures may not be available, and creative thinking and alternative approaches to minimize or prevent these problems may be required.

In many countries, criminal actions against the company—and even its individual officers—are possible for the sale or distribution of allegedly unsafe products or related activities. Learn what potential criminal laws are implicated, consult with experienced practitioners in the applicable countries, and coordinate the defense of the criminal charges with U.S. investigations, U.S. litigation, and the overall government and public-relations strategies.

PUBLIC RELATIONS

Message management is critical. While "no comment" may have been the typical response years ago, it is almost never the best approach today. With nearly instantaneous publication of news and events via the internet, Twitter, Facebook, blogs, and the like, the importance of getting ahead of adverse publicity with the company's story cannot be overemphasized. Widespread negative publicity increases the likelihood of lawsuits and government investigations.

In addition to facing media inquiries, the company may find itself under extreme pressure to respond to the federal government, state attorneys general, and federal, state, and local agencies—all demanding "immediate" answers and data in the form of civil investigative demands and otherwise. Tremendous pressure will also exist from business partners, distributors, and retailers, many of whom will be facing pressure themselves to respond to the media or consumers or to take action regarding the products. Although U.S. congressional and state attorney general investigations and hearings can sometimes be considered politically motivated grandstanding, they nonetheless certainly could have legal and public-relations ramifications.

In short, communicating with the media and the government—both accurately and timely—is a high priority. However, never sacrifice accuracy for speed. Despite pressure to say something to help resolve the situation, special care must be taken to limit responses to what is known to be factually accurate, together with appropriate indications of concern for and attention to safety. Communications in such situations will be closely examined. If later shown to be inaccurate, they will be used to cast the company in negative terms and deployed against the company in litigation or investigations.

The company's customers—obviously a key constituency—will also press for responses. They will understandably want to know the scope of the alleged problem and how the company is dealing with it. They also may demand redress for the time and expense they incur in responding to a problem they view as yours. The company must develop and execute a plan to address likely customer issues and concerns.

Another important group requiring attention is the company's employees. It is important that employee morale remain high and that employees understand that the company is doing not only what is right for the company, but what is right for those who use their company's products.

Consequently, an overall communications plan must be developed in conjunction with the company's corporate public-affairs department and outside consultants. Such a plan should anticipate media, government, and public inquiries, and it should dovetail with the company's overall strategy to resolve the crisis. It should also be designed not only to minimize damage to the company's reputation but to preserve applicable privileges.

PRIVILEGES AND CONFIDENTIALITY

In the heat of the crisis, obtaining accurate information may be your primary concern. But preserving the confidentiality of information and any applicable privileges is critical. Statements to Congress, the CPSC or other U.S. government agencies, or foreign governments likely will not be privileged or confidential. Other statements may be. While the company, of course, needs to communicate both internally and externally about the issues, care must be taken to ensure that inaccurate and damaging statements are not made inadvertently. This applies to all employees, including executives. Many understand that what is said to the media/public is not privileged, but sometimes less care is given to what is said to U.S. and foreign government officials or staff members, investigators, insurers, or employees. Communications with and among these groups must be planned and coordinated to ensure that privileged and confidential information is not divulged or that any potential risk of waiver is minimized.

It also is generally safest to assume that almost everything written or said by company personnel will be discoverable in subsequent litigation. Everyone should understand the consequences of misplaced, inaccurate, or careless language in all communications, including emails. Product issues should not be the subject of offhand comments or callous or sarcastic emails or other communications. Personnel need to be reminded that what they write or email may become alleged "admissions" in the eyes of plaintiff's counsel, making them witnesses in the litigation and potentially harming the company.

It is likely that various U.S. and foreign government entities will request the production of confidential information. The company may find itself balancing the need to provide necessary information with the need to preserve the confidentiality of that same information. Doing so can be extraordinarily difficult, particularly when a foreign government, with the power to adversely affect or effectively freeze the company's foreign business operations, demands information that will not be privileged or confidential once disclosed. For business reasons or otherwise, trade-offs sometimes must be made, but they must be debated thoroughly and the consequences fully understood. Care must be taken to obtain appropriate and enforceable confidentiality agreements, where possible, before production is made.

Communications with the company's in-house counsel in foreign countries also need to be considered. No one-size-fits-all rule applies regarding what is protectable privilege-wise in foreign countries. Foreign countries' privileges are not necessarily identical to U.S. privileges, and they are certainly not all consistent with each other. Last year, for example, the European Court of Justice held that communications between company management and in-house lawyers are not protected from disclosure or discovery in the context of investigations by the European Commission.[6] How far that ruling will ultimately extend may not be certain, but it clearly warrants stringent consideration when communicating about foreign-made product defects with foreign-based in-house counsel.

INSURANCE

The company should promptly take steps to maximize its insurance coverage, identifying potentially applicable insurance policies and making appropriate and timely notifications. You will want to quickly understand the relevant terms of any potentially available company policies offering coverage for product recalls, product liability, errors and omissions, and/or directors and officers.

As soon as possible, the company should analyze what may or may not be covered and under what circumstances. For example, some losses must be documented in certain ways under certain types of policies. Investigation costs may or may not be covered, depending on the actual or stated purposes of the investigation and whether they were incurred in connection with actual or anticipated government investigations or product liability or shareholder derivative litigation. Coverage may be affected by offers of indemnification the company makes to downstream business partners. Insurance could also affect selection of outside counsel and the structure of defense costs.

A communications plan with the company's insurers should be established early in the crisis. Whether coverage is clear or not, insurers may demand facts and other data relating to the company's products and actions. How that is handled by the company can affect ongoing litigation and the company's potential exposure. Tying in insurers early may assist in maximizing coverage, or at least in anticipating the insurers' positions, which may affect decisions about structuring the company's defenses.

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THE FDA FOOD SAFETY MODERNIZATION ACT: EXPANDING THE GOVERNMENT'S ABILITY TO PREVENT, DETECT, AND RESPOND TO FOODBORNE ILLNESS OUTBREAKS IN THE UNITED STATES

By John W. Edwards II and Laura E. Morris

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act ("FSMA"). This law is the first significant overhaul of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which Congress passed in 1938. The FSMA concentrates on three major goals for the nation's food safety program. The first goal is preventing the occurrence of national food hazards. The second goal is improving the detection of foodborne illness outbreaks and the government's response to such outbreaks when they do occur. The final goal is strengthening food safety requirements for imported foods. In order to effectuate these goals, the FSMA places new requirements on, and grants new authority to, the Department of Health and Human Services ("HHS") and the Food and Drug Administration ("FDA"). The legislation does not address the safety of food items regulated by the Department of Agriculture ("USDA"), such as meat, poultry, or processed eggs, which are subject to even more rigorous inspection and oversight than foods regulated by the FDA.

The FSMA had a tumultuous trip through Congress before it was passed. The legislation originated in the Senate, which initiated the food safety bill in its current form in November 2010. The Senate-originated bill, however, included fee provisions that violated the Origination Clause in the United States Constitution. To overcome this constitutional roadblock, the House attached the Senate's version of the food safety legislation to an omnibus appropriations bill. The Senate, however, refused to take up the omnibus bill, stalling the food safety legislation for weeks. Determined to pass the legislation, on December 19, 2010, the Senate amended a House shell bill to add the language of the Senate's food safety bill and sent the bill back to the House. The House voted to accept the changes to the House shell bill on December 21, 2010, finally clearing the bill for the White House.

Although the FSMA has now been signed into law, the legislation's efficacy is still uncertain. The Congressional Budget Office estimates that enforcement of the FSMA would require $1.4 billion annually, yet the FSMA does not include the required funding. Given the current budgetary issues, it is uncertain whether this Congress will allocate the funding necessary to implement the new law fully.

TITLE ONE: PREVENTING THE OCCURRENCE OF NATIONAL FOOD HAZARDS

Title One of the FSMA significantly expands the power of the government to establish preventive controls for national food safety. Perhaps the most significant preventive control provided in the legislation is the hazard analysis and control program. Under this program, owners, operators, or agents in charge of food facilities that manufacture, process, package, and handle food, such as factories and warehouses, are required to: (1) evaluate the hazards in their operations; (2) implement and monitor effective measures to prevent contamination; (3) reanalyze the hazards when necessary; and (4) have a plan in place to take corrective action if preventive controls have not been properly implemented or are found to be ineffective. Title One describes such hazards as "biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives," as well as those hazards "that occur naturally, or may be unintentionally introduced," and those "that may be intentionally introduced, including by acts of terrorism."

A hazard analysis and control program can be a formidable undertaking. For example, the FDA's Hazard Analysis Critical Control Points Program for Seafood ("Seafood HACCP") consists of more than 350 pages of detailed requirements and needed a substantial "mid-course correction."[1]

The requirements introduced by the hazard analysis and control program do not apply to numerous entities. For example, the following entities are exempt from the program:

- Farms
- Restaurants
- Other retail food establishments
- Nonprofit food establishments in which food is prepared for or served directly to the consumer
- Fishing vessels
- Entities that are determined to be "very small business[es]"
- Facilities that have average annual sales of less than $500,000
- Facilities that are required to comply with the Seafood HACCP, the Juice HACCP, and/or the government's standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

Title One places numerous requirements on HHS in an effort to prevent national food safety problems. For example, Title One requires the Secretary of HHS, in coordination with the Secretary of Agriculture, to review and evaluate relevant health data and other relevant information to determine the most significant foodborne contaminants. On the basis of this review and evaluation, the Secretary of HHS must issue contaminant-specific and science-based guidance documents prescribing action levels or regulations, when appropriate, to reduce the risk of serious illness or death, prevent food adulteration, or prevent the spread of communicable disease.

In response to the produce-related outbreaks that have occurred in recent years, Title One also requires the Secretary of HHS, in coordination with the Secretary of Agriculture and in consultation with the Secretary of Homeland Security, to publish a notice of proposed rulemaking setting minimum science-based standards for the produce industry. Intended to facilitate the safe production and harvesting of certain fruits and vegetables, these standards have been established for specific mixes or categories of foods comprising raw agricultural commodities and have been determined by the Secretary to minimize the risk of serious adverse health consequences or death.

The new legislation also requires the Secretary of HHS, in consultation with the Secretary of Education, to establish guidelines to be used on a voluntary basis to manage the risk of food allergies and anaphylaxis in schools and early-childhood education programs. The guidelines would address: (1) parental obligations to notify schools or early-childhood education programs of children's food allergies or risks of anaphylaxis; (2) food allergy education and management training of personnel in schools and early-childhood education programs; and (3) other elements that the Secretary determines necessary for the management of food allergies and anaphylaxis in schools and early-childhood education programs.

Title One further requires the Secretary of HHS to promulgate regulations to protect against the intentional adulteration of food. In doing so, the Secretary of HHS, in coordination with the Secretary of Homeland Security and in consultation with the Secretary of Agriculture, must conduct a vulnerability assessment of the food system; consider the uncertainties, risks, costs, and benefits associated with guarding food against intentional adulteration at vulnerable points; and determine the types of science-based mitigation strategies that are necessary to protect against adulteration. The regulations must establish appropriate mitigation strategies to protect food in the supply chain at specific vulnerable points and specify when implementation is required.

Finally, the new legislation requires the Secretary of HHS and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, to prepare a National Agriculture and Food Defense Strategy. In general, the National Agriculture and Food Defense Strategy must include a description of the process to be used by the various departments to achieve the following goals: (1) enhancement of the agriculture and food system; (2) improvement of the system's detection capabilities; (3) assurance of an efficient response to agriculture and food emergencies; and (4) security of agriculture and food production after an agriculture or food emergency. The National Agriculture and Food Defense Strategy must be made available to the relevant committees of Congress and to the public via the web sites maintained by HHS and the USDA.

Title One also gives the Secretary of HHS critical enforcement tools to prevent national food safety problems. First, the new legislation delineates a procedure by which the Secretary of HHS can gain access to records relating to an article of food that the Secretary reasonably believes will have serious adverse health consequences for humans or animals. Second, Title One provides the Secretary of HHS with the power to suspend the registration of a food facility if the Secretary determines that the facility packs, receives, or holds food that has a reasonable probability of having adverse health consequences for humans or animals and the facility was responsible for, and knew or should have known of, the potential hazard. Such a suspension would prohibit the facility from introducing food into interstate or intrastate commerce in the United States and from importing food into, or exporting food from, the United States. Finally, under the new legislation, the Secretary of HHS can assess and collect fees related to food facility reinspection, food recalls, the Voluntary Qualified Importer Program, and importer reinspection.

TITLE TWO: IMPROVING THE DETECTION OF FOODBORNE ILLNESS OUTBREAKS AND THE RESPONSE TO SUCH OUTBREAKS

Title Two of the FSMA significantly expands the power of the government to detect and respond to foodborne illness outbreaks. First, the legislation increases the FDA's inspection capabilities by requiring the number of inspections to be determined according to the level of risk posed by the facility. For example, Title Two requires the FDA to inspect domestic high-risk facilities at least once within the five-year period following the enactment of the law and at least every three years thereafter. In contrast, for domestic non-high-risk facilities, an inspection must be conducted at least once within the seven-year period following the enactment of the law and at least every five years thereafter. For foreign facilities, twice the number of inspections conducted during the previous year must be conducted each year for five years, beginning in 2011. Inspections of at least 600 foreign facilities must be conducted within the year following the enactment of the law.

Whether a domestic facility is determined to be high-risk under Title Two will depend on a number of factors, including but not limited to: (1) the known safety risks of the food manufactured, processed, packed, or held in the facility; (2) the compliance history at the facility; (3) the rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls; (4) whether the food at the facility meets the criteria for a priority inspection under § 801(h)(1) of the FFDCA; (5) whether the food and/or the facility has received certification under § 801(q) and/or § 806 of the FFDCA; and (6) any other criteria deemed necessary and appropriate by the Secretary of HHS.

Title Two specifically addresses the need for coordinated and integrated laboratory methods to detect contaminants around the country. The new legislation requires the Secretary of HHS to establish a program for the testing of food by accredited laboratories, as well as a publicly available registry of accredited laboratories and accreditation bodies recognized by the Secretary. Also, as a condition of recognition or accreditation, recognized accredited bodies are required to report to the Secretary any changes that might affect accreditation.

In addition, the Secretary of Homeland Security, in conjunction with the Secretary of HHS, the Secretary of Agriculture, the Secretary of Commerce, and the Administrator of the Environmental Protection Agency, is required to establish and maintain an agreement whereby registered laboratories can decide on common laboratory methods in order to reduce the time required to detect and respond to foodborne illness outbreaks; facilitate the sharing of knowledge and information related to health and agriculture; and identify means by which the laboratories can work cooperatively.

Under Title Two, the Secretary of HHS is also tasked with improving the tracking of food as it flows through the supply chain. As a consequence, the legislation requires HHS to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food, in order to prevent or mitigate a foodborne illness outbreak and to address credible threats of adverse health consequences or death as a result of the adulteration or misbranding of such food.

The pilot projects must reflect the diversity of the food supply and include at least three different types of foods that have been the subject of significant outbreaks during the five years preceding the enactment of the law. The pilot projects must be selected in order to develop and demonstrate methods for the rapid and effective tracing of food in a manner that is practicable for facilities of various sizes; develop and demonstrate technologies that enhance the tracking and

tracing of food; and assist in the promulgation of additional recordkeeping requirements for high-risk foods. In addition, the Secretary of HHS, in consultation with the Secretary of Agriculture, is required to establish a product-tracing system within the FDA in order to effectively and rapidly track and trace food that is in the United States or offered for import into the United States.

Title Two provides for states, localities, and tribes to work with the federal government in a coordinated fashion to prevent and respond to foodborne illness outbreaks; recommendations include training, grant programs, and the creation of resource centers. The law also requires foodborne illness surveillance systems to be established nationwide by the Secretary of HHS, acting through the Centers for Disease Control and Prevention, in order to improve the collection, analysis, reporting, and usefulness of data on foodborne illness. The Secretary of HHS must:

- Coordinate federal, state, and local foodborne illness surveillance systems.
- Facilitate the sharing of surveillance information among governmental agencies.
- Develop improved epidemiological tools for obtaining quality exposure data and microbiological methods for classifying cases.
- Improve the current capability to attribute a foodborne illness outbreak to a specific food.
- Publish current reports and findings from, and allow timely public access to, the surveillance systems.
- Facilitate scientific research by academic institutions.
- Integrate surveillance systems and data with other biosurveillance and public-health situational-awareness data.

Title Two gives the FDA mandatory recall authority for the first time. This recall authority allows the FDA to order a facility to stop distributing an article of food that has been adulterated or misbranded, threatening serious adverse health consequences, if the facility has refused to recall the product voluntarily and has had the opportunity for an expedited informal hearing. Once a food recall is in effect, the law requires the Secretary of HHS to publish a press release regarding the food recall in order to inform consumers and retailers. The press release shall, at the minimum, identify the food, the risk associated with the food, and similar foods that are not affected by the recall. Prior law, which allowed the FDA only to negotiate with businesses for voluntary recalls, sometimes impeded the expedited removal of contaminated food from the market.

TITLE THREE: STRENGTHENING FOOD SAFETY REQUIREMENTS FOR IMPORTED FOODS

Title Three significantly enhances the FDA's ability to oversee the millions of food products imported into the United States each year. Under Title Three, importers must verify, and sometimes even certify, the safety of food from their suppliers to ensure that the food meets the applicable requirements of the legislation. Verification activities may include monitoring records for shipment, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

Title Three emphasizes the importance of direct collaboration with foreign governments to assess the safety of imported foods. First, the new legislation gives the U.S. government the power to aid foreign governments in improving their food safety programs. This aid is through government-to-government support and U.S. recognition of bodies that accredit third-party auditors of foreign food facilities. Second, Title Three gives the Secretary of HHS the ability to enter into arrangements and agreements with foreign governments to facilitate the inspection of registered foreign facilities, factories, warehouses, and other establishments. However, if U.S. inspectors or other individuals designated by the Secretary of HHS are refused the right to inspect such a foreign facility, the FSMA requires food from that foreign facility to be refused admission into the United States.

MISCELLANEOUS PROVISIONS IN THE FSMA

Numerous provisions in the FSMA advance goals other than those described in the preceding three sections. For example, the FSMA contains a food safety whistleblower provision, which prohibits discrimination against and discharge of an employee who identifies, reports, or refuses to participate in a violation of the above regulations by an entity involved in the manufacturing, processing, packing, transporting, distribution, reception, holding, or importation of food. While such provisions are intended to enhance compliance, they can lead to retaliatory reporting by disgruntled employees and hamper employment relations.

The FSMA exempts small businesses and agricultural producers from much of the new regulatory scheme. For example, "very small businesses" and "small businesses"—to be defined by HHS in subsequent regulations—either will be exempt from many of the new requirements or will not have to begin complying with a number of the new regulations until one to two years after promulgation. In addition, for a number of provisions, the Secretary of HHS is required to issue a guide to help small entities comply with the new requirements.

Similarly, farms and other establishments that sell food directly to consumers, such as roadside stands, farmers' markets, and participants in community-supported agricultural programs, are granted certain exemptions and flexibilities under the FSMA. For example, as a result of what is known as the Tester-Hagan Amendment, farms that make at least half of their profits from direct-to-consumer sales and earn $500,000 a year or less (adjusted for inflation) are exempt from most of the new regulations by the FSMA. The Secretary of HHS, however, has the ability to revoke these exemptions if the farm or small business is involved in an outbreak.

Some farms are also exempt from the recordkeeping requirements intended to help the government trace food as it flows through the supply chain. Food packaged and produced on a farm has only minimal recordkeeping requirements if "the packaging of the food maintains the integrity of the product and prevents subsequent contamination or adulteration" and if the labeling of the product includes complete business-contact information for the farm. If a farm sells food directly to a consumer, it does not have to maintain any records. If a farm sells food directly to a grocery store, the store must maintain records documenting that farm. In this context, "sale of food" occurs when "food is produced on a farm" and "sale is made by the owner, operator, or agent in charge."

CONCLUSION

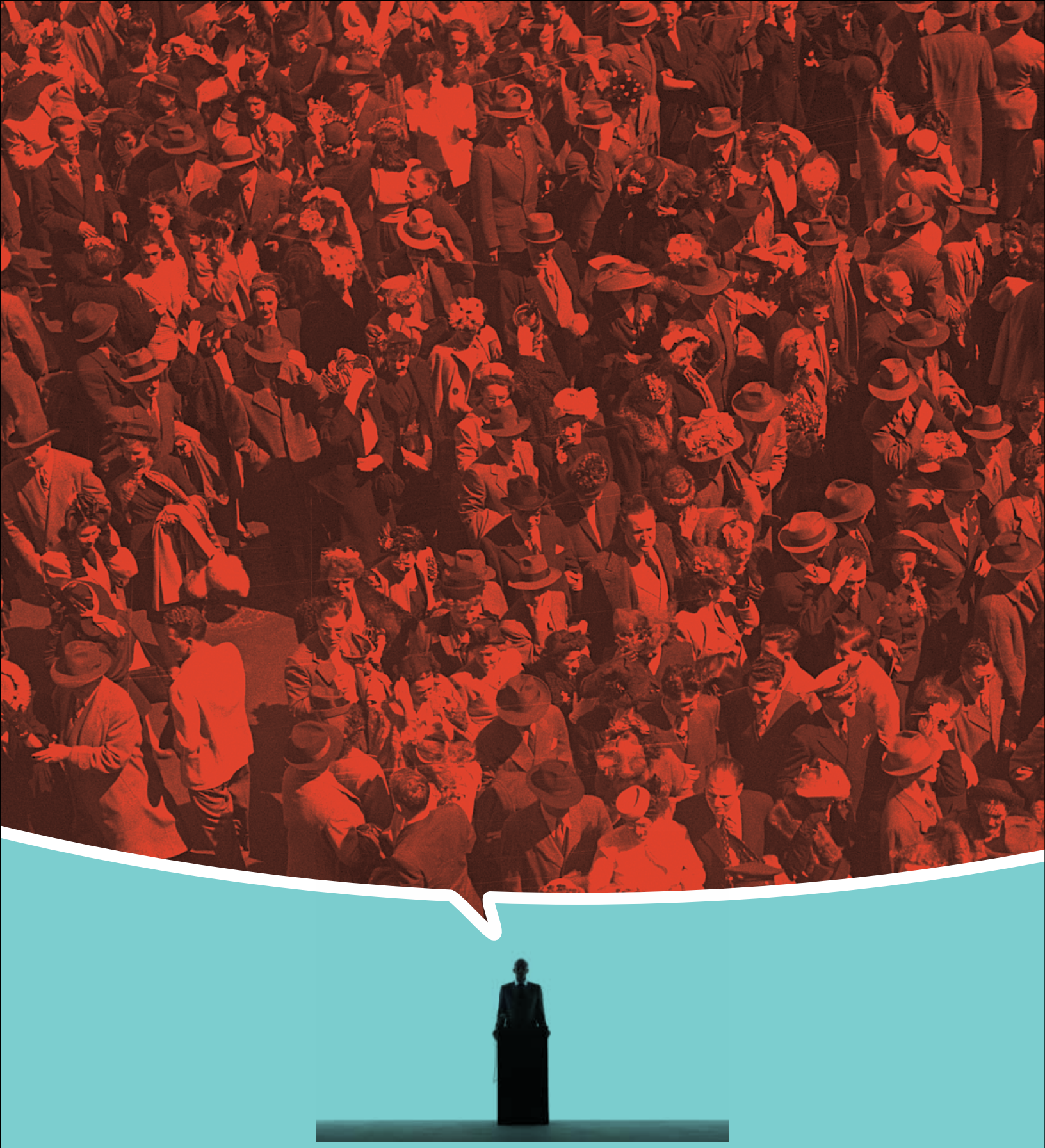
The FSMA contemplates great strides in preventing, detecting, and responding to potential foodborne illness outbreaks in the United States. The legislation significantly expands the powers of the U.S. government to regulate the food industry, allowing the FDA to create new food safety standards, issue mandatory food recalls, and impose severe penalties on those entities that fail to comply with the new regulations. The FSMA also significantly enhances the FDA's ability to oversee the millions of food products coming into the United States from other countries each year.

In addition, the FSMA imposes substantial new financial burdens and regulatory uncertainties on larger food producers while vaguely referring to new requirements and standards that will not be defined until the FDA issues the regulations required under the new law. Therefore, producers may not know the true extent of their responsibilities and costs under the new law until the regulations are finally promulgated—a matter of months or even years. Moreover, timely implementation and enforcement depend upon whether Congress provides the funding necessary to achieve the ambitious programs envisioned by the FSMA. ■

JOHN W. EDWARDS II
Silicon Valley
+1.650.739.3912
jwedwards@jonesday.com

LAURA E. MORRIS
Silicon Valley
+1.650.739.3957
lemorris@jonesday.com

[1] For more information on the Seafood HACCP, see the following web site maintained by the FDA: http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/SeafoodHACCP/default.htm (web site last visited May 20, 2011).



DAUBERT SCRUTINY OF EXPERT EVIDENCE IN CLASS CERTIFICATION PROCEEDINGS

By Cynthia H. Cwik, Amanda Pushinsky, and Justin T. Smith

Expert testimony is increasingly being presented during class-certification proceedings. As courts have considered expert testimony in determining whether the requirements for certifying a class have been met, questions have arisen about the appropriate standard of review for that expert testimony. The United States Supreme Court has never explicitly addressed the appropriate level of review for expert testimony presented in connection with class-certification proceedings. Lower courts have focused on the U.S. Supreme Court decision that generally governs the admissibility of expert evidence, the seminal decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[1]

In connection with class-certification proceedings, the Supreme Court previously stated that the district court may not consider a "preliminary inquiry into the merits" in deciding whether to certify a class.[2] In *Daubert*, the Supreme Court emphasized that courts must look beneath the surface of expert opinions, closely examine the expert's methodologies, and exclude testimony that is irrelevant or unreliable.[3] The *Daubert* decision, however, did not address the appropriate level of scrutiny of expert testimony presented in connection with class-certification proceedings, and some have argued that *Daubert* applies only to the use of expert testimony at trial.

More courts have begun to apply *Daubert*—at least in some form—to expert testimony offered in support of class certification, and the most recent decisions generally lean toward a higher level of scrutiny of expert testimony. Under one approach, courts do not subject the expert testimony to a full *Daubert* inquiry at the class-certification stage but instead conduct a limited review. As the decisions emerging from circuit courts over the last few years demonstrate, however, the current tendency is to apply higher levels of scrutiny to expert testimony at the class-certification stage. Given that

the decision whether or not to certify a class can often be case-determinative, this trend toward increased scrutiny of expert testimony at the class-certification stage has important ramifications for practitioners.

CIRCUIT OVERVIEW

The First Circuit. In *In re New Motor Vehicles Canadian Export Antitrust Litig.*,[4] the First Circuit generally held that if plaintiffs rely on a novel or complex theory to meet Rule 23's requirements, courts must conduct a "searching inquiry" into the factual merits of the theory.[5] The First Circuit determined that the plaintiffs' two-part theory of price manipulation was "both novel and complex" and not entirely supported by the testimony of the plaintiffs' expert.[6] In other words, certification was dependent on the ability of the plaintiffs' expert "to establish—whether through mathematical models or further data or other means—the key logical steps behind their theory."[7] Specifically, the Circuit held that "a more searching inquiry" by the district court into whether the plaintiffs could actually prove the key elements of their claims through common proof at trial was required.[8]

The court in *New Motor Vehicles* declined to specify a precise standard of proof that plaintiffs would be required to satisfy at the class-certification stage. However, the court made clear that the district court's analysis of expert testimony should be sufficiently thorough to identify, at a preliminary stage in the litigation, cases where "there is no realistic means of proof."[9]

The Second Circuit. *In re Initial Public Offering Sec. Litig.*[10] was one of the key decisions ushering in a more rigorous standard for expert testimony at the class-certification stage. *In re IPO* heightened the plaintiffs' burden on a class-certification motion in that it was no longer sufficient for plaintiffs to obtain class certification merely on the basis of unsupported legal conclusions or plausible expert methodologies.[11] The Second Circuit specifically stated that the plaintiffs' burden of proving each of the Rule 23 requirements was not lessened by overlap between a Rule 23 requirement and a merits issue, and it acknowledged that a district court may have to resolve underlying expert disputes to make such a determination.[12] However, *In re IPO* did indicate that district courts continue to have discretion to shape discovery and the extent of the hearing to ensure that class certification does not become a partial trial on the merits.[13]

GIVEN THAT THE DECISION WHETHER OR NOT TO CERTIFY A CLASS CAN OFTEN BE CASE-DETERMINATIVE, THIS TREND TOWARD INCREASED SCRUTINY OF EXPERT TESTIMONY AT THE CLASS-CERTIFICATION STAGE HAS IMPORTANT RAMIFICATIONS FOR PRACTITIONERS.

The Third Circuit. In *In re Hydrogen Peroxide Antitrust Litig.*,[14] the Third Circuit issued a significant decision that further raised the standard for the evaluation of expert testimony at the class-certification stage. More specifically, the Third Circuit holding requires district courts to engage in "rigorous" analysis of evidence in determining whether Rule 23 requirements have been met.[15] After the district court granted the plaintiffs' motion for class certification, the defendants argued on appeal that the plaintiffs had failed to satisfy Rule 23(b)(3)'s requirement that common questions of law or fact predominate over any questions affecting individualized issues. Both parties had submitted expert testimony on the question of commonality, but the district court failed to resolve the dispute between the experts on this issue.

The Third Circuit discussed the intersection between *Daubert* and class certification, holding that "[w]eighing conflicting expert testimony at the certification stage is not only permissible; it may be integral to the rigorous analysis Rule 23 demands."[16] The Third Circuit held that a district court's ruling that expert testimony should not be excluded under *Daubert* does not automatically mean the testimony should be "uncritically accepted as establishing a Rule 23 requirement."[17] On the other hand, "a district court's conclusion that an expert's opinion is admissible does not necessarily dispose of the ultimate question—whether the district court is satisfied, by all the evidence and arguments including all relevant expert opinion, that the requirements of Rule 23 have been met."[18] Accordingly, under *In re Hydrogen Peroxide*, where expert testimony is necessary for the class-certification determination, a district court must resolve disputes between competing experts, and neither credibility issues nor concern for addressing the merits of the case can impede the rigorous analysis required to resolve such disputes.[19]

The Fourth Circuit. In *Gariety v. Grant Thornton, LLP*,[20] the Fourth Circuit reversed the district court's certification order on the ground that it had not conducted a sufficiently rigorous analysis of the underlying facts, holding that "while an evaluation of the merits to determine the strength of plaintiffs' case is not part of a Rule 23 analysis, the factors spelled out in Rule 23 must be addressed through findings, even if they overlap with issues on the merits."[21] Although the Fourth Circuit did not squarely address the issue of the appropriate level of inquiry into expert testimony at the certification stage, *Gariety* suggests that it may endorse a relatively rigorous approach. Accordingly, district courts in the Fourth Circuit have engaged in *Daubert* analyses during class certification.[22]

The Fifth Circuit. In *Regents of Univ. of Cal. v. Credit Suisse First Boston (USA), Inc.*,[23] the Fifth Circuit reversed the district court's certification of the class of the former Enron shareholders, moving toward an express authorization of the merits inquiry at the class-certification stage and requiring the resolution of conflicting expert testimony.[24]

The Sixth Circuit. In *Rodney v. Northwest Airlines, Inc.*,[25] the district court did not simply accept the plaintiffs' allegations and expert methodologies on class impact and injury; it also considered the testimony of the defendants' expert that injury and damages could not be proved on a class-wide basis, ultimately denying the certification motion. The Sixth Circuit affirmed the denial of class certification, holding that "a court performing a 'predominance' inquiry under Rule 23(b)(3) may consider not only the evidence presented in the plaintiff's case-in-chief but the defendant's likely rebuttal evidence."[26] Although the Sixth Circuit has not clearly addressed the role of experts in class-certification proceedings, it held that "courts [should] take care to inquire into the substance of the underlying claims" to determine the type of evidence that will be needed at trial, which suggests that district courts must go beyond a cursory analysis and actually resolve conflicting expert testimony prior to certification.[27]

The Seventh Circuit. In *West v. Prudential Sec. Inc.*,[28] each side presented testimony by an established financial economist at the class-certification stage, and the district court held that the fact that both sides presented expert testimony was by itself enough to support class certification. Without specifically mentioning *Daubert*, the Seventh Circuit held that the district court's approach was an impermissible "delegation of judicial power to the plaintiffs," who could obtain certification simply by hiring an established expert.[29] The court held:

> A district judge may not duck hard questions by observing that each side has some support, or that considerations relevant to class certification also may affect the decision on the merits. Tough questions must be faced and squarely decided, if necessary by holding evidentiary hearings and choosing between competing perspectives.[30]

In *American Honda Motor Co. v. Allen*,[31] the Seventh Circuit held that when an expert's opinion is an essential element of class certification, the district court must definitively rule on any challenge to the expert's qualification or submissions, possibly entailing a full *Daubert* analysis.[32] Further, the district court must also resolve any challenge to the reliability of information provided by the expert if that information is relevant to establishing any of the Rule 23 requirements for class certification.[33]

The Eighth Circuit. *Blades v. Monsanto Co.*[34] was a putative class action in which the plaintiffs claimed an alleged price-fixing conspiracy in violation of the Clayton Act and the Sherman Act. The plaintiffs sought to use expert testimony to meet their burden for class certification. The Eighth Circuit affirmed the district court's findings and held that district courts may be required to resolve expert disputes at the class-certification stage.[35] The court also noted that "assumptions," "presumptions," and "conclusions" offered by the plaintiffs' expert were insufficient to establish Rule 23 requirements.[36]

The Ninth Circuit. A few district courts in the Ninth Circuit have recently addressed the issue of the admissibility of expert testimony at the class-certification stage. In *Campion v. Old Republic Home Protection Co., Inc.*,[37] the court noted that the "Ninth Circuit has not yet determined whether a full *Daubert* analysis is required at the class certification stage."[38] In that case, the court decided not to conduct a full *Daubert* analysis because the expert's opinions were not critical to the court's determination of the motion for class certification. In *Hovenkotter v. Safeco Ins. Co. of Ill.*,[39] although the court noted that it "need not conduct a full *Daubert* analysis as to the admissibility for trial of the expert's opinions" at the class-certification stage, it did hold that a court should conduct "a full and rigorous analysis of the admissibility of the expert's opinions *as they relate to class certification issues* and leave for trial the admissibility of their opinions as they relate to the merits of the underlying claims."[40] Similarly, in *Kennedy v. Jackson Nat. Life Ins. Co.*,[41] the court conducted a limited *Daubert* analysis of the expert's testimony.

The Tenth Circuit. In *Vallario v. Vandehey*,[42] the Tenth Circuit vacated a decision granting class certification and held that the district court abused its discretion by basing its class-certification ruling on an "unduly constrained view of the inquiry authorized by Rule 23."[43] The Tenth Circuit held that although "the merits of a movant's claims may not serve as the focal point of its class certification analysis[,] . . . this does not mean that a district court is categorically prohibited from considering any factor, in conjunction with its Rule 23 analysis, that touches upon the merits of a movant's claims."[44] Under *Vallario*, a district court must ensure that "the requirements of Rule 23 are met . . . through findings," even if such findings "overlap with issues on the merits."[45] Indeed, the Tenth Circuit wrote that the phrase "no merits inquiry" should not be "talismanically" invoked to limit a district court's inquiry into whether Rule 23's requirements have been met.[46] Overall, *Vallario* appears to stand for the proposition that the court may examine expert testimony to determine whether plaintiffs have satisfied Rule 23's requirements for class certification.

The Eleventh Circuit. In *Cooper v. Southern Co.*,[47] the plaintiffs alleged race discrimination based on Title VII and Section 1981 of the Civil Rights Act of 1866. The district court denied class certification due to the methodological deficiencies of the plaintiffs' expert, as the expert evidence could not demonstrate commonality. The Eleventh Circuit upheld the denial of class certification, stating:

> [t]he district court did not exclude [plaintiffs' expert's] reports because she was unqualified or because the reports were based on a wholly unreliable methodology; rather, the court accepted the reports' conclusions but determined that they still failed to establish that the named plaintiffs had claims in common with other class members . . . .[48]

The Eleventh Circuit did not specifically address the plaintiffs' argument that the district court applied an overly rigorous standard in evaluating their statistical expert at the class-certification stage.

CONCLUSION

The appropriate level of scrutiny for expert testimony presented at the class-certification stage is likely to remain an important issue for practitioners and the courts. A majority of federal appellate courts have already established heightened standards for district courts to apply to expert testimony used in class-certification proceedings, emphasizing that district courts must conduct a rigorous analysis when determining whether all the requirements of Rule 23 have been met.

In light of this recent Circuit trend, it is likely that it will become increasingly common for the parties to consider filing *Daubert* motions at the class-certification stage. In addition, there will likely be more requests for related evidentiary presentations. These developments can help ensure that class-certification decisions, which are often case-dispositive, are based on a sound, reliable foundation.

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CYNTHIA H. CWIK
San Diego
+1.858.314.1165
chcwik@jonesday.com

AMANDA PUSHINSKY
San Diego
+1.858.314.1123
apushinsky@jonesday.com

JUSTIN T. SMITH
Irvine
+1.949.553.7594
jtsmith@jonesday.com

[1] 509 U.S. 579 (1993).

[2] *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177 (1974).

[3] 509 U.S. 579 (1993).

[4] 522 F.3d 6 (1st Cir. 2008).

[5] 522 F.3d at 24.

[6] *Id.* at 27.

[7] *Id.* at 26.

[8] *Id.* at 31.

[9] *Id.* at 29.

[10] 471 F.3d 24 (2d Cir. 2006).

[11] 471 F.2d at 40–41.

[12] *Id.* at 42.

[13] *Id.* at 40–41; *see also Weiner v. Snapple Beverage Corp.*, 2010 WL 3119452, at *5 (S.D.N.Y. Aug. 5, 2010) (ruling that plaintiffs had failed to meet Rule 23(b)(3)'s predominance requirement because their expert's testimony was unreliable).

[14] 552 F.3d 305 (3d Cir. 2008).

[15] 552 F.3d at 323.

[16] *Id.*

[17] *Id.*

[18] *Id.* at 315 n.13.

[19] *See also Nafar v. Hollywood Tanning Systems, Inc.*, 339 Fed. Appx. 216, 223 (3d Cir. 2009) (remanding case to district court to consider defendant's expert evidence as to predominance claim as required by *In re Hydrogen Peroxide*).

[20] 368 F.3d 356, 358–59 (4th Cir. 2004).

[21] 368 F.3d at 366.

[22] *See, e.g., Rhodes v. E.I. du Pont de Nemours & Co.*, 2008 WL 2400944, at *10–12 (S.D. W. Va. June 11, 2008).

[23] 482 F.3d 372 (5th Cir. 2007).

[24] 482 F.3d at 381 (imposing prohibition against consideration of merits only insofar as they pertain to matters unrelated to class-certification requirements).

[25] 146 Fed. Appx. 783 (6th Cir. 2005).

[26] 146 Fed. Appx. at 787.

[27] *Id.* at 786.

[28] 282 F.3d 935 (7th Cir. 2002).

[29] 282 F.3d at 938.

[30] *Id.*

[31] 600 F.3d 813 (7th Cir. 2010) (per curiam).

[32] 600 F.3d at 815–16.

[33] *Id.* at 816.

[34] 400 F.3d 562, 569–70 (8th Cir. 2005).

[35] 400 F.3d at 575 (stating that "in ruling on class certification, a court may be required to resolve disputes concerning the factual setting of the case" including "the resolution of expert disputes concerning the import of evidence").

[36] *Id.* at 571.

[37] No. 09-748, 2011 WL 42759 (S.D. Cal. Jan. 6, 2011).

[38] *Id.* at *20.

[39] No. 09-0218, 2010 WL 3984828, at *4 (W.D. Wash. Oct. 11, 2010).

[40] *Id.*

[41] No. 07-0371, 2010 WL 2524360, at *12 (N.D. Cal. June 23, 2010).

[42] 554 F.3d 1259 (10th Cir. 2009).

[43] 554 F.3d at 1267.

[44] *Id.* at 1266.

[45] *Id.*

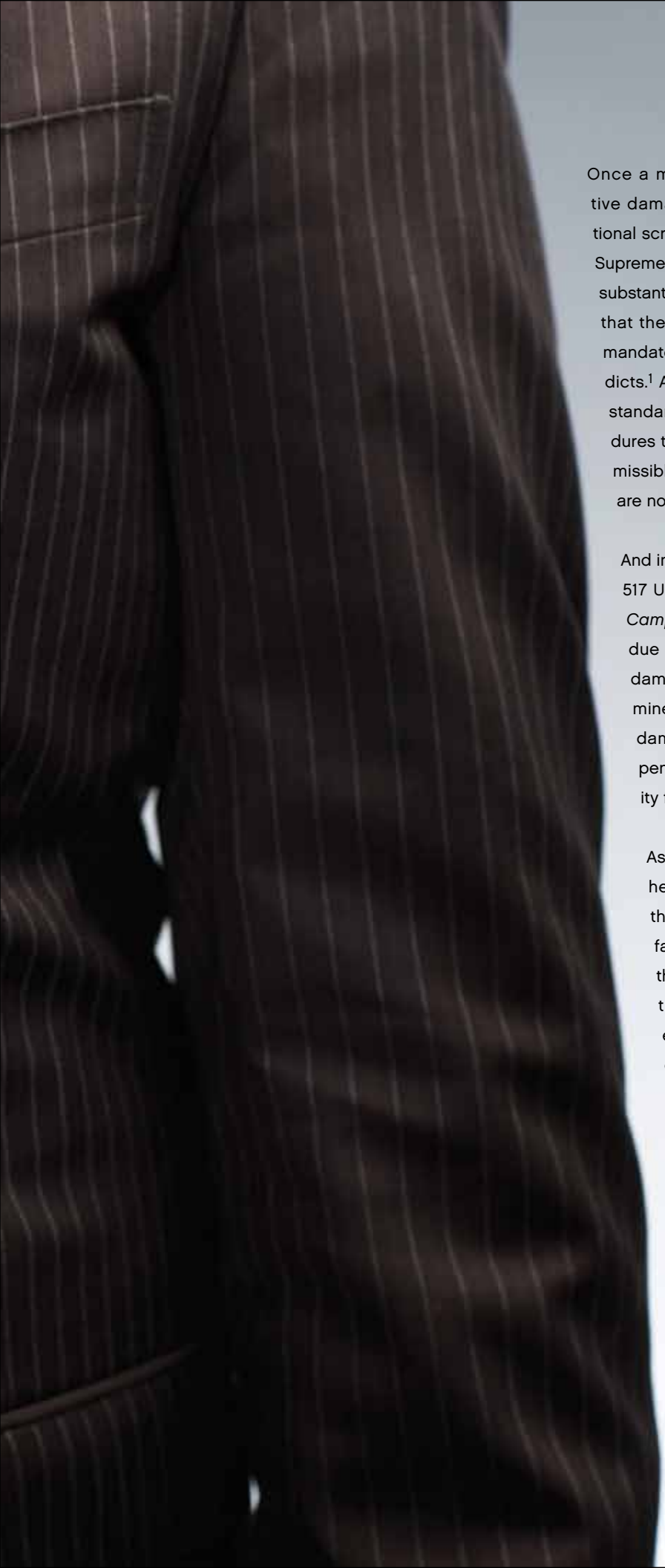
[46] *Id.* at 1267.

[47] 390 F.3d 695 (11th Cir. 2004), *overruled on other grounds by Ash v. Tyson Foods, Inc.*, 546 U.S. 454, 456–57 (2006).

[48] 390 F.3d at 717.

ONE SIZE DOESN'T FIT ALL:

A TAILORED APPROACH TO PUNITIVE DAMAGES ANALYSIS IN PRODUCT LIABILITY CASES



By Diane G.P. Flannery and Jason T. Burnette

Once a matter of almost exclusive state-law concern, punitive damages awards have come under increasing constitutional scrutiny in the last two decades. A series of United States Supreme Court decisions have fixed the procedures and set the substantive boundaries of punitive awards. It is now established that the Due Process Clause of the Fourteenth Amendment mandates meaningful judicial review of punitive damages verdicts.[1] An award of punitive damages is subject to a *de novo* standard of appellate review.[2] Trial courts must adopt procedures to ensure that punitive awards are not based on impermissible factors, such as evidence of harm to nonparties who are not before the court.[3]

And in a pair of decisions, *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), the Supreme Court held that due process forbids the imposition of "excessive" punitive damages, with the excessiveness of an award to be determined by the award's ratio to the amount of compensatory damages, by a comparison to available civil and criminal penalties, and by an application of so-called reprehensibility factors.

As the Court noted in *State Farm*, the last of these, reprehensibility, is "the most important indicium" of assessing the excessiveness of an award. The Court identified five factors to guide lower courts and juries in determining the reprehensibility of a defendant's conduct: (1) whether the harm caused was physical as opposed to merely economic; (2) whether the conduct showed an indifference to or reckless disregard of the health or safety of others; (3) whether the target of the conduct was financially vulnerable; (4) whether the conduct involved repeated actions or was an isolated incident; and (5) whether the harm was the result of the defendant's intentional misconduct.[4]

These five factors, however, were articulated in the context of cases involving economic torts. As a group, they provide a relatively poor framework for assisting juries and courts in their task of assessing reprehensibility in product liability cases, because many of them are present in *every* product liability action

and thus fail to distinguish among degrees of reprehensibility. Indeed, three of the five *State Farm* factors are present in almost every product liability case and thus provide no means of assessing *relative* reprehensibility:

- **Physical versus economic injury:** Product liability cases almost always involve physical injury.
- **Financial vulnerability:** Some courts have interpreted this factor not as *Gore* indicated—as pertaining to a defendant's *targeting* of a financially vulnerable plaintiff—but as referring to nothing more than the fact that the defendant has a greater net worth than the injured plaintiff or that the plaintiff's injuries left him or her in a financially vulnerable position.[5] Under this expansive (albeit incorrect) definition, this factor is present in nearly every product liability case, because the net worth of individual consumers is almost always smaller than that of product manufacturers.
- **Repeated misconduct:** To the extent courts construe this factor to refer to repeated sales, rather than to repeated acts of misconduct in designing or not redesigning a product, this factor is also present in almost every product liability case because nearly all goods are mass-produced and mass-marketed.

Reliance on these factors, at least as they have been interpreted by some of the courts, is tantamount to instructing the jury that three out of the five *State Farm* factors automatically cut in favor of greater reprehensibility. What is called for instead are factors that meaningfully aid juries and courts in situating—within the context of a product liability action—a particular defendant's conduct on a spectrum of conduct running from the least to the most reprehensible. Because the *State Farm* factors do not assist the jury in determining whether a defendant in a product liability case is "more blameworthy than others," it is therefore appropriate and necessary to develop a list of factors that do.

A MEANINGFUL ASSESSMENT OF REPREHENSIBILITY CALLS FOR PLACING A DEFENDANT'S CONDUCT ON A CONTINUUM OF BEHAVIOR

Punitive damages may be assessed only after a jury awards compensatory damages. Whether punitive damages are additionally appropriate (or, for that matter, constitutional) depends on whether the imposition of damages—in addition to damages that already make the plaintiff whole—is required either to punish that defendant or to deter such conduct in the future.[6] This hinges primarily on how reprehensibly the defendant has acted: the more reprehensible its conduct, the greater the need for a more substantial financial penalty to punish and deter that conduct; the less reprehensible, the lesser the need for a substantial penalty (or any penalty) to punish or deter. "Some wrongs," the Supreme Court has explained, "are more blameworthy than others."[7] Reprehensibility is therefore not a yes-or-no proposition, but rather a matter of *degree*.[8] The factors must in turn function as a tool to help juries and courts place the defendant's conduct along this spectrum of reprehensible behavior.

These factors need not be—and *should* not be—static across all torts, for what may be a helpful factor in assessing reprehensibility in an intentional or economic tort might be present in *all* product liability torts and thus of no value in assessing the *degree* of a product liability defendant's reprehensibility. Relying solely on the *State Farm* factors will therefore deny juries and courts access to several helpful yardsticks for evaluating reprehensibility not mentioned in that case. In other words, there is a substantial downside to a "one size fits all" approach, and there is thus a real need to fashion factors useful in assessing degrees of reprehensibility in product liability actions. Importantly, at no point has the Court ever held that these five factors are the definitive five factors that must always be applied to assess reprehensibility for any and all purposes and in any and all cases. To the contrary, the Court in *Gore* observed that it is entirely legitimate for "the level of punitive damages" to vary for "different classes of cases."[9]

THE FACTORS FOR ASSESSING REPREHENSIBILITY SHOULD LOOK TO A TYPICAL PRODUCT LIABILITY DEFENDANT'S CONDUCT

In determining the factors that will be most useful in assessing the reprehensibility of a defendant's conduct in a product liability case, the logical place to start is by selecting factors that evaluate the reprehensibility of a product liability defendant's conduct at each stage of the typical course of conduct for such a defendant. Usually, the defendant has designed a product that has subsequently injured others, including the plaintiff. Thus, there are two general categories of factors: (1) the defendant's conduct in initially designing the product; and (2) the defendant's conduct in responding to any injuries in light of its knowledge or belief about whether its product caused those injuries. These two categories may be assessed using a number of individual factors:

(1) Whether the defendant, in designing the product, attempted to comply with applicable government or industry safety standards	(I) Factors pertaining to a defendant's initial design decision
(2) Whether the defendant engaged in safety testing	
(3) Whether the defendant took steps to warn consumers about possible injuries	
(4) Whether the defendant affirmatively concealed its knowledge of defects known to cause injury	
(5) Whether the defendant erected a mechanism for receiving customer complaints and monitoring product safety	(II) Factors pertaining to a defendant's reaction to subsequent injuries
(6) Whether and how the defendant investigated product-related injuries	
(7) Whether the defendant voluntarily took measures to make its product safer	
(8) Whether the defendant issued new or additional safety warnings	

Product Design. When designing a product, a defendant's conduct may be viewed as more reprehensible, or less so, depending on the following factors:

Whether the defendant, in designing the product, attempted to comply with applicable government or industry safety standards. A defendant that takes the time to consult relevant safety protocols—whether government or industry standards—and thereafter incorporates them into its product design is acting in a responsible (and nonreprehensible) fashion that is not to be punished or deterred. Similarly, when a product is so novel or cutting-edge that appropriate safety standards do not yet exist, a designer that attempts to meet the standards that are most analogous will not be considered to have acted reprehensibly; indeed, taking the additional step of trying to comply with the most analogous safety standards for the new product is the very antithesis of punitive-damages-worthy conduct. What *is* reprehensible is a defendant that, in the face of clearly applicable standards, elects to ignore them entirely. As one would expect, the law mirrors this logic. In many states, compliance with applicable standards is a complete defense to punitive damages[10] or cuts against a finding of liability.[11] Even if not a bar, compliance or attempted compliance is at a minimum almost universally viewed as weighing against the imposition of punitive damages.[12]

Whether the defendant engaged in safety testing. A defendant that engages in product safety testing is acting cautiously and not reprehensibly. What matters in this regard is the quantity and quality of safety testing, the resources devoted to it, and whether the testing is reasonable. Any awards conferred for product safety and use of the product by persons or entities charged with public safety are, by their very nature, pertinent to demonstrate the reasonableness and nonreprehensibility of the defendant's testing protocols. Conversely, a defendant that "rush[es] into production" without pertinent testing or fails to test at all may warrant a punitive damages award to punish or deter.[13]

Whether the defendant took steps to warn consumers about possible injury. A defendant that knows its product may cause injury is not acting as reprehensibly if it warns consumers about that danger, as compared to a different defendant that, aware of the risk, does nothing to cure the defect and nothing to warn others of it. Most products are not designed to be completely injury-proof, and trying to make them so would often be unreasonable because it would rob them of their intended function and utility: a knife is a knife only if it has a cutting blade, and a bicycle is a bicycle despite its tendency to tip over when ridden. For such products, it is entirely plausible (and certainly not a basis for punitive damages) for a defendant to choose to warn against the risk rather than to ameliorate the so-called defect that causes the injury. Defendants that make this choice are acting responsibly—not reprehensibly.[14]

Whether the defendant affirmatively concealed its knowledge of defects known to cause injury. Having learned that its safety testing was defective or that its product has defects causing injury that can be either remedied or warned against, a defendant that conceals the evidence of such defects in order to make its product more marketable is engaged in far more reprehensible conduct than a defendant that is "upfront" with itself and with consumers by taking corrective measures. To be sure, a defendant need not disclose every step of its design and testing process or every conclusion it draws along the way. But defendants that learn of risks and actively try to suppress them and keep them secret are more likely to warrant punishment and need deterrence.[15]

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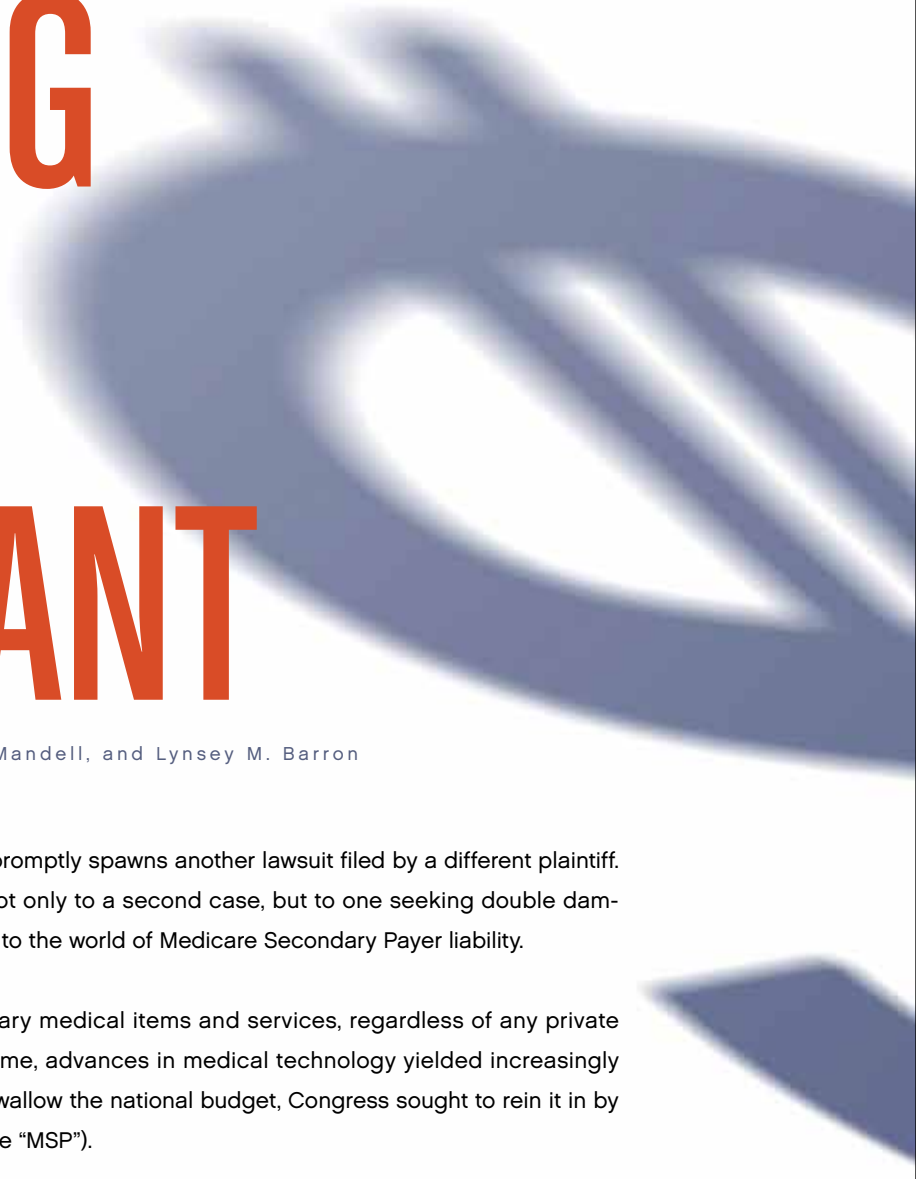
MEDICARE AND THE SETTLING TORT DEFENDANT



By David J. Bailey, Carol A. Hogan, Jeffrey A. Mandell, and Lynsey M. Barron

Every tort defendant's nightmare is a settlement that promptly spawns another lawsuit filed by a different plaintiff. But far more nightmarish is a settlement that leads not only to a second case, but to one seeking double damages, plus interest, with virtually no defense. Welcome to the world of Medicare Secondary Payer liability.

Medicare originally paid for its beneficiaries' necessary medical items and services, regardless of any private coverage apart from workers' compensation.[1] Over time, advances in medical technology yielded increasingly expensive benefits. Fearing that the program would swallow the national budget, Congress sought to rein it in by passing the Medicare Secondary Payer Act of 1980 (the "MSP").

The MSP converted Medicare from a first responder to a backstop. It bars Medicare from paying for any benefit where "payment has been made or can reasonably be expected to be made" by any "primary plan"—defined as "a group health plan or large group health plan, . . . a workmen's compensation law or plan, an automobile

or liability insurance policy or plan (including a self-insured plan) or no fault insurance."[2] To ensure timely care and treatment, the MSP permits "conditional payments" through the Centers for Medicare and Medicaid Services ("CMS"), with the "condition" being that CMS *must* seek reimbursement.[3] The MSP facilitates that condition by giving the government subrogation rights[4] or an alternative double-damages remedy against any entity that would be responsible for payment, as well as "any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity" (*e.g.*, a plaintiff or plaintiff's counsel receiving settlement or judgment payments).[5]

If this were simply a matter of determining primacy among multiple layers of insurance, there would be little cause for concern. But what started as a largely noncontroversial effort to shield Medicare benefits with private insurance contracts has moved far beyond that. As the media reported huge tort settlements and verdicts in the 1980s and 1990s, the government took notice. Seeking a share of those settlements and verdicts, the government argued in a series of cases that the term "self-insured" in the MSP's definition of "primary plan" included settling product liability defendants that had not purchased outside insurance policies to protect themselves in the event of injuries due to product defects.[6]

After a number of courts rejected that argument, Congress amended the MSP in 2003 to "clarify" that "[a]n entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part."[7] Congress further "clarified" that:

> [a] primary plan's responsibility . . . may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.[8]

The 2003 amendments effectively eliminated tort defenses as a barrier to Medicare reimbursement. Once "responsibility" is "demonstrated" through a settlement with or a release given by a Medicare beneficiary, the only issues are when and how much the settling defendant must pay—or must ensure that the plaintiff and the plaintiff's attorney pay to CMS. Emboldened by these "clarifications," the government recently sued a number of plaintiffs' lawyers and settling companies for more than $135 million in the aftermath of an Alabama toxic tort settlement.[9]

When conditional payments equal or exceed the consideration for a settlement, CMS may claim the entire settlement amount, even if the defendant settled on a cost-of-litigation basis and even if medical expenses represented only a small fraction of the total damages alleged. CMS refuses to recognize any private effort to differentiate medical expenses from other alleged damages in a settlement agreement.[10] Several courts have deferred to CMS's view that "[t]he only situation in which Medicare recognizes allocations of liability payments to nonmedical losses is when payment is based on a court order *on the merits of the case*."[11]

Things got even worse in 2007, when Congress enacted Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007.[12] Obscured and largely unpublicized at the time, that legislation mandated reports of settlements and bolstered what had been a toothless reporting regulation (42 C.F.R. § 411.25) with statutory fines of up to $1,000 *per day* for even inadvertent failure to report a settlement.[13] In response, CMS has designed a complicated, internet-based reporting system that stands to increase reimbursement demands exponentially when it takes effect for "self-insureds" in January 2012.[14]

Logically (and fairly), CMS should pursue the plaintiff, not the defendant, for expenditures resulting from the injury alleged, as CMS's regulations acknowledge.[15] The MSP does not require that, however. Moreover, CMS has made it plain that only a beneficiary/plaintiff may contest preliminary and final CMS determinations of claims for reimbursement.[16] A settling defendant has no standing to participate in any way in CMS's elaborate five-tier administrative hearing process.[17] If the plaintiff is insolvent or otherwise fails to pay what CMS demands, the defendant may be held liable for twice the amount of the claim at issue, even though the defendant has not admitted, and no court has adjudicated, that the defendant's acts or omissions caused the plaintiff's injuries, and even though the defendant has had no opportunity to challenge CMS's calculation of the amount subject

to reimbursement. It seems inconceivable that such a system could pass constitutional muster.

Because CMS is a federal agency, its actions obviously fall within the ambit of the Fifth Amendment. Equally clear is that a deprivation of money falls within the category of "property" protected by the Due Process Clause.[18] It follows that CMS cannot deprive any defendant of dollars demanded as Medicare reimbursement without affording due process.

The Supreme Court "consistently has held that some form of hearing is required before an individual is finally deprived of a property interest."[19] "The constitutional right to be heard is a basic aspect of the duty of government to follow a fair process of decisionmaking when it acts to deprive a person of his possessions."[20] Although the opportunity to be heard in defense does not always have to precede deprivation, it generally should, absent "'extraordinary situations,'" which should only rarely arise in connection with MSP demands.[21] Regardless of timing, the opportunity to be heard "must provide a real test[,]" "'aimed at establishing the validity, or at least the probable validity, of the underlying claim'" on which the deprivation is to be founded.[22]

In holding in *Goldberg v. Kelly*, 397 U.S. 254 (1970), that due process requires a pre-termination hearing before the government can suspend welfare payments to an eligible recipient, the Court dismissed arguments similar to those CMS likely would assert—that "governmental interests in conserving fiscal and administrative resources" outweigh competing property interests.[23] The Court explained that "'[w]hile the problem of additional expense must be kept in mind, it does not justify denying a hearing meeting the ordinary standards of due process.'"[24] "The fundamental requisite of due process of law is the opportunity to be heard. The hearing must be at a meaningful time and in a meaningful manner."[25] As a result, "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses."[26]

Goldberg does not stand alone. Just to highlight two more examples among many, the Court also has held that due process requires the state to conduct a hearing before enacting a wage garnishment[27] or before the sheriff seizes personal property.[28] If, as *Goldberg* holds, recipients of benefits provided under government largesse have a property interest in the continuation of their benefit payments sufficient to trigger due process requirements, it must be the case that a hearing is required when the government seeks to take property already in a person's lawful possession. And if, as the other examples show, due process requires a hearing before the state imposes a temporary deprivation of personal property where two private parties dispute who has the stronger interest, then surely the state cannot forgo such a hearing in a situation distinguished only by the substitution of the government for one of the private parties claiming rightful ownership. The only hearing provided in a double-damages action arguably falls far short of constitutional requirements because the defendant cannot raise a defense; thus, the proceedings assure a settling defendant neither a meaningful "opportunity to speak up in his own defense"[29] nor a meaningful opportunity "to confront and cross-examine" the persons whose knowledge underlies and determines the amount at issue.[30]

If CMS were to exercise its subrogation rights and litigate the plaintiff's claim, it would have to make a prima facie case, against which the defendant could defend itself and as to which it could reach a definitive compromise. Subrogation also would permit an equitable apportionment that would recognize the plaintiff's other elements of damage and scale down the defendant's potential Medicare liability accordingly.[31] But the MSP allows the government to sit out the original litigation and then to sweep in after settlement to take money from the defendant, armed with a presumption of liability—on the thin basis that the defendant chose to settle with the plaintiff—yet provides no process for the rebuttal of that presumption. That is fundamentally unfair.

ADDRESSING AND MINIMIZING RISKS

In short, there is good reason to question the MSP's constitutionality insofar as it would impose liability upon a settling defendant that admits no fault.[32] That said, standing, ripeness, and sovereign-immunity principles may very well prevent a defendant from mounting a constitutional attack until CMS files suit and the defendant faces the risk of liability head-on. This makes due process arguments something of a last-ditch defense. To address and hopefully minimize the risks upfront, there are a number of measures to consider.

Assess the plaintiff's Medicare status at the outset if it is not obvious. Ask opposing counsel about this at the first

preliminary case management or Federal Rule of Civil Procedure 26(f) conference. To avoid wasting valuable interrogatories or document requests limited by local rules, it may be advisable to cover Medicare disclosures in case management orders or "Lone Pine" questionnaires. Otherwise, consult CMS's MSP Mandatory Reporting GHP User Guide[33] to determine the data that will satisfy CMS's reporting requirements for settlements and adverse judgments. Gather that and any Medicare-related correspondence through discovery requests, and follow up in depositions. While opposing counsel may object to items aimed at Section 111 reporting and potential MSP liability, at least one reported decision permits discovery along these lines.[34]

Think twice before trying to discover facts that might induce CMS to waive its claim. Such facts may include, for example, the adequacy of the plaintiff's financial resources to meet the plaintiff's normal needs, any undue hardship the plaintiff might experience if required to reimburse Medicare for conditional payments, whether the plaintiff's ordinary monthly expenses equaled or exceeded the plaintiff's monthly income from all sources, and other considerations suggesting that reimbursement would not comport with equity and good conscience. This may prove counterproductive. For example, in *Roland v. Sebelius*, answers to one defendant's interrogatories on such matters were introduced by CMS in administrative proceedings, resulting in denial of a requested waiver.[35]

Consider that defensive terms in settlement agreements may offer only incomplete protection against potential MSP liability. Some plaintiffs' counsel may resist including MSP provisions altogether. Others may insist on prompt disbursement of settlement funds before final resolution of CMS claims, leaving the defendant open to the risk of the plaintiff's future inability to pay those claims upon demand. Because CMS will give at most preliminary estimates of its claims before a settlement is reached (and then only to the plaintiff or the plaintiff's attorney), the defendant may be forced to evaluate a settlement on the basis of substantially incomplete information.[36] When drafting a settlement agreement, consider representations as to Medicare benefits received or the lack thereof, requirements to report or determine initial and final claims (a potentially time-consuming process), commitments by both the plaintiff and the plaintiff's counsel to pay reimbursement claims when due, related indemnity and hold-harmless clauses, cooperation clauses, hold-back requirements for future medical expenses, waivers of any rights of action for double damages, and explicit references to Medicare in releases and covenants not to sue. Although forms developed for these matters often refer to "Medicare liens," that terminology has been held to be inaccurate and could pose difficulties.[37]

Specify each defendant's contribution separately. If multiple defendants are covered by the same settlement agreement, specify each defendant's contribution separately to preempt any argument that the total settlement amount determines a defendant's individual obligation. It may be best to require a separate release/settlement document for each defendant.

Aggregate lump-sum settlements in mass tort cases pose particular problems. Some have proposed carving out Medicare beneficiaries and treating them separately.[38] Plaintiffs' lawyers may balk at this approach, because it has the potential to create conflicts between their Medicare and non-Medicare clients that could require separate counsel (with a resulting requirement to share contingent fees). It may be possible to negotiate separate terms for the Medicare-eligible group only after all plaintiffs have accepted and undertaken a neutral allocation proceeding. To avoid triggering a premature reporting obligation, a mass tort settlement should not take effect until the lump sum is allocated and each plaintiff has agreed to the allocation by signing a release accepting the allocated sum as settlement consideration.[39] Conditions precedent expressed in preliminary agreements with plaintiffs' counsel should make that delayed effect explicit.

Some courts have held that CMS cannot lay claim to amounts clearly due to settling parties who are not Medicare beneficiaries or to damages clearly meant to compensate for something besides medical expenses.[40] These holdings have prompted efforts to define away the problem by specifying the medical component as a mere fraction of the total settlement proceeds. As noted above, CMS takes a dim view of contractual allocations and has persuaded judges to sweep aside a number of these attempts. Still, a few courts have sympathized with such efforts, especially regarding future medical expenses, because CMS steadfastly has refused to devise procedures for advance review of future "set-asides" outside the workers' compensation context, making it very difficult to determine whether honestly estimated

hold-backs will satisfy subsequent CMS demands.[41] In some cases, settling parties have obtained court orders purporting both to determine the amount due to Medicare and to absolve the parties from any further MSP liability upon payment of the specified sum, despite the fact that CMS did not take part in the proceedings.

A recent Eleventh Circuit decision adds fuel to the fire. In *Bradley v. Sebelius*, the parties settled a wrongful death claim before any suit was filed.[42] After CMS demanded payment of medical expenses in full, which would have left the claimants with little to divide among themselves, the claimants petitioned a probate court to apportion the settlement. Although notified, CMS declined to participate.[43] The probate court reduced the medical-expense component to a mere $787.50.[44] When CMS refused to accept the probate court's apportionment, the claimants' representative paid the full claim and sued the Secretary of HHS for a refund, which the district court denied.[45] On appeal, the Eleventh Circuit reversed that ruling. Reasoning that CMS's position "would have a chilling effect on settlement" that would force tort claims to trial, it reinstated the probate-court decision.[46] This suggests that courts' patience with the MSP's procedural deficiencies may be wearing thin.

Interpleader is an obvious answer for defendants faced with conflicting demands by plaintiffs and CMS. Unfortunately, the government routinely removes state interpleader actions and, wherever sued, typically asserts sovereign immunity as an argument for dismissal.[47] Yet the government sometimes proves willing to participate in the interpleader action.[48] Accordingly, interpleader may be worthwhile in an appropriate case.

When the time comes to cut a settlement check, should Medicare be named as a payee? Plaintiffs may fear this will tie up funds unnecessarily and indefinitely, but defendants naturally will prefer it, because it would ensure CMS reimbursement and eliminate the risk of a double-damages action. In *Wall v. Leavitt*, a federal magistrate considered naming Medicare as a payee to be a "practical necessity" even though the MSP does not expressly require that.[49] In *Tomlinson v. Landers*, however, a different magistrate rejected an argument to that effect and held that disagreement over how to make out the settlement check showed that the parties' minds had never met on settlement.[50] And in *Zaleppa v. Seiwell*, a Pennsylvania judge found that adding Medicare as payee on a check issued to pay a judgment violated state law.[51]

All of this illustrates that there's no fail-safe answer to MSP liability. In some cases, the inability to address MSP concerns with any finality may prevent the parties from settling.[52] Practice standards are still evolving. The steady flow of new decisions in this area may suggest better ways to address this serious problem, and Congress may yet weigh in.[53] Stay tuned. ■

DAVID J. BAILEY
Atlanta
+1.404.581.8260
djbailey@jonesday.com

CAROL A. HOGAN
Chicago
+1.312.269.4241
chogan@jonesday.com

JEFFREY A. MANDELL
Washington
+1.202.879.7628
jmandell@jonesday.com

LYNSEY M. BARRON
Atlanta
+1.404.581.8559
lbarron@jonesday.com

[1] *See, e.g.*, Peter A. Corning, "The Evolution of Medicare . . . *From Idea to Law*," ch. 4, *The Fourth Round—1957 to 1965* (1969), *available at* http://www.ssa.gov/history/corningchap4.html (all web sites herein last visited Apr. 4 , 2011); *see also Health Ins. Ass'n of Am. v. Shalala*, 23 F.3d 412, 414 (D.C. Cir. 1994).

[2] 42 U.S.C. § 1395y(b)(2)(A).

[3] *See id*. § 1395y(b)(2)(B)(i). The MSP confers rights and responsibilities upon the Secretary of the Department of Health and Human Services ("HHS"), who in turn has delegated authority over Medicare to CMS. For simplicity, this article uses "CMS" at some points to refer to that agency alone and at others to refer to the Secretary and/or HHS. References to "the government" encompass all three, as well as responsible officials in the Department of Justice and appropriate Offices of United States Attorneys.

[4] *Id.* § 1395y(b)(2)(B)(iv).

[5] *Id.* § 1395y(b)(2)(B)(iii).

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CY PRES . . . SAY WHAT?
STATE LAWS GOVERNING DISBURSEMENT OF RESIDUAL CLASS-ACTION FUNDS

By Emily C. Baker and Lynsey M. Barron

Unclaimed or leftover funds at the resolution of class-action cases are common. In some cases, members of the class cannot be located or identified. In others, class members may be unable or unwilling to claim their shares of a settlement or judgment. And in some instances, courts can order that no distribution be made to class members because their shares are so small that the cost of notice and disbursement exceeds the value of the claims. Whatever the reason, these unclaimed funds, particularly in consumer class actions, have increasingly become the target for *cy pres* awards, or charitable contributions, in federal court.[1]

As the number of these awards rises, opponents and proponents alike have weighed in on the propriety of such distributions. Opponents note that recipients of *cy pres* awards typically have little connection to the issues in the case and are merely being used as a tool by the plaintiffs' bar to drive up attorneys' fees. Still others claim that *cy pres* awards are replacing coupon settlements as a result of the Class Action Fairness Act of 2005, or "CAFA." CAFA, among other things, requires that in class-action settlements where coupons are awarded, attorneys' fees be based only on those coupons the class redeems, rather than the total dollar value of the agreement. Even if a significant portion of the class fails to redeem coupons, *cy pres* distributions can be incorporated into a settlement in order to drive up the value of the agreement upon which fees are based. Proponents, on the other hand, often counter that *cy pres* awards are a practical alternative to allowing the leftover money simply to revert to the defendant(s), which chips away at whatever deterrent effect such lawsuits have.

Regardless, this trend has not gone unnoticed at the state level. In just the last few years, several states have passed laws either requiring or allowing residual funds from class-action settlements or judgments (or both) to go to charities, legal aid providers, or other nonprofit organizations. Ultimately, what happens to leftover class-action funds will depend on whether the parties are in state or federal court—and if in state court, which one. By detailing those state laws that direct *cy pres* distribution of residual class-action funds, this article seeks to show why unwary parties in those jurisdictions could, in some instances, lose the right to reclaim those funds or, at a minimum, forgo any say in where those funds are directed. In either event, such laws can affect the ability and willingness of parties to settle class-action cases.

CY PRES: A BRIEF BACKGROUND

The term *cy pres* comes from the French phrase "*cy-près comme possible*," meaning "as near as possible." The doctrine was rooted in the law of trusts, such that when the terms of the trust resulted in its dissolution due to impossibility, changed circumstances, or the like, courts attempted to give effect to the intent of the trust by putting the funds to the next best use.[2] Therefore, *cy pres* was a way

to deal with bequests that could no longer be made—such as a donation to something that no longer exists.

Cy pres was, for the most part, restricted to the trusts context until class-action lawsuits became more prevalent in the latter part of the 20th century and the issue of what would happen to leftover or unclaimed class funds became the subject of debate and commentary.[3] This money was traditionally just returned to the defendant(s).[4] Other alternatives for how to dispose of unclaimed funds included distributing that money to those class members who did make a claim or allowing the money to escheat to the state.[5] Criticism of these various approaches, however, led to the use of *cy pres* in the class-action context. In recent years, the leftover or earmarked class funds have often been directed to charities or nonprofit organizations—unlike early *cy pres* class-action settlements, which typically directed leftover money to a different set of consumers or individuals.

EXISTING STATE STATUTES AND RULES GOVERNING DISBURSEMENT OF RESIDUAL CLASS-ACTION FUNDS

Not surprisingly, where there are state rules or statutes governing *cy pres* disbursement of residual class-action funds, virtually all contain an express provision that *cy pres* does not apply to a judgment against a public agency or public employee. Moreover, most states with such statutes or rules permit the settling parties to allow for the reversion of unclaimed class-action money to the defendant, and most seem to direct at least a portion of any residue to legal services organizations for the indigent.[6] There is wide variation, however, in terms of whether the *cy pres* statutes are mandatory, the default, or merely suggested.

At the less restrictive end are Massachusetts and Tennessee, whose *cy pres* laws govern both class-action settlements and judgments.[7] In both states, courts "may provide for the disbursement of residual funds," and the laws are clear that judgments and settlements are not required to provide for residual funds. In almost superfluous language, the Tennessee statute states: "A distribution of residual funds to a program or fund which serves the pro bono legal needs of Tennesseans including, but not limited to, the Tennessee Voluntary Fund for Indigent Civil Representation is permissible but not required." And, even after a judgment is entered or a settlement approved, either party may move, or the court may act *sua sponte*, to arrange for residual funds. Although *cy pres* distributions are equally discretionary in Massachusetts, any residuals must be directed either to a charity or foundation "which support[s] projects that will benefit the class or similarly situated persons consistent with the objectives and purposes of the underlying causes of action on which relief was based" or to the state's IOLTA Committee for indigent representation.[8]

Unlike the laws of Massachusetts and Tennessee, Washington's *cy pres* law distinguishes between settlements and judgments.[9] That is, even though *cy pres* is the default, settling parties may contract around *cy pres* distributions. However, if the class wins a judgment, residual funds *must* be distributed according to the statute. In that latter situation, of the remaining funds, at least 25 percent must go to the Legal Foundation of Washington to support access-to-justice programs for indigent clients, and the balance may be distributed "to any other entity for purposes that have a direct or indirect relationship to the objectives of the underlying litigation or otherwise promote the substantive or procedural interests of members of the certified class."

South Dakota is the only state where *cy pres* distribution applies solely to class-action settlements.[10] There, residual funds must be distributed to the "Commission on Equal Access to Our Courts," and the courts, upon finding "good cause" to do so, may designate up to 50 percent of any residual amount to a charity. It should be noted, however, that the settling parties, pending court approval, can agree that any unclaimed funds revert to the defendant.

At the more aggressive end of the spectrum are North Carolina, California, and Illinois. The *cy pres* statutes of North Carolina and California are almost identical and apply to both class-action settlements and judgments.[11] Both contain a statement of legislative intent, which seeks to ensure that unpaid class funds are used "to further the purposes of the underlying causes of action, or to promote justice for all [citizens of the state]."[12] Courts in both states must determine the amount payable to all class members if all are actually paid what they are entitled to under the settlement or judgment, and they must set a date by which the parties are to report how much was actually paid. In North Carolina, the court must direct the defendant(s) to divide any residual balance between the "Indigent Person's Attorney Fund" and the North Carolina Bar "for the provision of civil legal services

for indigents." In California, interest on the fund begins to accrue from the date of judgment and must be directed toward: (i) a charity that supports projects that benefit either the class or "similarly situated persons"; (ii) an organization that "promote[s] the law consistent with the objectives and purposes of the underlying cause of action"; (iii) a child-advocacy program; or (iv) a legal services organization for the indigent. If the class action is a multistate or national case brought under California law, the residual must be distributed to "provide substantial or commensurate benefit to California consumers." Notably absent from the statutes of both North Carolina and California is any language suggesting that parties may recommend, or that the court may approve, a settlement or judgment that would include a reversion to the defendant(s) of any unpaid funds.

At least one California court has noted that if such an option is expressly provided for in a settlement agreement and subsequently approved by a court, it must not conflict with the statute.[13] In *In re Microsoft*, the settlement agreement specified that one-third of any unclaimed remainder was to be retained by the defendant, with the remaining two-thirds to be issued as vouchers enabling low-income schools to obtain Microsoft products. Although the *cy pres* distribution to the schools did not fall within the strict confines of Cal. Code Civ. Proc. § 384(b), the California Court of Appeals found that the provision was legal because the *cy pres* statute's purpose is "to prevent a subsequent reversion of residue to a defendant when that reversion was not a part of the settlement terms that were previously scrutinized during the approval process."[14]

Similar to those of North Carolina and California, Illinois's *cy pres* statute is mandatory.[15] The primary difference is the end to which the residual funds must be directed. Under the Illinois law, if money remains in a common fund after judgment for the class, the money must be distributed to a nonprofit that "has a principal purpose of promoting or providing services that would be eligible for funding under the Illinois Equal Justice Act."[16] If money remains in a settlement fund, the court has discretion to distribute for "good cause" up to half the money to another charity that serves the public good.

CONCLUSION

The irony of *cy pres* distributions in the settlement context cannot be overstated. As one scholar recently noted, the primary goal of *cy pres* distributions is to guarantee that even if few injured parties claim a share of the settlement, the defendant will be adequately punished.[17] But in the case of a class-action settlement, the settling defendant has not been found liable, has not admitted liability, and may in fact be settling for reasons wholly unrelated to its liability. Plaintiffs' attorneys, on the other hand, have strong motivation to seek or provide for *cy pres* distribution because it is often difficult or costly to identify class members, prove their claims, and distribute the settlement.[18] In these instances, and absent *cy pres*, the size of the fund (and, more important, the resulting attorneys' fees) can be significantly smaller. As a result, there may be a push, heavily supported by the plaintiffs' bar, to expand *cy pres* laws into other states.

Nevertheless, whether state *cy pres* rules and statutes will significantly affect the class-action resolution process remains to be seen. CAFA ostensibly expanded federal jurisdiction over class actions,[19] and federal courts authorize *cy pres* distributions with some frequency where there are residual or undistributed class-action funds.[20] Because of this increased access to federal courthouses, some commentators have speculated that state *cy pres* rules or statutes governing the distribution of unclaimed class-action funds will have minimal impact on settlements and judgments in state court.[21] And, to date, there have been few cases in these states interpreting these laws (although most of those statutes are fairly recent enactments). In any event, parties facing putative class actions in any of the seven states that currently have *cy pres* class-action statutes or rules on the books must understand and be prepared to address what will happen with residual or unclaimed class-action funds. ■

EMILY C. BAKER
Atlanta
+1.404.581.8466
ecbaker@jonesday.com

LYNSEY M. BARRON
Atlanta
+1.404.581.8559
lbarron@jonesday.com

[1] Martin H. Redish *et al.*, "Cy Pres Relief and the Pathologies of the Modern Class Action: A Normative and Empirical Analysis," 62 *Fla. L. Rev.* 617, 620 (2010).

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[2] *See id.* at 625.

[3] *See id.* at 624.

[4] *See id.* at 631.

[5] *See id.*

[6] The practice of handing residual money over to legal services organizations for the indigent is so prevalent that these organizations have come to rely on *cy pres* distributions to finance their work. Adam Liptak, Sidebar, "Doling Out Other People's Money," *N.Y. Times*, Nov. 26, 2007. Note that this approach stands in contrast to the view that, to the extent possible, residual funds should be used only to "effectuate . . . the interests of silent class members." *Six Mexican Workers v. Ariz. Citrus Growers*, 904 F.2d 1301, 1309 (9th Cir. 1990); *see also* 5 Jerold S. Solovy *et al*., *Moore's Federal Practice* – Civil ¶ 23.171 (2011). In considering nonstatutory *cy pres* in a federal class action, the Ninth Circuit concluded that *cy pres* is designed to provide the "next best" alternative to compensating injured class members and thus is not appropriate when the proposed distribution is unrelated to the interests of silent class members. *Six Mexican Workers*, 904 F.2d at 1308–09. The court proposed escheat (to the state) as an alternative, if no appropriate charity could be identified. *Id.* at 1309.

[7] Tenn. Code Ann. § 23.08; Mass. Civ. Proc. 23(e).

[8] This provision was added in 2008 at the recommendation of the Massachusetts IOLTA Committee. *Id.* Reporter's Notes (2008).

[9] Wash. Civ. R. 23(f).

[10] S.D. Codified Laws § 16-2-57 (2008).

[11] Cal. Code Civ. Proc. § 384; N.C. Gen. Stat. § 1-267.10 (2009).

[12] Both also contain language indicating that the use of residual funds in this manner "is in the public interest, is a proper use of the funds, and is consistent with essential public and governmental purposes." *Id.*

[13] *See In re Microsoft I-V Cases*, 135 Cal. App. 4th 706 (2006).

[14] *Id*. at 721.

[15] 735 Ill. Comp. Stat. 5/2-807 (2009).

[16] The Illinois Equal Justice Act, 30 Ill. Comp. Stat. 765/1 *et seq*., established a system for distributing money to organizations that provide for civil defense for the indigent.

[17] *See* Redish *et al*., *supra* note 1, at 638.

[18] *Id.* at 640–41.

[19] Pub. L. No. 109-2. CAFA extends federal jurisdiction to cases where the aggregate claims of the class exceed $5 million and in which "(A) any member of a class of plaintiffs is a citizen of a State different from any defendant; (B) any member of a class of plaintiffs is a foreign state or a citizen or subject of a foreign state and any defendant is a citizen of a State; or (C) any member of a class of plaintiffs is a citizen of a State and any defendant is a foreign state or a citizen or subject of a foreign state." 28 U.S.C. § 1332(d)(2).

[20] *See* Redish *et al*., *supra* note 1, at 620 (noting that, among the range of alternatives for dispensing of unclaimed funds in federal court, *cy pres* relief is the one most often granted).

[21] *See* Sam Yospe, "Cy Pres Distributions in Class Action Settlements," 2009 *Colum. Bus. L. Rev*. 1014, 1059 n.154 (2009).

Reaction to Subsequent Injuries. When a manufacturer-defendant's product causes injuries after its sale to consumers, another useful gauge of its reprehensibility is the defendant's reaction. Its reaction is, of necessity, dependent on its knowledge or belief about the *cause* of the injuries. If, for example, people are harmed only when the product is used criminally (*e.g.*, a gun) or misused (*e.g.*, a folding table as a toboggan), the defendant is not acting reprehensibly in concluding that its product is not the cause of the injuries. Additional factors to evaluate reprehensibility in a product liability case should include:

Whether the defendant has erected a mechanism for receiving customer complaints and monitoring product safety. A defendant that has set up a system for accepting customer complaints and for monitoring reported injuries is more likely to be aware when injuries can be traced to a common defect and is less likely to be willfully blind to the knowledge that a product defect is the cause of injuries. Such a system enables a defendant to react more quickly. It is the type of behavior to be encouraged (not punished or deterred), and it consequently cuts against an award of punitive damages.

Whether and how the defendant has investigated product-related injuries. A defendant that knows of repeated product-related injuries and, in the face of such information, makes the conscious decision not to investigate the cause of those injuries (through further product testing or otherwise) acts more reprehensibly than a defendant that attempts to ascertain whether its product is defective and has played any role in those injuries. A defendant's failure to conduct extensive testing immediately after the first product-related injury is unlikely to be of any significance, for the justification and need for testing will likely not be apparent at first and may grow (or dissipate) over time. The jury's role here is to assess whether the testing that was done was appropriate given the surrounding circumstances, which tie directly to whether that reaction was more understandable (and hence less reprehensible) or more callous (and hence more reprehensible).[16] Along the same lines, a defendant's cooperation with any outside investigations indicates a willingness and desire to ascertain any defects and is to be encouraged, thus weighing against a finding of greater reprehensibility.

Whether the defendant voluntarily took measures to make its product safer. A defendant that voluntarily takes action to make its product safer—even if it is not certain whether its product is unsafe in the first place—is acting far less reprehensibly than a defendant that, in the face of certain knowledge of its product's flaws, does nothing.[17] Voluntary action, even at the urging of government or industry groups, is to be encouraged, not punished or deterred.[18] Moreover, the more certain the defendant's knowledge and the more grave the potential injury, the more reprehensible the defendant is for inaction and the more responsible it is for action, which can vary from offers to repair to wholesale product recall, depending upon the certainty and severity of the injuries.

Whether the defendant issued new or additional safety warnings. Where repair or recall of a product is infeasible (because redesign would negate the product's intended purpose or functionality), unwarranted (because the risk of injury is remote and its severity minor), or even unnecessary (because injuries stem from misuse rather than a product defect), a defendant has the ability to issue new or additional warnings. Doing so weighs against a finding of reprehensibility, while failing to take this action can potentially be more reprehensible—particularly in the face of knowledge that the product is in fact defective and coupled with the defendant's failure to try to make the product safer.

CONCLUSION

The U.S. Supreme Court's project of constitutionalizing punitive damages is not yet complete. There is a particular need to resolve the mismatch between the factors that have been identified for assessing reprehensibility in economic tort cases and the typical facts at issue in product liability cases. The work must begin in the lower courts. In states where juries have the first-line responsibility to ensure a reasonable and nonexcessive punitive damages verdict, trial courts should take the first step of providing a suitable instruction that recasts the reprehensibility factors along the lines outlined above. If the jury returns a verdict that includes punitive damages, both trial courts and appellate courts should review those verdicts in light of the manufacturer's design and post-design conduct. And counsel must attempt to convince these courts that they should not reflexively point to a set of factors never intended to be exclusive and that, in product liability cases at least, are a poor fit. ■

DIANE G.P. FLANNERY
Atlanta
+1.404.581.8579
dgflannery@jonesday.com

JASON T. BURNETTE
Atlanta
+1.404.581.8724
jtburnette@jonesday.com

[1] *Honda Motor Co. v. Oberg*, 512 U.S. 415, 420–21 (1994).

[2] *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001).

[3] *Philip Morris USA v. Williams*, 549 U.S. 346, 353–57 (2007).

[4] *State Farm*, 538 U.S. at 419.

[5] *See, e.g.*, *Century Surety Co. v. Polisso*, 139 Cal. App. 4th 922, 965 n.21 (2006).

[6] *State Farm*, 538 U.S. at 419 ("It should be presumed that a plaintiff has been made whole for his injury by compensatory damages, so punitive damages should only be awarded if the defendant's culpability, after having paid compensatory damages, is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence.").

[7] *Gore*, 517 U.S. at 575.

[8] *See, e.g., id.* at 568 (noting need for "flexibility in determining the level of punitive damages").

[9] *Id*.

[10] *See, e.g.*, Ohio Rev. Stat. Ann. § 2307.80(D)(1).

[11] *See, e.g.*, *DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000).

[12] *See, e.g.*, *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1317 (11th Cir. 1994).

[13] *Smith v. Ingersoll-Rand Co.*, 214 F.3d 1235, 1253–54 (10th Cir. 2000).

[14] *See, e.g.*, *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1317 (11th Cir. 2000) ("We have repeatedly held that the issue of punitive damages should not go to the jury when a manufacturer takes steps to warn the plaintiff of the potential danger that injured him; such acts bar a finding of wantonness.").

[15] *See, e.g.*, *Shurr v. A.R. Siegler, Inc.*, 70 F. Supp. 2d 900, 938–39 (E.D. Wis. 1999).

[16] *See, e.g.*, *Lakin v. Senco Prods., Inc.*, 925 P.2d 107, 119 (Or. Ct. App. 1996) (punitive damages proper against nail-gun manufacturer where manufacturer had long been aware of tendency of its nail guns to "double fire," yet it conducted no tests to determine when, or how frequently, double firing occurred).

[17] *See Duran v. Hyundai Motor Am., Inc.*, 271 S.W.3d 178, 207–08 (Tenn. Ct. App. 2008) (no punitive damages, as a matter of law, where defendant voluntarily recalled product).

[18] *In re Exxon Valdez*, 270 F.3d 1215, 1242 (9th Cir. 2001) ("Reprehensibility should be discounted if defendants act promptly and comprehensively to ameliorate any harm they cause in order to encourage such socially beneficial behavior.").

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[6] *See*, *e.g.*, *Thompson v. Goetzmann*, 337 F.3d 489 (5th Cir. 2003); *Mason v. Am. Tobacco Co.*, 212 F. Supp. 2d 88 (E.D.N.Y. 2002); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 174 F. Supp. 2d 1242 (N.D. Ala. 2001); *United States v. Philip Morris, Inc.*, 156 F. Supp. 2d 1 (D.D.C. 2001); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 202 F.R.D. 154 (E.D. Pa. 2001); *In re Diet Drugs*, MDL No. 1203, Civ. A. 99-20593, 2001 WL 283163 (E.D. Pa. Mar. 21, 2001); *United States v. Philip Morris, Inc.*, 116 F. Supp. 2d 131 (D.D.C. 2000); *In re Dow Corning Corp.*, 250 B.R. 298 (Bankr. E.D. Mich. 2000).

[7] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 301(b), codified at 42 U.S.C. § 1395y(b)(2)(A).

[8] *Id.* § 301(c), codified at 42 U.S.C. § 1395y(b)(2)(B)(ii).

[9] *See* Complaint, *United States v. Stricker*, No. 1:09cv2423 (N.D. Ala. Dec. 1, 2009).

[10] *See* Centers for Medicare & Medicaid Services, *Medicare Secondary Payer Manual*, ch. 7, § 50.4.4 (2011), *available at* https://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019017 ("MSP Manual").

[11] *Id.* (emphasis added); *see Zinman v. Shalala*, 67 F.3d 841 (9th Cir. 1995); *Hadden v. United States*, No. 1:08-CV-10, 2009 WL 2423114 (W.D. Ky. Aug. 6, 2009) (appeal pending); *accord Denekas v. Shalala*, 943 F. Supp. 1073, 1081 (S.D. Iowa 1996).

[12] Pub. L. No. 110-173.

[13] *See* 42 U.S.C. § 1395y(b)(7) (requiring submission of information by group health plans); *id.* § 1395y(b)(8) (requiring submission of information by liability insurers, including "self-insurers").

[14] *See* Jennifer C. Jordan, "Medicare Secondary Payer Enforcement: Shifting the Burden of Medicare to the Private Sector," 39 *The Brief* 1, 14 (2009), *available at* http://www.medval.com/wordpress/wp-content/uploads/2010/07/Jordan-Jennifer-Medicare-Secondary-Payer-as-published.pdf. The risk of reimbursement liability and related statutory penalties will not necessarily be confined to cases involving traditional negligence and "personal injury" claims but could apply as well to any case in which a plaintiff gives a general release after incurring medical expenses conditionally paid by Medicare. *See* Transcript of Town Hall Teleconference on Section 111 of the Medicare, Medicaid, & SCHIP Extension Act of 2007, 42 U.S.C. § 1395y(b)(8), at 26 (Oct. 14, 2010), *available at* https://www.cms.gov/MandatoryInsrep/Downloads/Oct242010NGHPTranscript.pdf.

[15] 42 C.F.R. § 411.24(h)–(i).

[16] *See* MSP Manual, ch. 7, § 50.8.2.

[17] *See id.*; *see also*, *generally*, Woody R. Clermont, *Introduction to Medicare and the Office of Medicare Hearings and Appeals* (2009).

[18] *See Bd. of Regents of State Coll. v. Roth*, 408 U.S. 564, 576–78 (1972).

[19] *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976).

[20] *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972).

[21] *Id.* at 90 (quoting *Boddie v. Conn.*, 401 U.S. 371, 379 (1971)).

[22] *Id.* at 97 (quoting *Sniadach v. Family Finance Corp. of Bay View*, 395 U.S. 337, 343 (1969) (Harlan, J., concurring)).

[23] 397 U.S. at 265.

[24] *Id.* at 261 (quoting *Kelly v. Wyman*, 294 F. Supp. 893, 901 (S.D.N.Y. 1968)).

[25] *Id.* at 267 (internal quotation marks and citations omitted).

[26] *Id.* at 269.

[27] *See Sniadach*, 395 U.S. at 342.

[28] *See Fuentes*, 407 U.S. at 96.

[29] *Id.* at 81.

[30] *Goldberg*, 397 U.S. at 269.

[31] *See* MSP Manual, ch. 7, § 50.4.4 ("The only situation in which Medicare recognizes allocations of liability payments to nonmedical losses is when payment is based on a court order on the merits of the case.").

[32] A federal district court recently rejected a due process challenge to the MSP under different circumstances. *See Benson v. Sebelius*, --- F. Supp. 2d ---, No. 09-1931 (RMU), 2011 WL 1087254 (D.D.C. Mar. 24, 2011). In that case, the court affirmed that CMS may collect from the proceeds of a wrongful death settlement obtained by an heir of the decedent where the underlying suit sought to recover, among other damages, medical costs that had been paid by Medicare. The court rejected the argument that CMS violated the heir's due process rights by threatening to seek interest payments if he delayed payment or that HHS did so by hearing his challenge to the calculation of the amount due only after the deadline for payment. Either of these is a weaker due process argument than those potentially available to a settling defendant from which CMS seeks to collect without providing any opportunity for a hearing at all.

[33] Centers for Medicare & Medicaid Services, *GHP User Guide* (2010), *available at* https://www.cms.gov/MandatoryInsRep/Downloads/GHPUserGuideV3.1.pdf.

[34] *See Seger v. Tank Connection, LLC*, No. 8:08CV75, 2010 WL 1665253, at *4–6 (D. Neb. Apr. 22, 2010).

[35] No. 3:08-CV-2084-K, 2010 WL 70855, at *1, *4 (N.D. Tex. Jan. 6, 2010).

[36] *See* MSP Manual, ch. 7, § 50.4.2.

[37] *See Zinman v. Shalala*, 835 F. Supp. 1163, 1171 (N.D. Cal. 1993), *aff'd*, 67 F.3d 841 (9th Cir. 1995) ("The MSP statute does not state that Medicare has a lien, it articulates Medicare's right as a claim to recover from entities who, pursuant to the statute, are required to pay primary. Nor does Defendant contend that Medicare's right is a lien. The Secretary maintains that Medicare's right is superior to a lien."); *see also* Glenn E. Bradford and Melinda M. Ward, "The Medicare 'Super Lien' Revisited," 56 *J. Mo. Bar* 44 (2000), *available at* http://www.mobar.org/journal/2000/janfeb/bradford.htm.

[38] *See*, *e.g.*, Tara Kelly, "New Reporting Deadlines Affect Mass Torts Settlements," 8 *Mass Torts* 1, 16 (2010), *available at* http://www.kslaw.com/imageserver/KSPublic/Library/publication/MassTorts-Summer2010__TaraKelly.pdf.

[39] *See* Model Rules of Prof'l Conduct R. 1.8(g) (2010).

[40] *See*, *e.g.*, *Bradley v. Sebelius*, 621 F.3d 1330, 1339–40 (11th Cir. 2010); *Denekas*, 943 F. Supp. at 1081.

[41] *See*, *e.g.*, *Big R Towing v. Benoit*, No. 10-538, 2011 WL 43219 (W.D. La. Jan. 5, 2011); *Goetz v. Allouez Marine Supply, Inc.*, No. 09-cv-670-wmc (W.D. Wis. Dec. 21, 2010); *Finke v. Hunter's View, Ltd.*, No. 07:4267 (WRW/RLE), 2009 WL 6326944 (D. Minn. Aug. 25, 2009).

[42] *Bradley*, 621 F.3d at 1332.

[43] *See id.* at 1332–33.

[44] *See id.* at 1333–34.

[45] *See id.* at 1334.

[46] *Id.* at 1339.

[47] *See Coastal Rehab. Servs. v. Cooper*, 255 F. Supp. 2d 556 (D.S.C. 2003); *Hat Ranch, Inc. v. Babbitt*, 932 F. Supp. 1 (D.D.C. 1995); *cf. Portman v. Goodson*, No. 3:10CV-313-S, 2011 WL 773427 (W.D. Ky. Feb. 28, 2011); *Hicks v. Chamberlain*, No.

10-144-DLB, 2010 WL 4226698 (E.D. Ky. Oct. 22, 2010); *Lusker v. Sec'y of U.S. Dep't of Health & Human Servs.*, No. 8:09-CV-2193-T-17TBM, 2010 WL 76456 (M.D. Fla. Jan. 7, 2010).

48 Consider *Farmers Insurance Exchange v. Forkey*, No. 2:09-cv-00462-GMN-GWF, 2010 WL 5477726 (D. Nev. Dec. 29, 2010), where the insurer moved for interpleader and paid its policy limits after an accident victim's widow and HHS both made claims under the victim's policy, and where HHS straightforwardly, and successfully, asserted its right to a share of the proceeds.

49 Civ. No. S-05-2553 FCD GGH, 2008 WL 4737164, at *6 (E.D. Cal. Oct. 29, 2008).

50 Case No. 3:07-cv-1180-J-TEM, 2009 WL 1117399, at *4–5 (M.D. Fla. Apr. 24, 2009).

51 2010 PA Super. 208 (2010). *But see Haskell v. Graham*, No. 08-cv-05880 (N.D. Ill. June 10, 2010) (refusing to sanction a defendant that deposited judgment funds with the clerk of court pending resolution of Medicare issues).

52 *See* Rick Swedloff, "Can't Settle, Can't Sue: How Congress Stole Tort Remedies from Medicare Beneficiaries," 41 *Akron L. Rev.* 557, 588 (2008).

53 *See* H.R. 1063 (The Strengthening Medicare And Repaying Taxpayers (SMART) Act of 2011), introduced in the 112th Congress, 1st Session, *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112hr1063ih/pdf/BILLS-112hr1063ih.pdf; *see also* Medicare Advocacy Recovery Coalition, The Strengthening Medicare and Repaying Taxpayers (SMART) Act, *available at* http://www.marccoalition.com/MSP__Reform.html (synopsizing proposed SMART Act).

design, testing, and manufacture of the product; changes to the design; cases, claims, or complaints relating to the product; advertising; sales data; profits; and on and on. And, of course, the company has a duty to preserve relevant evidence even absent a notice letter. The company has thousands of employees on its word processing and email systems, not to mention laptops, and like most companies, it has an auto-delete function that deletes all unsaved emails after 60 days. If the letter, which presages an overbroad request for production of documents, is observed literally, the company will have to spend thousands of dollars to alter its email system, search its servers, and share the documents, emails, back-up tapes, and, potentially, hard drives. If it does nothing, the company will predictably be faced with a costly sideshow in the litigation revolving around whether potentially relevant materials were lost.

In this scenario, which is playing out daily across America in state and federal courts, defendant corporations should not have to act or take limited action at their own peril. While no one can doubt that discovery is a necessary part of our system and that the litigation system must have effective ways to deal with miscreants who knowingly destroy clearly relevant and discoverable information, it borders on the absurd and is patently unfair to expect a corporation to bear tens of thousands of dollars or more in e-discovery costs just because a plaintiff has filed a small and nonmeritorious case.

A company that has the best intentions of complying with its discovery obligations, and immediately consults with conscientious, competent in-house and outside counsel, can rarely find a clear answer about what it must do or need not do at this stage of the case. One can find in some reported decisions rather draconian language to the effect that, when a lawsuit arises, all disposal of email relating to the subject of the suit must cease without regard to the amount in controversy. Sanctions for failure to forecast a court's ruling correctly can be severe, even case-dispositive.

Other courts, more enlightened in my view, are embracing the concept of proportionality, *i.e.*, the notion that fairness requires some balancing of the plaintiff's right to reasonable

discovery with a defendant's right not to have to bear discovery burdens disproportionate to the subject and size of the case. *Compare Pension Committee of the University of Montreal Pension Plan v. Banc of America Securities, LLC*, No. 05 Civ. 9016, 2010 WL 184312 (S.D.N.Y. Jan. 15, 2010), *with Rimkus Consulting Group, Inc. v. Cammarata*, 2010 U.S. Dist. LEXIS 14573 (S.D. Tex. Feb. 19, 2010) ("Whether preservation or discovery conduct is acceptable in a case depends on what is reasonable, and that in turn depends on whether what was done—or not done—was *proportional* to that case and consistent with clearly established applicable standards.").

Some plaintiffs, of course, want to impose or threaten to impose large, one-sided, nonrecoverable litigation costs on a defendant corporation. This cost creates pressure to settle, not for amounts related to the merits or the amount potentially recoverable, but in order to avoid e-discovery costs. That is not right. It is the antithesis of the purpose of the discovery rules "to secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. P. 1.

The company's dilemma is made even more difficult if the law is not clear in the venue where the case is pending or if cases are pending in multiple jurisdictions with different rules or decisional law. Even if the cases relate to different products or transactions, a company cannot easily use a particular e-discovery methodology for one case while taking a different approach in another case at roughly the same time.

A second scenario, which can be even more unfair and unsettling to a corporation, is when a government agency, a state attorney general, or the Department of Justice launches an investigation. The company may know nothing more than the general parameters of the inquiry, but predictably, the government's view is that the targeted corporation must halt its normal document-retention program and save everything. Trying to use e-discovery burdens to force a company to make a deal to pay a penalty or fine is unconscionable.

E-discovery rules must be fair, proportionate, and uniform. Companies should know what they must do at the outset, there should be safe harbors—procedures whereby defendants can get quick rulings on the scope of discovery obligations—and, most important, there should be a mechanism whereby defendants can recover costs of excessive e-discovery demands against the parties who seek to impose them.

Although it is often desirable to have the case law develop slowly, jurisdiction by jurisdiction, in the case of e-discovery this is not so. The present discord in the reported cases is untenable and unfair to litigants who operate, sell, or can be sued in multiple jurisdictions. Scores of conferences and CLE programs talk about this problem, scores of law firms and consultants offer their services to assist companies in handling e-discovery responses, and scores of well-intentioned judges try to make thoughtful rulings. But too few creative legal minds in positions of authority are working on developing a sensible and fair set of uniform rules that litigants can safely observe in state and federal cases.

This seems to be the kind of issue that a committee of the American Bar Association's Litigation Section would be ideally suited to handle. The ABA can assemble a group that brings together state and federal expertise, represents a variety of perspectives, and can promulgate guidelines or standards that, if followed in good faith by a litigant with e-discovery issues, should create a presumption of propriety, *i.e.*, a safe harbor. Congress will not act. The Supreme Court and federal rules committees are not likely to represent perspectives relating to smaller cases—and probably cannot act as quickly as an ABA group could. State courts and their rules committees are wrestling with these issues across the land, but they are not likely to have the bigger case perspectives, nor will their efforts result in a uniform set of guidelines.

Until these issues can be clarified, litigants will spend too much time and money walking through this discovery minefield. And the onerous obligations and costs continue to make litigation in the U.S. the conspicuous aberration from litigation in Europe, Japan, and the rest of the world.

I have focused on this topic because, as I continually check what the litigators in our U.S. offices are working on for clients in every jurisdiction, our lawyers are forced to spend inordinate amounts of time on e-discovery issues for clients who only want to do what is right and to know what is required. Clients are rightly frustrated that the law is neither clear nor fair—and that e-discovery has become twisted into a tool of extortion by which litigants can try to impose costs and burdens to coerce settlements unrelated to the merits of the cases.

Needless to say, Jones Day can deliver knowledgeable lawyers with experience handling e-discovery problems in

jurisdictions across the country. Our size and depth make it likely, when a client comes to us with this kind of issue, that the legal research has already been done. What I wish we could deliver, however, is certainty and rationality, but until the law becomes settled and balanced on these questions, frustration will remain.

* * *

Since the last issue of *Practice Perspectives*, Jones Day trial teams have achieved some notable victories.

Jones Day is entering our third year defending R.J. Reynolds Tobacco Company in "*Engle* progeny" lawsuits across the State of Florida. There are more than 9,000 plaintiffs with *Engle* progeny cases pending in Florida, which are the result of the Florida Supreme Court's decertification of the statewide *Engle* class action brought against Reynolds and other cigarette manufacturers by Florida residents and their survivors claiming smoking-related illnesses. If those individual plaintiffs are able to prove membership in the former class, they are able to rely in their individual trials on certain generalized findings of culpability made by the jury during the class-action trial.

Since January 2011, Jones Day attorneys have represented Reynolds in eight *Engle* progeny cases that have been tried throughout Florida. On March 28, after two weeks of trial, the jury returned a complete defense verdict for Reynolds in the *Oliva* trial in Clay County, Florida. *Oliva* was the first progeny case tried in that jurisdiction, and Reynolds was the lead defendant. On April 4, Reynolds prevailed with a defense verdict in the *Weick* case in Tampa, Florida, after 11 days of trial. The jury deliberated for approximately 30 minutes before finding in favor of Reynolds. The following week, on April 13, Reynolds was the only one of four defendants to receive a defense verdict from the jury in the *Tullo* trial in West Palm Beach, Florida. After 14 days of trial, the jury found that Reynolds was not at fault for causing the decedent's injuries, even as it returned a plaintiff's verdict against the other three defendants. Two of the other eight progeny cases tried so far this year by Jones Day have ended in mistrials. It has been a "One Firm" undertaking for the client, with trial teams led by attorneys from Jones Day's offices in Atlanta, Chicago, Cleveland, Columbus, New York, San Diego, and Washington.

A team led by Rick McKnight, John Goetz, and Sharyl Reisman obtained a defense verdict for Yamaha in a closely watched case in state court in Orange County, California. The case arose from the rollover of a Yamaha Rhino, an off-road, side-by-side vehicle. The jury found, after a three-month trial, that misuse caused the accident. Yamaha retained Jones Day in 2008 to lead the coordination of its defense in hundreds of cases brought by a group of plaintiffs' law firms across the country, including a federal multidistrict proceeding, statewide coordinated proceedings in California and Georgia, and cases in 35 other states. The program's success and Yamaha's aggressive defense of its innovative vehicle have been the subject of editorials in *The Wall Street Journal* and in various other publications covering off-road vehicles.

As ever, we thank you for being a reader of our publication, and we look forward to receiving your comments. ■

MICKEY POHL
Pittsburgh
+1.412.394.7900
pmpohl@jonesday.com

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THIRD-PARTY CLAIMS

The company may want to consider potential indemnification or other claims against third parties. The success of such claims may depend on, for example, the contract terms, applicable law, the financial wherewithal of the third parties, foreign government attitudes about protecting that country's businesses and employees, and the company's desire to pursue such claims. Planning for potential claims should be addressed early in the process, as obtaining necessary evidence and interviews may not be as effective—or even possible—after a lapse of time.

INTERNAL BUSINESS CHANGES

The company also may need to address underlying issues related to the design or manufacture of the allegedly defective product, keeping in mind that the company's actions might be admissible in subsequent litigation and, at a minimum, are likely to be scrutinized heavily by regulators or other government entities, both in the U.S. and abroad. Company executives may be grilled by a U.S. congressional committee—not to mention the media and plaintiff's counsel—about whether they identified the cause of the alleged problem and whether and how they are fixing it. Such issues will be uppermost in the minds of politicians, investigators, reporters, and the public.

Whether making changes makes sense depends, of course, on the underlying problem. It also may be influenced by what is necessary to appease Congress or government regulators or to resolve pending litigation. What may make good business sense in any country—and, indeed, what might be the "right thing" to do—must still be done in a manner that, if possible, minimizes subsequent adverse litigation decisions and publicity, takes into account privileges and confidentiality, and considers the impact of the changes on other relevant issues.

The situation becomes more problematic if the company's foreign-made products must be recalled in the U.S. but are still being sold in other countries. Not only must each of those countries' health/safety/recall laws be addressed, but other potential actions, such as withdrawing the products from those markets, must be considered. Whether alternative avenues, *e.g.,* informal recalls or withdrawals, are appropriate will depend on the relevant countries' laws, regulations, and culture. Retaining a law firm with relevant experience and a broad international reach is vital.

CONCLUSION

You may lose your weekend, and many others. And the difficulty of the tasks you face may appear overwhelming. But if you approach the crisis with a coherent, well-developed, and well-executed strategy and organize and staff the effort wisely, not only can you help your client successfully navigate the crisis, but it can become a rewarding personal and professional experience. ■

THOMAS E. FENNELL
Dallas
+1.214.969.5130
tefennell@jonesday.com

W. KELLY STEWART
Dallas
+1.214.969.5134
kellystewart@jonesday.com

[1] For a more detailed discussion of this issue, *see* J. Edwards and G. Garrett, "Coordinating Investigations Between U.S. Companies and Their Subsidiaries or Suppliers Overseas," *Practice Perspectives: Product Liability & Tort Litigation* (Fall 2010).

[2] 15 U.S.C. § 2064(b).

[3] *See, e.g.*, 16 C.F.R. 1115.14(d).

[4] *See Pension Committee of the Univ. of Montreal Pension Plan v. Banc of America Sec., LLC*, 685 F. Supp. 2d 456, 466 (S.D.N.Y. 2010).

[5] *See In re Flag Telecom Holdings, Ltd.*, 236 F.R.D. 177, 180 (S.D.N.Y. 2006).

[6] *See Akzo Nobel Chemicals Ltd v. European Commission*, No. C-550/07 P (2010).

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