

Vol. 1 No. 4 October 2008

PROTE: *Solutio*

SOLUTIONS FOR YOU

Tort Reform Victory

Limiting Adverse Verdicts in Mississippi

The Complexities of Pharmaceutical Pricing

An Interview with E. M. Kolassa, Ph.D.



DEAR CLIENTS:

The times in which we live are supercharged with complex issues — economic, constitutional, political, market, technology and communication, among others. Each issue operates within its own universe but spills over into many others. How several of these work within the universe of healthcare and the law is spotlighted in this issue of *Pro Te: Solutio*.

When it comes to economic markets and questions of pricing, does one size fit all? No, according to Dr. E. M. “Mick” Kolassa, Ph.D. and author of several books including *Elements of Pharmaceutical Pricing*. Dr. Kolassa explains how “derived demand” and the physician/patient/payer triad make this market a different animal. In a recent interview, he explores key points as well as public policy debate, litigation pitfalls, and other effects on pharmaceutical pricing.

Tort reform is always a hot topic, especially in states such as Mississippi that have seen its effects and experienced its aftermath. Learn more about the surprising economic benefits states can experience when damages caps are enacted. On the flip side, once caps are enacted, they will be challenged. Whether you find you’ve received an adverse verdict and need to file a motion to amend — or are called upon to defend the constitutionality of damages caps — you’ll find information and insights here.

Also in this issue, what is a RiskMAP and why does the FDA want you to develop one? A summary of the 2005 *Guidance for Industry: Development and Use of Risk Minimization Action Plans* highlights why risk assessment and risk minimization are part of an ongoing process, what tools are important, and how to implement and evaluate a RiskMAP.

Pro Te: Solutio is available exclusively to Butler Snow Pharmaceutical, Medical Device, and Healthcare Industry clients as a resource to keep you abreast of issues and provide you with a wealth of solution-based information. As always, our goal is to help you avoid risk and litigation — protecting your time and assets for the important work you do in healthcare.

We want to make a difference for those dedicated to making a difference in the lives of others.



CHRISTY D. JONES
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PRO TE: *Solutio*

Vol. 1 No. 4 October 2008

SHARING SOLUTIONS

It's human nature to share problems. But how often is someone willing to share solutions? Butler Snow wants to do just that — provide scenarios and the solutions that turned a client's anxiety into relief and even triumph. That's why we created this magazine, *Pro Te: Solutio*, which explores how real-life legal problems have been successfully solved.

That's also why we at Butler Snow redesigned and expanded our unique health-oriented industry group, now comprised of two major sections that handle business and litigation. The Pharmaceutical, Medical Device, and Healthcare Industry Group has more than 50 multi-disciplinary attorneys who provide creative solutions for the complex issues of the healthcare industry. This group includes product liability and commercial litigators; corporate, commercial, and transaction attorneys; labor and employment attorneys; intellectual property attorneys; and those experienced in government investigations.

Pro Te: Solutio is a quarterly magazine available only to the clients of Butler Snow. If you have questions or comments about its articles, you're invited to contact group co-chairs Christy Jones and Charles Johnson, as well as any of the attorneys listed on the last page of this publication.

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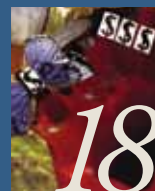
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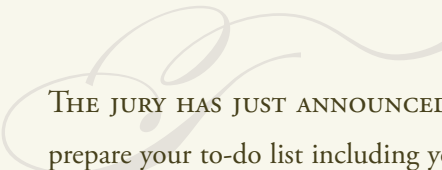
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LIMITING ADVERSE VERDICTS: TORT REFORM VICTORY IN MISSISSIPPI



THE JURY HAS JUST ANNOUNCED its verdict finding your company liable for a million dollars in damages. As you mentally prepare your to-do list including your new trial motion and list of items to be raised on appeal, you should also consider what caps are placed on non-economic and/or punitive damages in the jurisdiction and if the award can be reduced at the trial court level. The previous issue of *Pro Te: Solutio* provides a compendium of state legislation that caps the amount of non-economic damages that can be recovered in personal injury suits. Mississippi is on the list, highlighting Miss. Code Ann. §11-1-60 (2007).¹ Section 11-1-60(2)(b) provides: “In any civil action filed on or after September 1, 2004, [...] in the event the trier of fact finds the defendant liable, they shall not award the plaintiff more than One Million Dollars (\$1,000,000.00) for noneconomic damages.”²

ECONOMIC BENEFITS OF DAMAGES CAPS

In 2002, the American Tort Reform Association (ATRA) published its first listing of *Judicial Hellholes*. Mississippi's 22nd Judicial Circuit, which includes Copiah, Claiborne, and Jefferson Counties, topped the list.³ The report describes judicial hellholes “as ‘magnet courts’ or even ‘magic jurisdictions’ — magic in that they can seemingly pull million or billion dollar verdicts out of a hat and create causes of action previously unknown or procedural rules that are foreign to due process.”⁴ In 2003, Mississippi's 22nd Judicial Circuit was again listed among the top jurisdictions as a judicial hellhole.⁵ During the 2002 special session, the Mississippi legislature passed two pieces

of tort reform legislation, including one piece that focused solely on capping medical malpractice litigation with a \$500,000 cap on non-economic damages and a second that included caps on punitive damages for all tort claims.⁶ Despite these reforms, Mississippi's economy continued to suffer.⁷ The second wave of tort reform, which includes the current version of Miss. Code Ann. §11-1-60, was enacted in 2004 and became effective September 1, 2004. Since the enactment, insurance companies have returned to the state, Medical Assurance Company of Mississippi has ceased raising its rates, the state has been successful in recruiting new business due to the lower costs of doing business, and the mass-tort

industry was virtually eliminated.⁸ Mississippi has not appeared on ATRA's judicial hellhole list since 2003.

PROCEDURAL CONSIDERATIONS

With tort reform and statutory caps in place in the majority of states, an initial thought upon an adverse verdict must be whether the cap is applicable and should be implemented to reduce the judgment. Immediately upon receiving an adverse verdict that is above the statutory limitations for damages, you must file a Motion to Amend the Judgment or Alter the Final Judgment. The motion should include the date of judgment, the amount of judgment, the applicable statute, the amount once

the limitation is applied, and a proposed amended judgment. Some state statutes, including Miss. Code. Ann. §11-1-60, provide that the trier of fact shall not be advised of the limitations and that the judge shall appropriately reduce any award. A strict reading of this would appear to give the court the power to reduce the award *sua sponte*, but motion practice may be required. The motion to alter the judgment must be filed at the trial court level.⁹

DEFENDING THE CONSTITUTIONALITY OF DAMAGES CAPS

Recently, Butler Snow defended the constitutionality of the caps portion of Section 11-1-60 in a premises liability action filed against the owner of a convenience store.¹⁰ This is the first challenge to Mississippi's tort reform efforts enacted in 2004. In July 2008, the Humphreys County Circuit Court imposed the \$1 million dollar limitation on non-economic damages found in Miss. Code Ann. §11-1-60 and reduced the \$4 million verdict. The plaintiff challenged the amended judgment. After receiving the parties' written papers and hearing the oral argument, the trial court denied the plaintiff's constitutional challenge to §11-1-60.¹¹

The plaintiff challenged Miss. Code Ann. §11-1-60 on the following grounds:

1) It violates the right to trial by jury enumerated in the Seventh Amendment of the United States Constitution and Section 31, Article 3 of the Mississippi Constitution.

2) It violates Section 24 of the Mississippi Constitution, which provides for the right to a remedy by due course of law.

3) It violates the Equal Protection Clause and Due Process Clause of the Fourteenth Amendment of the United States Constitution.

4) It violates the provisions for Separation of Powers in the Mississippi Constitution.

The challenging party bears the heavy burden to show the statute is unconstitutional, and a state law may be struck down "on constitutional grounds only where it

appears beyond all reasonable doubt that the statute under review is unconstitutional."¹² The presumption is that State Legislature acted properly when enacting statutes. The Mississippi Supreme Court has recognized deference to the legislature in promulgating similar statutes that impose limitations on what types of damages and what amounts are recoverable.¹³

In determining whether an act of the Legislature violates the Constitution, the courts are without the right to substitute their judgment for that of the Legislature as to the wisdom and policy of the act and must enforce it, unless it appears beyond all reasonable doubt to violate the Constitution. Nor are the courts at liberty to declare an Act void, because in their opinion it is opposed to

are created by statute; the damages are statutorily defined. Accordingly, the legislature has the power to limit them, expand them, or take them away entirely.

The due process analysis requires that the statute at issue be related to a proper legislative purpose. Most of the caps on damages were enacted into statutes as part of tort reform in the early part of this century to combat rising insurance prices and a tremendous influx of lawsuits. The limitations placed on non-economic damages help serve several salutary purposes. First, the presence of limitations provisions enables individuals and businesses to make better informed risk assessment decisions in connection with their respective purchase of real property, goods, and services;

THE *second wave* OF TORT REFORM, WHICH *includes* THE *current* VERSION OF MISS. CODE ANN. §11-1-60, *was enacted* IN 2004 AND BECAME EFFECTIVE SEPTEMBER 1, 2004.

SINCE THE ENACTMENT, *insurance companies* HAVE *returned* TO THE STATE, MEDICAL ASSURANCE COMPANY OF MISSISSIPPI *has CEASED raising its rates*, THE STATE HAS BEEN *successful* IN RECRUITING *new business* DUE TO THE *lower costs* OF DOING BUSINESS, *and* THE MASS-TORT INDUSTRY WAS *virtually* ELIMINATED.

MISSISSIPPI *has not* APPEARED ON ATRA'S JUDICIAL *hellhole* LIST SINCE 2003.

a spirit supposed to prevail the Constitution, but not the expressed words.¹⁴

In arguing for the constitutionality of a damage limitation, consider whether other statutes that impose limitations have been upheld as constitutional under the State and Federal Constitutions. For example, statutes of limitations have routinely been upheld even though they cut off an injured party's right to recover damages after a certain time specified by that same statute. The Constitution, State and Federal, does not forbid either: A) the creation of new rights; or B) the abolition of old rights recognized by the common law to obtain a permissible legislative objective.¹⁵ An important concept to note in your argument is that non-economic damages themselves

asset management; estate planning; personal careers; and business strategies. These statutes also provide casualty and property liability insurers with the ability to improve the predictability of the outcome of the amount of damages that can be awarded for personal injury claims made against their policies. The statutes also have the ancillary purpose of improving the business climate by making the state a more attractive place for professionals and businesses to operate, thereby creating greater employment opportunities. Finally, the limitation statutes enable injured parties and alleged tortfeasors to be in a better position to evaluate the merits of their cases and the range of verdicts that are possible, thereby increasing the likelihood of settlement in close

cases and reducing the burden imposed on the court system.

In our case, the State Attorney General intervened as a non-aligned party and supported the constitutionality of Section 11-1-60(2)(b), adopting the legal arguments presented on behalf of the defendants. In Mississippi, as with most states, the State Attorney General is authorized by statute to intervene on behalf of the State in pending litigation to defend the constitutionality of a state statute.¹⁶ In some states, parties must give notice to the attorney general of any constitutional challenge to a statute. Regardless of whether your state requires notice, from a defense standpoint, alert the attorney general of the suit and your position as soon as possible. The means and method of notifying the attorney general in hopes that he will take action to bolster your side will depend on the working relationship you or your firm has with the Office of the Attorney General and the circumstances of the individual case.

In our matter, we anticipate an appeal by plaintiff to the Mississippi Supreme Court. Once a case is at that level, other interested organizations may want to have their views about these issues known to the court through the filing of *amicus curia* briefs. One entity that may have an interest in filing an amicus brief is the state defense bar association. Additionally, depending on the circumstances of the case, the American Tort Reform Association (ATRA), Defense Research Institute (DRI), Lawyers for Civil Justice (LCJ), or United States Chamber of Commerce may be willing to get involved in the matter.¹⁷ The Advanced Medical Technology Association (AdvaMed), the Medical Device Manufacturer's Association (MDMA), the Pharmaceutical Research & Manufacturers of America (PhRMA), and the Product Liability Advisory Council (PLAC) are some of the organizations in the healthcare industry that may have an interest in the matter. Should your company find itself defending the constitutionality of a damages limitation at the appellate level, consider reaching out to one or more of the agencies that potentially may have an interest in the matter and requesting their assistance.

Mississippi is not the only jurisdiction to be faced with a constitutional challenge to newly enacted damages caps. Last December, in the context of a pharmaceutical case, the Ohio Supreme Court upheld legislation that limits non-economic and punitive damages.¹⁸ The Ohio Supreme Court specifically found that the statute limiting non-economic damages did not violate Ohio's constitutional right to a jury trial, the right to an open court and remedy under the Ohio Constitution, the Due Process Clause, or the Equal Protection Clause. In its twenty-five page majority opinion, the Ohio Supreme Court outlined the various reasons the plaintiff's challenges to the statute were rejected and will serve as a good starting point for a general overview of the issues. The opinion also includes a footnote citing nineteen other jurisdictions that have upheld the limits on non-economic damages.¹⁹ Also, the previous issue of *Pro Te: Solutio* notes that the state supreme courts in Alabama, Illinois, New Hampshire, Oregon, and Washington struck down legislation that attempted to limit damages.²⁰

With only approximately half of the state courts being faced with addressing these challenges, we should expect future decisions that impact how tort reform will evolve and succeed. Mississippi is facing its first challenge to the tort reform that was so desperately needed for our economy and that has reshaped our reputation from a litigation standpoint. We'll keep you posted on the results.

¹ *Pro Te: Solutio*, Vol. 1, No. 3, p. 18 (July 2008).

² Miss. Code Ann. §11-1-60(2)(b) (2007). Subpart (2)(a) of §11-1-60 places a \$500,000.00 cap on non-economic damages in medical malpractice actions.

³ ATRA, Judicial Hellholes Reports (2002), found at <<http://www.atra.org/reports/hellholes/>>.

⁴ ATRA, Judicial Hellholes Reports (2003), found at <<http://www.atra.org/reports/hellholes/2003/>>

⁵ *Id.*

⁶ Percy, *Checking Up on the Medical Malpractice Liability Insurance Crisis in Mississippi: Are Additional Tort Reforms the Cure?*, 73 MSJ 1001, (Miss. L. J. 2004).

⁷ Ross, Charlie, Op-ed, *Jackson Action: In Mississippi, Tort Reform Works*, Wall St. J., September 15, 2005. "Prior to the legislation, [...] insurance companies were fleeing the state. Others were refusing to write new policies. The medical field was particularly strained: Liability insurance was in many cases unaffordable, and in some cases unavailable."

⁸ *Id.*

⁹ *Arrington v. Galon-Med, Inc.*, 947 So.2d 719 (La. 2007) (dismissing challenge to limitation statute when raised for first time on appeal and stating that litigants must raise constitutional challenges in trial court rather than appellate court).

¹⁰ *Lymas v. Double-Quick, Inc.*, No. 2007-0072, (Circuit Court of Humphreys County).

¹¹ *Lymas v. Double-Quick, Inc.*, No. 2007-0072, Order, (Circuit Court of Humphreys County Sept. 18, 2008).

¹² *Wells by Wells v. Panola County Bd. of Educ.*, 645 So. 2d 883, 888 (Miss. 1994).

¹³ *Pathfinder Coach Division of Superior Coach Corp. v. Cottrell*, 62 So.2d 383, 385 (Miss. 1953).

¹⁴ *Id.*

¹⁵ *Wells by Wells v. Panola County Bd. of Educ.*, 645 So. 2d 883, 890 (Miss. 1994).

¹⁶ See Miss. Code Ann. §7-5-1.

¹⁷ To increase the likelihood of gaining support from an agency such as these, you must notify them of the matter and issue as soon as possible. Each agency has a process for submitting proposals which can be found on the agency's website. In addition, the law firm handling the issue likely has a relationship with one or more of the entities that can be a good starting point.

¹⁸ See *Arbino v. Johnson & Johnson*, 880 N.E.2d 420 (Ohio 2007).

¹⁹ *Arbino v. Johnson & Johnson*, 880 N.E.2d 420, 444, fn 8 (Ohio 2007). As of the date of the opinion, courts have upheld limits on noneconomic damages in at least nineteen other jurisdictions: Alaska (*Evans v. Alaska*, 56 P.3d 1046 (Alaska 2002)); California (*Fein v. Permanente Med. Group*, 38 Cal.3d 137, 211 Cal. Rptr. 368, 695 P.2d 665 (1985)); Colorado (*Garhart v. Columbia/HealthONE, L.L.C.*, 95 P.3d 571 (Colo. 2004)); Florida (*Mizrahi v. Miami Med. Ctr., Ltd.*, 761 So.2d 1040 (Fla.2000)); Idaho (*Kirkland v. Blaine Cty. Med. Ctr.*, 134 Idaho 464, 4 P.3d 1115 (2000)); Indiana (*Johnson v. St. Vincent Hosp., Inc.*, 273 Ind. 374, 404 N.E.2d 585 (1980)); Kansas (*Samsel v. Wheeler Transp. Servs., Inc.*, 246 Kan. 336, 789 P.2d 541 (1990), overruled on other ground in *Bair v. Peck*, 248 Kan. 824, 811 P.2d 1176 (1991)); Maine (*Peters v. Saff*, 597 A.2d 50 (Me. 1991)); Maryland (*Murphy v. Edmonds*, 325 Md. 342, 601 A.2d 102 (1992)); Missouri (*Adams v. Children's Mercy Hosp.*, 832 S.W.2d 898 (Mo. 1992)); Montana (*Meech v. Hillhaven W., Inc.*, 238 Mont. 21, 776 P.2d 488 (1989)); Nebraska (*Gourley v. Nebraska Methodist Health Sys., Inc.*, 265 Neb. 918, 663 N.W.2d 43 (2003) [\$1.25 million cap on all damages]); New Mexico (*Fed. Express Corp. v. United States*, 228 F.Supp.2d 1267 (D.N.M.2002)); Oregon (*Griest v. Phillips*, 322 Ore. 281, 906 P.2d 789 (1995)); South Carolina (*Wright v. Colleton Cty. School Dist.*, 301 S.C. 282, 391 S.E.2d 564 (1990)); Texas (*Rose v. Doctors Hosp.*, 801 S.W.2d 841 (Tex.1990) [cap on all damages]); Utah (*Judd v. Drezga*, 2004 UT 91, 103 P.3d 135); Virginia (*Pulliam v. Coastal Emergency Servs. of Richmond, Inc.*, 257 Va. 1, 509 S.E.2d 307 (1999) [cap on all damages]); and West Virginia (*Robinson v. Charleston Area Med. Ctr., Inc.*, 186 W.Va. 720, 414 S.E.2d 877 (1991)).


²⁰ See *Pro Te: Solutio*, Vol. 1, No. 3, p. 18 (July 2008).

WRITTEN by ALYSON JONES



RISK MANAGEMENT POST APPROVAL

A Summary of FDA's *Guidance for Industry:
Development and Use of RiskMAPs*



THE FDA PUBLISHED three risk management guidance documents: (1) *Premarketing Risk Assessment*, (2) *Development and Use of Risk Minimization Action Plans*, and (3) *Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*. In issue three of *Pro Te: Solutio*, we discussed Premarketing Risk Assessment. In this article, we will discuss RiskMAPs.

In 2005, The U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, and Center for Biologics Evaluation and Research published *Guidance for Industry: Development and Use of Risk Minimization Action Plans*. This guidance provides nonbinding recommendations to develop, implement,

and evaluate risk minimization action plans (RiskMAPs) for prescription drug products.

Risk management involves risk assessment and risk minimization and is an ongoing process. A sponsor must assess the prescription drug product's risk/benefit ratio then implement tools to minimize risks while maintaining the product's benefits. Once the tools are in place, a sponsor must decide if the product is effective and re-evaluate the risk/benefit ratio. Risk minimization aims to minimize a product's risk while maintaining its benefits. For more than half of products, routine risk minimization measures are adequate to minimize risk and maintain benefits. However, some products may benefit from a RiskMAP.

I. WHAT IS A RISKMAP?

A RiskMAP is a “strategic safety program designed to meet specific *goals* and *objectives* in minimizing known risks of a product while preserving its benefits.”¹ A RiskMAP focuses on one or more safety-related health results or aims and uses certain tools to attain the goals. When developing a RiskMAP, FDA recommends that the goals focus on achieving certain health results related to known risks. FDA recommends

that sponsors' goals be “pragmatic, specific, and measurable program objectives that result in processes or behaviors leading to achievement of RiskMAP goals.”² The objectives are intermediate steps to achieve the goal(s). Different systems or tools can be utilized in RiskMAPs.

Due to risk management's ongoing process, a RiskMAP may be considered during the premarketing or postmarketing risk

assessment. FDA recommends that sponsors utilize appropriate information such as (a) clinical development program data, post marketing surveillance, and Phase 4 studies and (b) the product's intended population and use to determine if a RiskMAP should be considered. However, FDA may also recommend a RiskMAP based on its own interpretation of a sponsor's risk information.





Risk management involves risk assessment and risk minimization and is an ongoing process. A sponsor must assess the prescription drug product's risk/benefit ratio then implement tools to minimize risks while maintaining the product's benefits.



A. Risk Minimization Tools

There are three categories of RiskMAP tools:

- Targeted education and outreach
- Reminder systems
- Performance-linked access systems

Targeted education and outreach tools seek to increase awareness and responses of people who may stop or lessen a product's risk (i.e. physicians or consumers). FDA recommends targeted education and outreach “(1) when routine risk minimization is known or likely to be insufficient to minimize product risks or (2) as a component of RiskMAPs using reminder or performance-linked access systems.”³ Sponsors can use targeted education and outreach in addition to their routine risk minimization programs without implementing a RiskMAP.

Some examples of targeted education and outreach are:

- Healthcare practitioner letters
- Patient package inserts
- Direct-to-consumer advertising emphasizing appropriate patient use.

Another category of tools is reminder systems. Reminder system tools prompt or remind healthcare practitioners and patients

in prescribing or using products to minimize risk. FDA recommends reminder system tools in addition to targeted education and outreach “when targeted education and outreach tools are known or likely to be insufficient to minimize identified risks.”⁴ A consent form signed by a patient acknowledging that he/she read the material and agrees to follow instructions is an example of this type of tool.

Performance-linked access systems may disrupt a patient's care because they link a product's access to lab results or other documentation. FDA suggests sponsors consider tools in this category only when:

- (1) products have significant or otherwise unique benefits in a particular patient group or condition, but unusual risks also exist, such as irreversible disability or death, and
- (2) routine risk minimization measures, targeted education and outreach tools, and reminder systems are known or likely to be insufficient to minimize those risks.⁵

Some examples of performance-linked access systems tools include prescription only by specially certified practitioners and product dispensing limited to pharmacies or practitioners who elect to be specially certified.⁶

B. FDA Site to Describe RiskMAP Tools

FDA intends to assist sponsors by developing a RiskMAP website that will offer information for RiskMAP design and describe the current RiskMAP tools. FDA also intends to summarize information regarding the effectiveness of RiskMAP tools.

II. DEVELOPING A RISKMAP

FDA recommends sponsors use the tools in each of the three categories that are most appropriate for the product's goals and objectives. FDA further recommends that sponsors consider factors in choosing the tools for a RiskMAP such as maintaining the broadest possible access to the product with the least burden to the healthcare system, identifying key stakeholders who have the ability to minimize risk and defining the stakeholders' roles, considering tools based on effectiveness and trying to avoid unintended consequences of a particular tool. It is recommended that the RiskMAP design be:

- Compatible with current technology
- Applicable to both outpatient and inpatient use
- Accessible to patients in diverse locales, including non-urban settings



A sponsor is encouraged to send FDA “data, all analyses, conclusions regarding effectiveness, and any proposed modifications to the RiskMAP.” FDA would then assess the information provided and discuss the RiskMAP evaluation with the sponsor.



- Consistent with existing tools and programs or systems that have been shown to be effective with similar products, indications, or risks.⁷

FDA may also require tools to minimize risks for products that present serious risks to public health. Some of the tools that FDA may implement are FDA-requested product recalls, guidance documents, and judicial enforcement procedures.

III. RiskMAP EVALUATION PROCESS

FDA recommends that sponsors periodically evaluate their RiskMAP to determine the RiskMAP’s effectiveness. Sponsors are encouraged to use evidence-based performance measures to determine if goals have been achieved. FDA recommends that sponsors use “at least two different quantitative, representative, and minimally biased evaluation methods for each critical RiskMAP goal” to avoid skewing the assessment of the RiskMAP.⁸

FDA also recommends that sponsors go one step further to evaluate the effectiveness of the RiskMAP tools. Sponsors are encouraged to evaluate the effectiveness of tools prior to implementation, if possible. Two

factors that play a significant part in tool effectiveness are acceptability and unintended consequences. After evaluating these aspects, a sponsor can improve the use of the tool.

Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research will develop internal manuals and policies for the review of RiskMAPs. Sponsors may submit RiskMAPs to FDA if desired. If a sponsor does so, FDA recommends that the sponsor describe when periodic evaluation results will be submitted to FDA. A sponsor is encouraged to send FDA “data, all analyses, conclusions regarding effectiveness, and any proposed modifications to the RiskMAP.”⁹ FDA would then assess the information provided and discuss the RiskMAP evaluation with the sponsor.

If a sponsor submits a RiskMAP before marketing approval, it will normally be submitted to the new drug application (NDA) or biologics license application (BLA). If a sponsor submits a RiskMAP in the post-market phase, FDA recommends that the sponsor submit the RiskMAP as a supplement to the appropriate NDA or BLA. However, if a sponsor wants to submit a

RiskMAP during Phases 1 to 3 studies, the sponsor can send the RiskMAP to the investigational new drug application.

IV. CONCLUSION

FDA offers several recommendations to sponsors to develop, implement, and evaluate RiskMAPs. Following these recommendations or implementing RiskMAP tools will help to minimize risks of products and to achieve the intended goals and objective of a product.

¹ *Guidance*, at 5.

² *Id.*

³ *Id.* at 8.

⁴ *Id.* at 9.

⁵ *Id.* at 10.

⁶ *Id.*

⁷ *Id.* at 11.

⁸ *Id.* at 15.

⁹ *Id.* at 17.



WRITTEN by
EFFIE V. BEAN COZART



OOPS! THE DOG ATE MY PACEMAKER

A LOWER STANDARD FOR SPOILIATION CLAIMS



YOU'VE JUST DISCOVERED that the artificial hip at issue in a contentious products liability case against your company was fractured during testing. What implications will this have for the case? Because many courts will impose sanctions when key evidence is lost, destroyed, or altered, recent changes to long-standing case law create opportunities and risks for manufacturers in the health-care industry.

As a general rule, most jurisdictions allow a spoliation inference when a party willfully destroys, alters, loses, conceals, or mutilates relevant evidence.¹ Courts infer from the intentional destruction of the evidence that it would have been harmful to the destroying party's case. Although rebuttable, the inference acts as a sanction against those who cause evidence spoliation, unless the spoliation occurs in the normal course of activity. Courts frequently remedy the issue by granting a negative-inference jury instruction.

Although the Federal Rules of Civil Procedure do not specifically address the consequences of evidence spoliation, sanctions against parties who abuse the rules of the court are available under Rule 37. Available sanctions include taking facts as established as the non-destroying party claims and prohibiting the destroying party from supporting certain claims or defenses on the issue.² The most severe penalty, dismissal of an action, is becoming more frequent when inadvertent spoliation of evidence is at issue.

Some state courts have amended their rules to address spoliation claims specifically.³ For example, Tennessee allows sanctions, including dismissal of the action or default judgment, against a party who "discards, destroys, mutilates, alters, or conceals evidence."⁴ Regardless of the jurisdiction, all courts have the inherent power to protect the judicial process by imposing sanctions on those who willfully (and sometimes inadvertently) spoliates evidence.⁵

RECENT CHANGES

Generally, most courts require some variety of willfulness in the act of spoliation.⁶ Others require only notice on the part of the destroyer that he or she is under a duty to protect relevant evidence before dismissal is allowed as a sanction.⁷ In these jurisdictions, situations when evidence is destroyed

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DESTROYING PARTY'S CASE.



through inadvertence or routine activity usually will not warrant a dismissal of the action, but the less severe sanctions are still available. Inadvertent spoliation of evidence occurs when a party allows, but does not necessarily willfully cause, evidence to be destroyed, lost, or otherwise altered. Although the law varies by jurisdiction, some state courts are changing how to handle this situation.

Recently, the Tennessee Court of Appeals made such a change. In *Cincinnati Insurance Co. v. Mid-South Drillers Supply, Inc.*, No. M2007-00024-COA-R3-CV, 2008 WL 220287 (Tenn. Ct. App. Jan. 25, 2008), a drilling company's insurer sued the supplier of an allegedly defective air hose after a malfunction damaged the driller's equipment. The trial court dismissed all claims against the supplier because the insurer's investigator inadvertently destroyed the hose.⁸ The appellate court affirmed, recognizing the dismissal sanction for intentional destruc-

tion of crucial evidence, and held dismissal as appropriate when any lighter sanction would not sufficiently remedy a defendant's prejudice resulting from a plaintiff's destruction of evidence.⁹ Significantly, this holding applies even when the spoliation of evidence occurs inadvertently through no malfeasance of the destroyer.¹⁰

The Tennessee Court of Appeals found the reasoning in *Citizens Insurance Co. of America v. Juno Lighting, Inc.*, 635 N.W.2d 379 (Mich. Ct. App. 2001), persuasive.¹¹ In that case, a fire insurer sued a lighting fixture manufacturer whose product allegedly caused a fire.¹² Finding that the plaintiff spoliated evidence by failing to preserve all of the lighting fixtures during an investigation, the trial court dismissed the action as a sanction because the case could not be tried fairly.¹³ The plaintiff appealed to the Court of Appeals of Michigan, which affirmed, holding that dismissal was not an abuse of discretion because courts need to have full authority to discourage "unscrupulous" behavior.¹⁴ The *Cincinnati Insurance* court was not the first to discard notice and willfulness as requirements for dismissal. For example, in *DeLong v. A-Top Air Conditioning Co.*, 710 So. 2d 706 (Fla. Dist. Ct. App. 1998), the trial court dismissed the plaintiffs' personal injury claims based on spoliation of evidence because one plaintiff *inadvertently* lost or misplaced a piece of relevant and material evidence.¹⁵ The decision was affirmed on appeal.¹⁶ Likewise, in *Sponco Mfg., Inc. v. Alcover*, 656 So. 2d 629 (Fla. 1995), the court affirmed a default judgment against a manufacturer who discarded an allegedly defective ladder, even though no evidence showed that the manufacturer *willfully* destroyed the ladder.

APPLICATIONS FOR HEALTH INDUSTRY

Although most courts still hold to the traditional rules, some, like the *Cincinnati Insurance* and *DeLong* courts, are liberating dismissal sanctions for destruction of evidence. What do these changes mean for you? If a defendant-manufacturer spoliates evidence (even accidentally) and the plaintiff's case is severely prejudiced by the lost

evidence, there is a risk of default judgment being entered against that defendant. Conversely, if a plaintiff destroys or alters crucial evidence (even inadvertently) the defense can seek a dismissal sanction if its case is severely prejudiced by the spoliation.

Can a defendant in the healthcare industry always claim "severe prejudice" because of lost evidence? No. Case law generally reflects a common approach to the "severe prejudice" analysis: In most cases, a litigant's case is prejudiced to the point of warranting a dismissal when that litigant cannot adequately defend the claims against it. Examples include lost opportunities to test the evidence, explore alternative causes, or disprove a claim of proper usage. In cases when the destruction of evidence makes it all but impossible for the defendant to negate the plaintiff's allegations, courts may order dismissal of the plaintiff's claim regardless of whether the evidence was lost through willfulness or inadvertence.

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HANDLE THIS SITUATION.



This doctrine has direct implications on the health industry. A prominent example is an explanted medical device. Such a situation has many possibilities for spoliation of evidence, beginning from the moment the device is removed. During explantation, the device could be damaged in a way that disallows testing for any alleged manufacturing defect. The device could be discarded and incinerated. Components of the device could be altered during steriliza-

tion. If preserved beyond the hospital, the device could be altered or discarded by the plaintiff himself. Or the plaintiff's investi-

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gator could alter or destroy the device during testing. Regardless of how the spoliation occurs, courts following *Cincinnati Insurance* may dismiss the entire action if the spoliation — whether or not intentional — places severe prejudice on the defendant-manufacturer in trying its case.

In some jurisdictions not following this rule, dismissal is unavailable unless it is shown that the plaintiff or his agent intentionally destroyed the evidence. In jurisdictions requiring notice, it must be shown that the plaintiff or his agent knew how important the device would be to any litigation the plaintiff would bring. If these requirements are met, dismissal of the plaintiff's case may be warranted. If the requirements are not met, all is not lost; lesser sanctions are still available to provide the burdened defendant with some remedy.

An example case of dismissal as a sanction for non-inadvertent spoliation is *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. Ct. 2006). In *Creazzo*, the plaintiffs sued the manufacturer of an implantable neurological electrical pulse generator on a theory of manufacturing defect.¹⁷ The trial court held that dismissal was appropriate due to the substantial prejudice placed on the defendant-manufacturer after the device was lost by the hospital staff following explantation surgery.¹⁸ The appellate court affirmed, finding no abuse of discretion in

awarding dismissal as a sanction for spoliation of evidence.¹⁹

Creazzo shows dismissal as an appropriate sanction for spoliation of evidence in a jurisdiction requiring the spoliating party to have notice of the inevitable need to test the evidence. In *Creazzo*, the plaintiffs actually commenced the litigation ten months prior to explantation surgery.²⁰ The court reasoned that even though the device was lost by the hospital staff and not by one of the litigants, the plaintiffs bore the responsibility for evidence preservation when they "were fully aware of their pending action and the need to preserve the device[;]" thus, dismissal was appropriate.²¹

What should a healthcare industry defendant do to safeguard itself from suffering the same fate? First, act immediately when presented with an opportunity to inspect the product. In some instances, however, inspection of every allegedly defective product is cost-prohibitive. In such cases, manu-

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facturers should respond to an opportunity for inspection by demanding important evidence be preserved for future testing. After the suit is commenced, attorneys may choose to file for protective orders for the evidence. Every precaution should be taken to ensure that essential evidence is preserved. Setting up these demands and protections may help insulate the manufacturer from the possibility that a court will view the defendant as the spoliating party.

CONCLUSION

When a plaintiff destroys important evidence and the defendant has lost the opportunity to adequately defend the claims made against it, some courts will dismiss the lawsuit as an inadequate sanction. Because of recent changes in the law of some jurisdictions, even inadvertent spoliation may warrant dismissal. By taking the proper precautions, health industry defendants can avoid being burdened by the same situation and may even be able to take advantage of evidence spoliation in the form of a dismissed complaint.

¹ E.g., *Dowdle Butane Gas Co. v. Moore*, 831 So. 2d 1124 (Miss. 2002); *Bronson v. Umphries*, 138 S.W.3d 844 (Tenn. Ct. App. 2003).

² *Id.*

³ See *Tenn. R. Civ. P. 34A*.

⁴ *Id.* at 34A.02.

⁵ See, e.g., *Wysbrod v. Wittjen*, 798 So. 2d 352 (Miss. 2001); *Strickland v. Strickland*, 618 S.W.2d 496 (Tenn. Ct. App. 1981).

⁶ See, e.g., *Iverson v. Xpert Tune, Inc.*, 553 So. 2d 82 (Ala. 1989); *Stahl v. Wal-Mart Stores, Inc.*, 47 F. Supp. 2d 783 (S.D. Miss. 1998).

⁷ E.g., *State Farm Fire & Cas. Co. v. Broan Mfg. Co.*, 523 F. Supp. 2d 992 (D. Ariz. 2007).

⁸ *Cincinnati Ins.*, 2008 WL 220287, at *3.

⁹ *Id.* at *6.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Juno Lighting*, 635 N.W.2d at 380.

¹³ *Id.* at 381.

¹⁴ *Id.* at 383.

¹⁵ *DeLong*, 710 So. 2d at 707.

¹⁶ *Id.*

¹⁷ *Creazzo*, 903 A.2d at 26.

¹⁸ *Id.* at 29.

¹⁹ *Id.* at 32.

²⁰ *Id.* at 27.

²¹ *Id.* at 29.

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A FIFTY-STATE SURVEY OF THE MEDICAL PEER REVIEW PRIVILEGE

THE MEDICAL PEER REVIEW PRIVILEGE safeguards the disclosure of information acquired or generated during an internal peer review of medical treatment and patient care from discovery and trial in civil litigation. The process of peer review may occur in hospitals, non-hospital institutional providers (such as freestanding surgery centers), medical practice groups, and third-party payers of healthcare expenses.¹ By keeping information privileged, the peer review process serves to provide “a safe forum in which medical professionals can review the quality of care and work to reduce medical errors.”²

The degree of protection afforded to information related to the peer review process depends on a variety of factors. For example, no recognized medical peer review privilege exists under federal law. In 1986, Congress passed the

Health Care Quality Improvement Act, which established federal guidelines for peer review.³ The Act provides immunity for participants under certain circumstances; however, it does not protect peer review documents or discussions from disclosure in litigation.⁴

With the exception of New Jersey, all states and the District of Columbia have enacted statutes affording some degree of protection of the disclosure of peer review information. State statutes differ widely in scope, and courts generally construe these statutory privileges narrowly because such privileges “contravene the fundamental principal that the public [...] has the right to every man’s evidence.”⁵ The following survey provides an overview of state statutes concerning the medical peer review privilege.⁶

Alabama: ALA. CODE §6-5-333(D) (2008) “All information, interviews, reports, statements, or memoranda furnished to any [medical peer review] committee as defined in this section, and any findings, conclusions, or recommendations resulting from the proceedings of such committee are declared to be privileged.”

Alaska: ALASKA STAT. §18.23.030(a) (2008) “All data and information acquired by a review organization in the exercise of its duties and functions shall be held in confidence and may not be disclosed to anyone except to the extent necessary to carry out the purposes of the review organization and is not subject to subpoena or discovery.”

Arizona: ARIZ. REV. STAT §36-445.01 (2008) “All proceedings, records and materials prepared in connection with the reviews provided for in §36-445, including all peer reviews of individual healthcare providers practicing in and applying to practice in hospitals or outpatient surgical centers and the records of such reviews, are confidential and are not subject to discovery” unless expressly exempt.

Arkansas: ARK. CODE ANN. §20-9-503 (West 2008) “The proceedings and records of a peer review committee shall not be subject to discovery or introduction into evidence in any civil action against a provider of professional health services arising out of the matters which are subject to evaluation and review by the committee.”

California: CAL. EVID. CODE §1157 (West 2008) “Neither the proceedings nor the records of organized committees of medical, medical-dental, podiatric, registered dietitian, psychological, marriage and family therapist, licensed clinical social worker, or veterinary staffs in hospitals, or of a peer review body, as defined in Section 805 of the Business and Professions Code [...] shall be subject to discovery.”

Colorado: COLO. REV. STAT. §25-3-109 (2008) “The records, reports, and other information [...] shall not be subject to subpoena or discoverable or admissible as evidence in any civil or administrative proceeding.”

Connecticut: CONN. GEN. STAT. §19a-17b (2008) “The proceedings of a medical review committee conducting a peer review shall not be subject to discovery or

introduction into evidence in any civil action for or against a healthcare provider arising out of the matters which are subject to evaluation and review by such committee, and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to the content of such proceeding.”

Delaware: DEL. CODE ANN. tit. 24, §1768 (2008) “The records and proceedings of committees and organizations [...] are confidential and may only be used by those committees or organizations and the members thereof. The records and proceedings are not public records and are not available for court subpoena, nor are they subject to discovery. A person in attendance at a meeting of any such committee or organization is not required to testify as to what transpired at the meeting.”

District of Columbia: D.C. CODE §44-805 (2008) “The files, records, findings, opinions, recommendations, evaluations, and reports of a peer review body, information provided to or obtained by a peer review body, the identity of persons providing information to a peer review body [...] shall be confidential and shall be neither discoverable nor admissible into evidence in any civil, criminal, legislative, or administrative proceeding.”

Florida: FLA. STAT. ANN. §395.0193(8) (West 2008) “The investigations, proceedings, and records of the peer review panel [...] shall not be subject to discovery or introduction into evidence in any civil or administrative [proceeding, ...] and a person who was in attendance at a meeting of such group or its agent may not be permitted or required to testify in any such civil or administrative action as to any evidence or other matters produced or presented during the proceedings of such group or its agent or as to any findings, recommendations, evaluations, opinions, or other actions of such group or its agent or any members thereof [...]” *See also id.* at §766.101.

Georgia: GA. CODE ANN. §31-7-133(a) (West 2008) “The proceedings and records of a review organization shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action; and no person who

was in attendance at a meeting of such organization shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings or activities of such organization or as to any findings, recommendations, evaluations, opinions, or other actions of such organization or any members thereof.”

Hawaii: HAW. REV. STAT. §624-25.5 (2008) “Neither the proceedings nor the records of peer review committees, quality assurance committees, or case review forums shall be subject to discovery [...]. Information protected shall not include incident reports, occurrence reports, or similar reports that state facts concerning a specific situation, or records made in the regular course of business by a hospital or other provider of healthcare.”

Idaho: IDAHO CODE ANN. §39-1392b (2008) “All peer review records shall be confidential and privileged, and shall not be directly or indirectly subject to subpoena or discovery proceedings or be admitted as evidence, nor shall testimony relating thereto be admitted in evidence, or in any action of any kind in any court or before any administrative body, agency, or person for any purpose whatsoever.” *See also id.* at §39-1392e (2008) (sets forth limited exceptions to privilege and confidentiality).

Illinois: 735 ILL. COMP. STAT. 5/8-2101 (2008) “All information, interviews, reports, statements, memoranda, or other data of committees of hospitals used in the course of internal quality control or medical study for the purpose of reducing morbidity or mortality, or for improving patient care, is privileged and neither admissible in evidence or discoverable.”

Indiana: IND. CODE §34-30-15-1 (2008) “Information and materials submitted or disclosed to the agency under this subsection are confidential and privileged from use as evidence in an administrative or judicial proceeding.”

Iowa: IOWA CODE ANN. §147.135(2) (West 2008) “Peer review records are privileged and confidential, are not subject to discovery, subpoena, or other means of legal compulsion for release to a person other than an affected licensee or a peer review committee, and are not admissible in evidence in a judicial or administrative proceeding other than a proceeding involving licensee discipline or a proceeding brought by a licensee who is the subject of a peer review record and whose competence is at issue.”

Kansas: KAN. STAT. ANN. §65-4915(B) (2008) “The reports, statements, memoranda, proceedings, findings, and other records submitted to or generated by peer review committees or officers shall be privileged and shall not be subject to discovery, subpoena, or other means of legal compulsion for their release to any person or entity or be admissible in evidence in any judicial or administrative proceeding.”

Kentucky: KY. REV. STAT. ANN. §311.377(2) (West 2008) “At all times in performing a designated professional review function, the proceedings, records, opinions, conclusions, and recommendations of any committee, board, commission, medical staff, professional standards review organization [...] shall be confidential and privileged and shall not be subject to discovery, subpoena, or introduction into evidence, in any civil action in any court or in any administrative proceeding before any board, body, or committee [...]”

Louisiana: LA. REV. STAT. ANN. §13:3715.3 (West 2008) “Any records of a medical peer review committees shall be confidential wherever located and shall be used

by such committee and the members thereof only in the exercise of the proper functions of the committee and shall not be available for discovery or court subpoena [...]”

Maine: ME. REV. STAT. ANN. TIT. 32, §2599 (2008) “All proceedings and records of proceedings concerning medical staff reviews and hospital reviews conducted by committees of physicians and other healthcare personnel on behalf of hospitals located within the State, when these reviews are required by state or federal law or regulations or as a condition of accreditation by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association Committee on Hospital Accreditation are confidential and are exempt from discovery without a showing of good cause.” *See also id.* at tit. 32, §3296.

Maryland: MD. CODE ANN., HEALTH OCC. §1-401 (2008) “The proceedings, records, and files of a medical review committee are not discoverable and are not admissible in evidence in any civil action.”

Massachusetts: MASS. GEN. LAWS ANN. ch. 111, §204 (West 2008) “The proceedings, reports and records of a medical peer review committee shall be confidential and shall be exempt from the disclosure of public records [...] and no person who was in attendance at a meeting of a medical peer review committee shall be permitted or required to testify in any such judicial or administrative proceeding [...]”

Michigan: MICH. COMP. LAWS ANN. §331.533 (West 2008) “The identity of a person whose condition or treatment has been studied under this act is confidential and a review entity shall remove the person's name and address from the record before the review entity releases or publishes a record of its proceedings or its reports, findings, and conclusions. [...]The] record of a proceeding and the reports, findings, and conclusions of a review entity and data collected by or for a review entity under this act are confidential, are not public records, and are not discoverable and shall not be used as evidence in a civil action or administrative proceeding.”

Michigan: MICH. COMP. LAWS ANN. §331.20175 (West 2008) “The records, data, and knowledge collected for or by individuals or committees assigned a professional review function in a health facility or agency [...] are confidential [and] shall be used only for the purposes provided in this article, are not public records, and are not subject to court subpoena.”

Minnesota: MINN. STAT. §145.64(1) (2008) “Data and information acquired by a review organization, in the exercise of its duties and functions, or by an individual or other entity acting at the direction of a review organization, shall be held in confidence, shall not be disclosed to anyone except to the extent necessary to carry out one or more of the purposes of the review organization, and shall not be subject to subpoena or discovery.”

Mississippi: MISS. CODE ANN. §41-63-9(1) (2008) “The proceedings and records of any medical or dental review committee shall be confidential and shall not be subject to discovery or introduction into evidence in any civil action arising out of the matters which are the subject of evaluation and review by such committee.”

Missouri: MO. REV. STAT. §537.035(4) (2008) “The interviews, memoranda, proceedings, findings, deliberations, reports, and minutes of peer review committees, or the existence of the same, concerning the healthcare provided any patient are privileged and shall not be subject to discovery, subpoena, or other means of legal

- compulsion for their release to any person or entity or be admissible into evidence in any judicial or administrative action for failure to provide appropriate care.”
- Montana: MONT. CODE ANN. §37-2-201(2) (2008) “The proceedings and records of professional utilization, peer review, medical ethics review, and professional standards review committees are not subject to discovery or introduction into evidence in any proceeding [...]”
- Nebraska: NEB. REV. STAT. §71-2048 (2008) “The proceedings, minutes, records, and reports of any medical staff committee or utilization review committee as defined in section 71-2046, together with all communications originating in such committees, are privileged communications which may not be disclosed or obtained by legal discovery proceedings unless (1) the privilege is waived by the patient and (2) a court of record, after a hearing and for good cause arising from extraordinary circumstances being shown, orders the disclosure of such proceedings, minutes, records, reports, or communications.”
- Nevada: NEV. REV. STAT. §49.265 (2008) “The proceedings and records of organized committees of hospitals, and organized committees of organizations that provide emergency medical services [...], having the responsibility of evaluation and improvement of the quality of care rendered by those hospitals or organizations [...] are not subject to discovery proceedings.”
- New Hampshire: N.H. REV. STAT. ANN. §151:13-a (2008) “Records of a hospital committee organized to evaluate matters relating to the care and treatment of patients or to reduce morbidity and mortality and testimony by hospital trustees, medical staff, employees, or other committee attendees relating to activities of the quality assurance committee shall be confidential and privileged and shall be protected from direct or indirect means of discovery, subpoena, or admission into evidence in any judicial or administrative proceeding”.
- New Mexico: N.M. STAT. ANN. §41-9-5 (West 2008) “All data and information acquired by a review organization in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to anyone except to the extent necessary to carry out one or more of the purposes of the review organization or in a judicial appeal from the action of a review organization [...]”
- New York: N.Y. PUB. HEALTH LAW §2805-m (McKinney 2008) “None of the records, documentation, or committee actions or records required pursuant to sections twenty-eight hundred five-j and twenty-eight hundred five-k of this article, the reports required pursuant to section twenty-eight hundred five-l of this article nor any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions of this chapter shall be subject to disclosure under article six of the public officers law or article thirty-one of the civil practice law and rules, except as hereinafter provided or as provided by any other provision of law.” *See also id.* at §6527 (3) “Neither the proceedings nor the records relating to performance of a medical or a quality assurance review function or participation in a medical and dental malpractice prevention program nor any report required by the department of health [...] shall be subject to disclosure [...]. The prohibition relating to discovery of testimony shall not apply to the statements made by any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting.”
- North Carolina: N.C. GEN. STAT. §131E-95(B) (2008) “The proceedings of a medical review committee, the records and materials it produces, and the materials it considers shall be confidential and not considered public records. ‘Public records’ shall not be subject to discovery or introduction into evidence in any civil action against a hospital, an ambulatory surgical facility licensed under Chapter 131E of the General Statutes, or a provider of professional health services which results from matters which are the subject of evaluation and review by the committee.”
- North Dakota: N.D. CENT. CODE §23-34-03 (2008) “Peer review records are privileged and are not subject to subpoena or discovery or introduction into evidence in any civil or administrative action.”
- Ohio: OHIO REV. CODE ANN. §2305.252 (West 2008) “Proceedings and records within the scope of a peer review committee of a healthcare entity shall be held in confidence and shall not be subject to discovery or introduction in evidence in any civil action against a healthcare entity or healthcare provider, including both individuals who provide healthcare and entities that provide healthcare, arising out of matters that are the subject of evaluation and review by the peer review committee.”
- Oklahoma: OKLA. ST. ANN. TIT. 63, §1-1709 (West 2008) “All information, interviews, reports, statements, memoranda, or other data furnished by reason of this section, and any findings or conclusions resulting from [peer review], are declared to be privileged communications which may not be used or offered or received in evidence in any legal proceeding of any kind or character, and any attempt to use or offer any such information, interviews, reports, statements, memoranda or other data, findings or conclusions, or any part thereof, unless waived by the interested parties, shall constitute prejudicial error in any such proceeding.”
- Oregon: OR. REV. STAT. §41.675(3) (2008) “All data shall be privileged and shall not be admissible in evidence in any judicial, administrative, arbitration, or mediation proceeding. This section shall not affect the admissibility in evidence of records dealing with a patient’s care and treatment, other than data or information obtained through service on, or as an agent for, a peer review body.”
- Pennsylvania: 63 PA. STAT. ANN. §425.4 (West 2008) “The proceedings and records of a review committee shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action against a professional healthcare provider arising out of the matters which are the subject of evaluation and review by such committee and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions, or other actions of such committee or any members thereof.”
- Rhode Island: R.I. GEN. LAWS §5-37.3-7 (2008) “The proceedings and records of medical peer review board shall not be subject to discovery or introduction into evidence.” *See also id.* at §23-17-25: “Neither the proceedings nor the records of peer review boards as defined in §5-37-1 shall be subject to discovery or be admissible in evidence in any case save litigation arising out of the imposition of sanctions upon a physician.”
- South Carolina: S.C. CODE ANN. §40-71-20 (2008) “All proceedings of and all data and information acquired by the committee [...] in the exercise of its duties are

confidential unless a respondent in the proceeding requests in writing that they be made public. These proceedings and documents are not subject to discovery, subpoena, or introduction into evidence in any civil action except upon appeal from the committee action.”

South Dakota: S.D. CODIFIED LAWS §36-4-26.1 (2008) “The proceedings, records, reports, statements, minutes, or any other data whatsoever [...] relating to peer review, are not subject to discovery or disclosure [...] and are not admissible as evidence in any action of any kind in any court or arbitration forum.”

Tennessee: TENN. CODE ANN. §63-6-219(e) (West 2008) “All information, interviews, incident or other reports, statements, memoranda or other data furnished to any committee as defined in this section, and any findings, conclusions, or recommendations resulting from the proceedings of such committee are declared to be privileged. All such information, in any form whatsoever, so furnished to, or generated by, a medical peer review committee, shall be privileged. The records and proceedings of any such committees are confidential and shall be used by such committee and the members thereof only in the exercise of the proper functions of the committee, and shall not be public records nor be available for court subpoena or for discovery proceedings.”

Texas: TEX. OCC. CODE ANN. §160.007 (Vernon 2008) “Unless disclosure is required or authorized by law, a record or determination of or a communication to a medical peer review committee is not subject to subpoena or discovery and is not admissible as evidence in any civil judicial or administrative proceeding without waiver of the privilege of confidentiality executed in writing by the committee.”

Utah: UTAH CODE ANN. §26-25-3 (West 2008) “All information, interviews, reports, statements, memoranda, or other data furnished [to medical review committee], and any finds or conclusions resulting from those studies are privileged communications and are not subject to discovery, use, or receipt in evidence in any legal proceeding of any kind or character.”

Vermont: VT. STAT. ANN. TIT. 26, §1443 (a) (2008) “The proceedings, reports, and records of review committees shall be confidential and privileged and shall not be subject to discovery or introduction into evidence in any civil action against a provider of professional health services arising out of the matters which are subject to evaluation and review by such committee.”

Virginia: VA. CODE ANN. §8.01-581.17 (West 2008) “The proceedings, minutes, records, and reports of any [review committee...] together with all communications, both oral and written, originating in or provided to such committees or entities, are privileged communications which may not be disclosed or obtained by legal discovery proceedings unless a circuit court, after a hearing and for good cause arising from extraordinary circumstances being shown, orders the disclosure of such proceedings, minutes, records, reports, or communications.”

Washington: WASH. REV. CODE ANN. §4.24.250 (West 2008) “The proceedings, reports, and written records of such committees or boards, or of a member, employee, staff person, or investigator of such a committee or board, are not subject to review or disclosure, or subpoena or discovery proceedings in any civil action, except actions arising out of the recommendations of such committees or

boards involving the restriction or revocation of the clinical or staff privileges of a healthcare provider.” *See also id.* at §70.41.200(3).

West Virginia: W. VA. CODE §30-3C-3 (2008) “The proceedings and records of a review organization shall be confidential and privileged and shall not be subject to subpoena or discovery proceedings or be admitted as evidence in any civil action arising out of the matters which are subject to evaluation and review by such organization, and no person who was in attendance at a meeting of such organization shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such organization or as to any findings, recommendations, evaluations, opinions, or other actions of such organization or any members thereof.”

Wisconsin: WIS. STAT. ANN. §146.38 (2008) “No person who participates in the review or evaluation of the services of healthcare providers or facilities or charges for such services may disclose any information acquired in connection with such review or evaluation [...]. No record may be used in any civil action for personal injuries against the healthcare provider or facility.”

Wyoming: WYO. STAT. ANN. §33-26-408 (2008) “Investigative notes, attorney’s notes and work product and reports, pleadings, correspondence, witness statements and deposition transcripts, and copies of original medical and prescription records in the possession of the board, whether acquired by the board, by any agent of the board, or by any agency that has cooperated with or provided information to the board regarding the investigation of a disciplinary docket, are not subject to disclosure by the board to any person or entity, nor are they subject to discovery in any civil or administrative action or admissible in any nonboard proceeding.” *See also id.* at 35-17-105.

¹ Susan O. Scheutzow, *State Medical Peer Review: High Cost But No Benefit — Is it Time for a Change?*, 25 Am. J.L. & Med. 7, 7 n. 1 (1999).

² Lisa M. Nijm, *Pitfalls of Peer Review: The Limited Protections of State and Federal Peer Review Law for Physicians*, 24 J. Legal Med. 541, 541 (2003) (“Nijm, Pitfalls of Peer Review”).

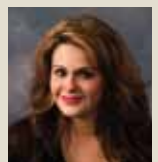
³ 42 U.S.C. §§11101-11152 (2002).

⁴ *Id.*

⁵ *Trammel v. United States*, 445 U.S. 40, 50 (1980).

⁶ This piece reports only stated portions of the various state statutes and gives an overview, rather than detailed analysis, of any particular statute.

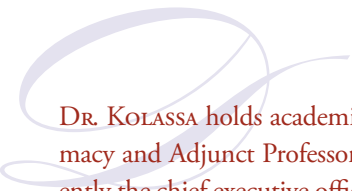
WRITTEN by
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THE UNIQUE COMPLEXITIES OF PHARMACEUTICAL PRICING

An Interview With E. M. “Mick” Kolassa, Ph.D.



DR. KOLASSA holds academic appointments as Adjunct Professor of Pharmacy Administration in the School of Pharmacy and Adjunct Professor of Pharmaceutical Business at the University of the Sciences in Philadelphia. He is presently the chief executive officer and managing partner for Medical Marketing Economics, LLC, with offices in Oxford, Mississippi, and Montclair, New Jersey. Prior to forming MME, Dr. Kolassa was Associate Professor of Pharmacy Administration and Associate Professor of Marketing at the University of Mississippi. He previously served as Director of Pricing and Economic Policy at Sandoz, where he created and instituted that company's first pricing and health economics departments, and has also held positions at The Upjohn Company, the Strategic Pricing Group, and Hastings Healthcare. Dr. Kolassa holds an MBA from Eastern Washington University and a Ph.D from the University of Mississippi. He has written and lectured extensively on pricing strategies and on the management of the pricing function and authored the book *Elements of Pharmaceutical Pricing*. A new update of the book is anticipated for release in 2009.

Q. In your book *Elements of Pharmaceutical Pricing*, you point out that in many ways, the pharmaceutical market may be “a different animal” from other economic markets. What are some of the big points of departure?

A. When a generic micro-economist or a generic academician who's got a background in marketing comes in and looks at

the pharmaceutical industry and tries to apply generic rules, things fall apart. That's because the pharmaceutical industry differs from most “normal” industries in a number of very important ways. First, pharmaceuticals are subject to what is called “derived demand,” which means that the demand for pharmaceuticals isn't based on the features of the product. It is based on the underlying disease. You can come

out with a wonderful new antibiotic, and that's not going to encourage people to go out and get infected.

Another big difference is that in most markets, the decision maker and the user and the payer tend to be the same one. What we've got in pharmaceutical markets is that the decision maker is the physician. He decides whether to use the product or not. But it's usually an insurer involved in

paying some portion of it, and then it's the patient who uses the product.

Q. You also describe pharmaceuticals as a “negative good.” Tell us what you mean by that.

A. Relating to the first issue of derived demand, pharmaceuticals are also what are called “negative goods.” That is, they don't provide the same type of utility, in eco-



nomie terms, as what are called “normal goods.” What they do is help to overcome a disutility. If I go out and get a chocolate ice cream sundae, I'm starting at zero and

going into positive. If I am getting a prescription filled, I'm starting at negative and trying to work my way towards zero.

People are never going to *want* to take pharmaceuticals, at least not for legitimate purposes. We know there are some folks out there who will abuse things, but by in large, people would rather not take the medicines; they would rather not have the disease.

Another issue with pharmaceuticals is that this is one of the most regulated industries around. You can't say something about a product unless it's in the package insert, and there's been litigation alleging the companies have said things that are not in the insert. The distinction I like to draw is that when Volvo ran a series of television ads stating that the life expectancy in America has gone up because their cars are so safe that fewer people were dying on the highways, they got awards for that advertising campaign. If a pharmaceutical made the claim, they would get a letter from the FDA telling them to cease and desist. So you've got those levels of regulation that the [other markets] don't have.

These things make the pharmaceutical industry very, very different, so in trying to apply generic [economic] models to them, [the models] get things wrong. Because of the differences in these products, pharmaceutical markets, for the most part, are relatively non-elastic in price. A change in price for a drug doesn't change the underlying disease, doesn't change the effectiveness of the drug for the physician, and for most patients, it doesn't even affect the price they pay for it. So, again, those simple economic models just fly in the face of what really happens in the industry.

Q. How much of an impact can public policy debate have — even without new or additional legislation or regulation — on pharmaceutical pricing?

A. If you will notice on the cover of my book, “public policy” is on there four times, it kind of surrounds everything. It has a very important role. The companies think

Pharmaceuticals are also what are called “negative goods.” That is, they don't provide the same type of utility, in economic terms, as what are called “normal goods.” What they do is help to overcome a disutility. If I go out and get a chocolate ice cream sundae, I'm starting at zero and going into positive. If I am getting a prescription filled, I'm starting at negative and trying to work my way towards zero.

quite seriously about public policy issues when setting the prices of their product. Some decide, *Okay we're going to weather the storm, and we'll figure out ways to deal with it.* Others say, *We're going to avoid profit maximization to also avoid the distraction of getting called to Washington, D.C., and have to testify as to what we are doing.* That's currently going on right now [... A] couple of senators are trying to make their mark by identifying companies that have large increases on products, and there are perfectly good not only business reasons but public health reasons for the price increases, but that doesn't matter. I once had a very influential senator say to me over a particular pricing issue when I laid the whole thing out, “You are right, that makes perfect sense. But that doesn't matter because this is good politics, and you're going down.” And that's sad.

Lately, it has been the pharmaceutical industry's turn to stand there and get punched, and they don't punch back very well. So, I think when somebody wants to make it [pharmaceutical pricing] an issue, it becomes an issue. But most of the companies are cognizant of that, and that affects a lot of things. For example, the Clinton

healthcare reform back in the early 1990s had a measurable effect on the industry. It really moderated price increases. Companies took the price pledge and didn't increase prices as aggressively as they had before. It shows up in the new product pricing decisions for a number of companies that say "I don't want this to get us into trouble."

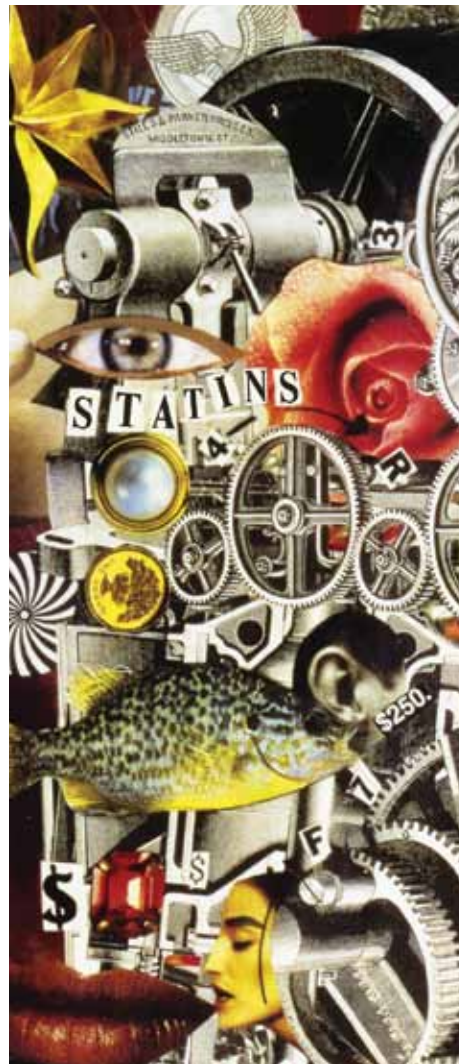
Q. In the book, you mention cultural differences among various manufacturers where pricing is involved. Are they really so different? What are some of the different drivers to be aware of?

A. Every company has different objectives, and that is another thing most economists fail to consider. Different companies look at things differently. Some companies want to set a price that it is profit-maximizing, some want to set a price that would allow them to maximize unit sales or market share. Those are different numbers. Some want to set a price such that the price won't get in the way of selling. Routinely, when we work with companies we say, *What's more important: the first year of sales or the fifth year of sales? Because that could lead to a different price. What kind of company do you want to be?* Just by their nature, some companies are more aggressive when it comes to setting higher prices, and some are much more timid — it's just the personality of the company. Not only do no two companies price the same way, there are several companies that don't price their own products in the same way.

Q. Can you briefly touch on why there can be such disparity in prices for similar drugs for similar markets?

A. Again, it has to do with company goals; it has to do with things like, if I'm the fourth entry into the market, even if I have a very, very good product, I'm going to have trouble getting people to pay attention to it. I might have to give up a little bit in price. So there may be any number of reasons. We can have two products of the same

chemical class and in the same market, but because of differences in their label, they will be used for two different things. So do



they set the price according to the label they have at launch, or do they set the price according to the label they think they are going to have after they get new indications approved? There's just a number of things that need to be considered....

Q. That leads me to wonder if you can give us an overview of some of the different pricing considerations over the life of a drug?

A. Absolutely. You set an initial price once the product is launched. And then, over the years, the market will change. [Consumers] will learn more about your product, new competitors will come into the market, and it changes the market posi-

tions. Sometimes that requires or suggests a price change, sometimes it doesn't, but it might change the way you manage your prices. It might mean that with the entry of new competitors, you don't change your list price but you do more contracting. It might be that the competitor that comes in isn't all that important, isn't a direct competitor, so you don't do anything at all. And it could be that the product has become less important to the company because new products have since been brought on, so you change your pricing approach just simply because I can go out and do a lot more contracting, just kind of let the product ride along, as opposed to aggressively marketing it. So there's trade offs to be made....

Q. You mentioned that, as opposed to most products, the pharmaceutical "decision maker" can occur in three different places: who orders the drug, who pays for the drug, and who uses the drug. Where do you put payers in terms of pricing decisions with pharmaceuticals?

A. They are a very important consideration. The reimbursement environment is growing in importance. However, there are a couple of things that folks need to realize. A payer is never going to like your price; it's either going to be acceptable or they don't like it. More important, the payer is never going to do anything to help you sell your product. They will do things to hurt you and in turn might indirectly help a competitor — but people who try to go out and, through discounts, get managed care support, that doesn't make sense. It is important to understand the steps that managed care may or may not take to limit the reimbursement and the use of a product, and price can be one of those things. Generally speaking, only when there are a number of close competitors will managed care be comfortable in saying, *Okay we are going to put you at a disadvantage because the market doesn't really need this.* But, for instance, as much as managed care doesn't like the price that a company might charge for

an important drug, when there is no competition, they are not going to put barriers in the way of it — most aren't — simply because it's an important medication.

Managed care is not in the business of hurting patients. Now, if there were four other products with the same label out there, they could be very aggressive and, through the use of differences in co-pay, actually move patients within the market. And it's



not because they are out there telling the physicians they have to prescribe this; it's because patients are saying, "Isn't there something cheaper?"

So, it really depends on how critically important your medicine is, and that's a

function of the disease. It's also a function of how many direct competitors are out there and whether they are really direct competitors. You know, there are categories such as the atypical anti-psychotics where, although there are lots of competitors in the market, those drugs aren't anywhere near interchangeable. So payers say *no*, the physician needs all of them, and I can't get dollars and cents in there to intervene and to upset this. It interferes with good patient care. So managed care needs to be considered more often. I like to say they are managing a lot less and caring a lot more when it comes to focusing on the patients. So it's a function of how important your drug is out there. The less distinctive and the less important [the medicine,] the more you are going to have to let price play a role competitively.

Q. In your book you use the analogy "your money or your life" to put the pharmaceutical market into context. How does the nature of the underlying disease treated affect pricing decisions?

A. They both play a huge role. I've been involved in probably thousands of pharmaceutical pricing decisions, and I've never seen people who weren't cognizant of the fact that we do have this power. Because of the importance medically and because of the economic value, I believe that almost all pharmaceuticals are underpriced relative to the value they deliver. Companies could charge more. They choose not to for a number of reasons. One of them being, they need to make sure they are affordable because the companies have a duty — most of them have this within their mission statements — that they want to make sure that patients who need their products aren't denied their products. If you can't pay for your electricity, the electric company shuts it off. If you can't pay your taxes, the IRS will charge you more because of it. If you can't pay for your drugs, the pharmaceutical company will figure out a way to give them to you. That's always in the back-

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ground. Andrew Solomon, who wrote a book about depression, called the pharmaceutical companies "idealistic capitalists" and everybody in the industry is sure that the next product they are associated with is going to be the one that changes everything.

We've been involved in the development, in the launch, of some products that are literally saving hundred of thousands of lives. It feels pretty good, but people also remember that Aunt Margaret is out there, and she's got to afford her drugs.

Q. It sounds as though pharmaceutical manufacturers are sensitive to their pricing?

A. Absolutely. In fact, almost thirty years ago now, an economist named Duncan Reekie concluded that the pharmaceutical industry is much more price sensitive than

its customers. That they are much more concerned about how price will affect their sales than they actually do.

Q. Where would you put product liability litigation in terms of pricing considerations?

A. It's driving prices higher. It really is. It's not moderating it. [...] I actually sit with companies that say, *You know, we are not doing anything wrong, but it's almost an inevitability that somebody [...] is going to come to us and sue us because they think they can.* They [manufacturers] are building that in. They are setting prices higher because they have to. That's a contingency — I actually had this discussion with Senator Pryor years ago when I was at Sandoz, and we set a price for a product that — it was a very toxic product that could kill up to 2% of the patients — and we put a monitoring system in place. And they said, *This monitoring system is anti-competitive, you're just charging people for it.* Sandoz said, *Okay, we can pull the monitoring system out, but we've got to be able to adjust the price to take into account the up to 2% of the people who are going to die; we are going to get sued for it, and we are going to build that in.* And we were charging \$10,000 a year for the drug and the monitoring, and they said, *That sounds fair; what would that mean?* I said we would have to charge \$16,000 a year to cover it. That's the reality of it, and people are thinking about it, so it's driving up the cost tremendously. Frankly, [litigation concerns] make the industry less profitable, and profits are what drive new drug discovery, so there's no [other] way for that to go. So those pricing controls are not very good, especially given the sort of legal theories that are floated out there, the loss of value theories and things along those lines that they're trying to pull in from securities law.

Q. Dr. Kolassa, I understand that you're presently involved in some of the nationwide average wholesale price (AWP) litigation, so I won't ask you any specifics on that front. What other potential litigation pit-

falls should pharmaceutical manufacturers be mindful of in the context of pricing?

A. As we've talked throughout, this is very complex, almost Byzantine sometimes, the way things are put together. We've got a combination of government requirements and government-imposed things coming



down one way, market differences forcing things to be done differently in another way, and what happens when an aggressive attorney looks at that stuff and says, *This doesn't make sense to me; it must be wrong.* I'm often reminded of two songs [from] the 1960s: "Louie, Louie" and Bob Dylan's "Subterranean Homesick Blues," both of which were banned from the radio. People couldn't understand them, so they assumed they were dirty or about drug abuse. If you will look at the lyrics of both of those songs, they are

very, very harmless, but because people couldn't understand them, they had to be dirty and they were banned from the radio. Well, because many of these people choose not to understand the intricacies of pharmaceutical pricing, it tends to become a big legal Rorschach test.

But I think that the litigation the last few years has really caused many people to be much more concerned and careful about just the language they use, just shortening it because it can be misinterpreted but [...] just because of the specialized language. [In] pharmaceuticals in general, because we are dealing with governmental and distribution and reimbursement and all these other systems in place, some bright young attorneys can find a phrase and twist it to be whatever they want. So, you know, I wish I could say, *Watch it, these are the pitfalls,* but it gets spun the way people want to spin it.

Q. What do you see as the upcoming trends or "next big thing" with pharmaceutical pricing?

A. Well, I think the next big wave — and this has been predicted in the U.S. for years — is that we will have some level of technology assessment organization at the national level that will determine whether the price is appropriate relative to the value of the product. BlueCross BlueShield Institute has already got something like that in place. Whether that becomes the national standard, I don't know. What that can do is [...] bring some levels of rationality to the system, but probably not. The British have NICE, the National Institute for Health and Clinical Excellence, that was supposed to do that, and now they are overturning their decisions right and left, and patients are dying right and left. I don't know other than let's wait and see what the next round of litigation is about.



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