

Vol. 1 No. 3 July 2008

PROTE: *Solutio*

SOLUTIONS FOR YOU

Interview With Professor Richard A. Nagareda

Author of Mass Torts in a World of Settlement

In-House Ambiguity

Privilege, Waivers, and Risks

FDA Premarketing Guidance

Risk Management Prior to Approval





DEAR CLIENTS:

More so than ever before, in the world at large and the healthcare industry in particular, knowledge is power. In this issue of *Pro Te: Solutio*, available exclusively to Butler Snow Pharmaceutical, Medical Device, and Healthcare Industry clients, we'd like to offer insights that can enrich your base of knowledge and add to your ability to see and assess risks early in the game.

In the healthcare industry, mass tort litigation is an ever-present possibility. So what's new? In his book, *Mass Torts in a World of Settlement*, Professor Richard A. Nagareda of Vanderbilt University gets "on the ground" with real-world issues confronting lawyers and litigants. An interview with Nagareda in this issue explains his premise on making peace in mass torts and how innovative attorneys are creating value for their clients.

Also in this issue, what happens during the premarketing phase of a new drug can have long lasting implications. Find out how to help alleviate concern and mitigate exposure with a summary of the FDA's *Guidance for Industry: Premarketing Risk Assessment*.

Just as important as knowing what data is crucial for submitting a New Drug Application, is understanding the rules of disclosure surrounding payments to physicians — especially when they may be changing to include medical device manufacturers. Learn more about current and proposed legislation as well as industry recommendations.

At Butler Snow, our relationship with our clients extends across evolving issues, geography, and time. We value that relationship and wish to provide you with a diversity of resources and information, including those found in *Pro Te: Solutio*. We welcome your input and reactions to this publication. Please contact us by phone or email, and let us know what other topics might be of interest to you. Our ultimate goal is to make a difference for those dedicated to making a difference in the lives of others.



CHRISTY D. JONES
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PRO Tē: *Solutio*

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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 Tē: 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 Tē: Solutio is a quarterly magazine available only to the clients of Butler Snow. While not a substitute for focused legal advice, through this medium, we share with you our viewpoints on approaches to issues you may face. If you have questions or comments about its articles, you're invited to contact group co-chairs Christy Jones and Charles Johnson, or any of the attorneys listed on the last page of this publication.

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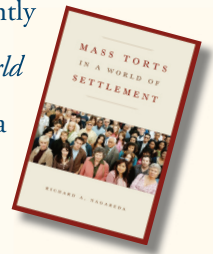
An Interview with Professor Richard A. Nagareda of Vanderbilt University Law School





PROFESSOR RICHARD A. NAGAREDA is director of the Cecil D. Branstetter Litigation and Dispute Resolution Program at Vanderbilt University Law School in Nashville, Tennessee, and is an authority on mass tort litigation. Last year he released a new book, *Mass Torts in a World of Settlement* (Univ. of Chicago Press), that has been a conversation-starter in the mass tort world. 🍷 Five years ago, Professor Nagareda taught me the rules of evidence.

He has won Vanderbilt's Hartman Award for teaching in the upper-level curriculum and currently holds the Tarkington Chair in Teaching Excellence. He has put his pedagogical skill to work in *Mass Torts in a World of Settlement*, proposing and defending a new way of looking at the mass tort world. Professor Nagareda offers a unique perspective as a scholar because prior to entering the "ivory tower" he practiced with the Department of Justice and with a private firm in Washington, D.C. He has described his book as "on the ground" in that it deals with real world issues being confronted by lawyers and litigants in the here and now of mass torts. 🍷 He graciously lent his time to answer some questions about his book, his scholarship, and his observations on today's mass tort climate.



Ben Scott: One of the major themes of your book is your argument that "a conception of mass torts primarily as a litigation problem obscures the reality that litigation operates as the prelude to administration" and that sometimes we "pound the square peg of mass torts into the round hole of

litigation." Can you give a brief summary of what you mean by that and why you see it as a problem that needs to be solved?

Prof. Nagareda: Whenever plaintiffs in mass tort litigation can make a credible threat to prevail at trial, everyone understands what the endgame will be. The end-

game will consist of some effort to resolve the litigation in whole, or at least in substantial part, by moving claims out of the tort system and into some form of private administrative compensation regime. The basic move here is the same one that tort law made in the early twentieth century in

the area of workers' compensation. We can label the vehicle for this move however we want — as a class action settlement, as a reorganization plan in bankruptcy, or as a series of private contracts with the major

behind reality here. Rather, it's legal doctrine that's lagging behind what sophisticated lawyers understand we need to do. My book isn't like many that one sees coming out of the academy these days. It

one were left to slog through the tort system for years. That being so, manufacturers should regard this form of "litigation" not so much as litigation in the courtroom sense but, rather, as another form of business transaction. The consequence is that folks on the business side of things shouldn't just give over the management of the matter to the folks "in legal." War is too important to be left to generals. So, too, one might say that mass tort litigation is too important to be left to litigators.

Scott: What are the practical, real-world benefits that manufacturers and their counsel can gain from taking a wider view of mass torts as an administrative challenge rather than simply high-volume litigation?

Nagareda: The benefit is to understand that making peace means creating value. For manufacturers, this value lies primarily in the gains from removing the overhang on the firm's share price and the inhibition of its markets for capital associated with ongoing mass tort litigation. To unlock that value, manufacturers and their counsel need to see the full range of options on the table — everything from contract-based approaches (as in the recent Vioxx deal) to prepackaged reorganizations in

plaintiffs' law firms involved. But the endgame will involve shifting from tort to administration. One of the core arguments in my book is that the law of mass torts hasn't caught up with this reality. Rather, it remains nostalgic for a past world that doesn't exist — one in which each individual claimant is entitled to her proverbial "day in court" and to all the autonomy in the resolution of her individual claim that comes with that stylized ideal. When the endgame of mass torts is a form of mass administration, notions of individual autonomy drawn from a bygone era hinder our thinking more than they help. One can't develop sensible solutions to any problem without first recognizing, in an unsentimental way, what the nature of the problem is in the first place.

Scott: What do you find to be the areas in which lawyers are mired in the past and slow to catch up to and be open to a new conception of mass tort? Particularly as to defense counsel?

Nagareda: Interestingly enough, it's not the lawyers on either side who are lagging

proceeds from a core respect for and appreciation of what real lawyers actually do in the real world. It's the lawyers in mass torts who are forward-looking and innovative, not the law.

Scott: What do you find to be the areas in which manufacturers seem to be slow to accept or adapt to mass tort, not simply as a new type of litigation, but as a new type of legal challenge altogether?

Nagareda: Making peace in mass tort litigation means putting together a complex business transaction — a deal that may well

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be worth just as much to the defendant manufacturer as any merger or leveraged buyout. Making peace means *creating value* — of bringing into being resources that would not otherwise be available if every-

bankruptcy (as in much of asbestos litigation today). Law school, in a way, inhibits this sort of cross-cutting vision by conveying the impression that contracts, civil procedure, professional responsibility, and



bankruptcy are completely distinct things. As many mass tort lawyers today understand, the reality is that these are much more overlapping and contiguous things. And the tough choice for lawyers and their clients today is often which category to emphasize in order to deal with what kind of mass tort problem.

Scott: What are your thoughts with regard to “bellwether cases,” both as to whether they are a legitimate part of the mass tort resolution process and whether that means that traditional litigation expertise will likely always remain an important piece of mass tort representation?

Nagareda: This is an important and quite desirable development, even in the short period since I finished writing my book. Bellwether trials played a huge role in enabling the settling lawyers in the Vioxx litigation to get a much more accurate handle on the viability of claims in that subject area. As a result, the defense “team” for any mass tort certainly has to include genuine trial lawyers. It’s just that the team also has to include business-side people and deal-making lawyers.

Scott: What attributes would you counsel drug and device manufacturers to seek in their mass tort counsel?

Nagareda: The most important attribute is the ability to see the full range of options available. Don’t hire a litigator who continues to think that contracts, professional responsibility, class actions, and bankruptcy are completely separate bodies of law. Hire someone who starts from the premise that the really innovative legal work today in mass tort litigation is being done in the uncharted areas betwixt and between these traditional categories.

Scott: You’ve said before that one of the

unique features of the mass tort landscape is that it is often the lawyers who are on the cutting edge of breaking new ground rather than judges or other governmental forces. Can you expound upon that a bit and why it is important?

Nagareda: Once one understands peace-making in mass torts as a kind of business deal-making, then it becomes clear that the

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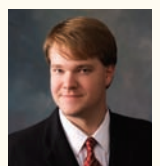
people setting the agenda are the people designing the deal. And those people are lawyers, not judges. The judges are situated in a much more reactive role. Still, I should underscore that many judges today have a much richer understanding of the real world of mass tort litigation than they did even a decade ago. My book is part of that effort, but the main movers here have clearly been lawyers, not academics.

Scott: You don’t stop at describing the unique world of mass tort, you propose a real-world solution of an administrative structure to govern resolution of mass tort claim rather than the ill-fit model of individual litigation. Can you briefly state the nature of your solution and why it may be appealing to manufacturers?

Nagareda: The hard question with which the law of mass torts continues to struggle is this: How can the law legitimately substitute a private compensation system for claimants’ preexisting right to sue in tort?

That’s the central question, regardless of the particular means selected to make that substitution. The core argument at the end of my book is that, once one recognizes that the basic move here is from tort to administration, our thinking should open up to consideration of the role that public administrative bodies might play in legitimizing the deal. The approach sketched in my

book offers manufacturers a *quid pro quo*: You can get real closure and real peace, but you need to acknowledge that what’s going on isn’t purely a private deal. Changing the compensation rules for people prospectively has a public dimension and accordingly should involve public institutions — not, I might add, to dictate solutions but, instead, to lend the force of law to sensible compromises crafted by private lawyers. All of this is in keeping with receptiveness in this country today to notions of genuine collaboration between the private and public sectors. Government cannot and should not try to solve every problem. But there is a role for government to enable and facilitate privately-crafted solutions.



INTERVIEW by BEN SCOTT



IN-HOUSE COUNSEL AND THE INTERNAL INVESTIGATION: WHAT HAVE YOU GOT TO LOSE?



AS A CONTEMPORARY IN-HOUSE COUNSEL, you probably provide more than just legal advice to your client. You wear multiple hats; in fact, you've got a whole closet full. Sometimes you're a legal advisor, sometimes a business counselor, sometimes a management consultant. Therein lies the problem when it is time to launch an internal investigation triggered by an employee complaint, a product concern, or threatened litigation. We think we know the basics: Communications between attorneys and their clients are privileged, and work prepared in anticipation of litigation is protected. Well, not so fast.

You'd better check to make sure you're wearing the right hat before you launch your investigation because you (and your client) have a lot to lose if you grab the wrong one. In fact, where the objectivity and independence of the investigation are crucial (e.g., where the results may be provided to a regulatory body), it may be wise to pass the hat to outside counsel.

A strong grasp on the basics of each potentially applicable privilege is essential in navigating the murky waters that often surround internal investigations. The attorney-client privilege, the work-product doctrine, and self-critical evaluation privilege may provide

protection, but each has strict requirements and can be inadvertently waived. Understanding the implications of waiver and knowing what you can do to more carefully preserve these privileges may save your job — and your company's reputation.

THE ATTORNEY-CLIENT PRIVILEGE

Generally, communications between clients and their attorneys are privileged. One of the requirements for the privilege to apply, however, is that the client must have sought legal advice, service, or assistance, as opposed to mere business advice. Accordingly, the attorney-client privilege does not

protect against discovery of business advice or underlying facts merely because those facts have been communicated to an attorney.¹ Thus, while it has long been established that a corporation may assert the attorney-client privilege to protect its communications with counsel,² if a communication sought to be protected by the privilege contains both legal and business advice, the privilege only applies to the legal opinions or advice. A close call may not fall in your favor. The burden will be on you, the party asserting the privilege, to demonstrate how each document satisfies all the elements of the privilege.³





WHILE IT HAS LONG BEEN ESTABLISHED THAT A CORPORATION MAY ASSERT THE ATTORNEY-CLIENT PRIVILEGE TO PROTECT ITS COMMUNICATIONS WITH COUNSEL, IF A COMMUNICATION SOUGHT TO BE PROTECTED BY THE PRIVILEGE CONTAINS BOTH LEGAL AND BUSINESS ADVICE, THE PRIVILEGE ONLY APPLIES TO THE LEGAL OPINIONS OR ADVICE.

Waiver of the attorney-client privilege may occur when there is a breach of confidentiality, whether inadvertent or intentional.⁴ Accordingly, the presence of a third party during a legal consultation will waive the privilege unless that party's presence was necessary to assist the attorney in rendering legal services.⁵ Similarly, intentional disclosure of attorney-client communications to a third party lacking a common legal interest will result in a waiver of the attorney-client privilege.⁶ Moreover, some courts have held that even if confidential work product is produced to a potential adversary under a confidentiality agreement, confidentiality has been voluntarily breached.⁷ Even disclosure of privileged information directly to a client's independent auditor, accountant, or tax analyst may destroy confidentiality.⁸ Simply put, the prevailing view is that once a client waives the privilege to one party, the privilege is waived to all.⁹

SELECTIVE WAIVER

Some courts, however, have recognized that a client may "selectively" waive the privilege under certain circumstances, most notably when disclosing to governmental entities. Unfortunately, "the case law addressing the issue of limited waiver [is] in a state of 'hopeless confusion.'"¹⁰

In one of the earliest reported decisions to address the issue, *Diversified Indus., Inc., v. Meredith*, the Eighth Circuit established the selective waiver doctrine, which provides that a party may disclose attorney-client privileged information to governmental agencies conducting an investigation without waiving the attorney-client privilege to

WAIVER OF THE ATTORNEY-CLIENT PRIVILEGE MAY OCCUR WHEN THERE IS A BREACH OF CONFIDENTIALITY, WHETHER INADVERTENT OR INTENTIONAL.

other parties (i.e. later litigants).¹¹ The Eighth Circuit reasoned that selective waiver is necessary because it encourages "corporations to employ independent outside counsel to investigate and advise them in order to protect stockholders, potential stockholders, and customers."¹²

After enjoying initial acceptance, the *Diversified* decision has since been routinely criticized and eventually rejected by a majority of jurisdictions that have addressed the issue. The District of Columbia, First,

Third, and Sixth Circuits have completely rejected the idea that the attorney-client privilege is not waived by virtue of the selective waiver doctrine by production to the government, even if the government and the company enter into a confidentiality agreement.¹³ The Federal, Second and Fourth Circuits have rejected the selective waiver doctrine but have not addressed it in a context in which the company and government entered into a confidentiality agreement.¹⁴ Indeed, "every other circuit to consider the matter has rejected the Eighth Circuit's [selective waiver] approach."¹⁵

Thus, in the context of an intentional or voluntary waiver of attorney-client privilege, counsel should assume that "when the client voluntarily discloses a confidential communication, the waiver will extend not only to the disclosed communication, but also to whatever additional communications must be provided to the third party in order to give that party a fair chance to meet the advantages gained by the privilege holder through the disclosure."¹⁶ Accordingly, courts refer to the waiver as extending to the subject matter of the disclosed communication. A client may not selectively waive only those communications that are favorable and then resist disclosure of the remaining portions of related correspondence that may be unfavorable.¹⁷

WORK-PRODUCT DOCTRINE

The work-product doctrine “is distinct from and broader than the attorney-client privilege.”¹⁸ The work-product doctrine protects from discovery materials prepared in anticipation of litigation.¹⁹ In a majority of jurisdictions, the privilege can apply where litigation is not imminent, “as long as the primary motivating purpose behind the creation of the document was to aid in possible future litigation.”²⁰ Protection extends to documents and tangible things, including a lawyer’s research, analysis of legal theories, mental impressions, notes, and memoranda of witness statements.²¹

Most courts have recognized that internal corporate investigations are conducted in anticipation of litigation and thus enjoy work-product protection. The Supreme Court in *Upjohn Co. v. U.S.*, while not expressly stating so, assumed that counsel’s notes of an internal investigation as to possibly illegal foreign payments were in anticipation of litigation.²² The *Upjohn* opinion supports treating internal investigations of corporate misconduct as having been done in anticipation of litigation, even when no action had as yet been filed or threatened.

Documents prepared for business reasons, as opposed to anticipation of litigation, are not entitled to protection. Accordingly, in *U.S. v. Gulf Oil Corp.* the court held that documents concerning a declaratory judgment action and prepared by counsel at the request of the company’s accountants were not work product.²³ The court reasoned that the documents were not created to assist in litigation but rather “for the business purpose of compiling financial statements which would satisfy the requirements of the federal securities laws” and thus were not entitled to the privilege.

Moreover, disclosure to the government or regulatory agencies such as the FDA may waive privileges related to the subject of the investigation. Waiver of work-product protection, however, generally is not construed as broadly as waiver of attorney-client privilege.²⁴

When evaluating the scope of work-product protection, or the implications of waiver,

courts draw sharp distinction between “fact” work product and “opinion” work product. So-called “fact” work product, the “written or oral information transmitted to the attorney and recorded as conveyed by the client,”²⁵ may be obtained upon a showing of substantial need and inability to otherwise obtain without material hardship.²⁶ However, absent waiver, a party may not obtain the “opinion” work product of his adversary; i.e., “any material reflecting the attorney’s mental impressions, opinions, conclusions, judgments, or legal theories.”²⁷

Furthermore, many of the reasons for disallowing selective waiver in the attorney-client privilege context also apply to the work-product doctrine.²⁸ Applying this logic to circumstances in which a corporation had disclosed work product to a governmental entity pursuant to a confidentiality agreement, the courts have held that the disclosure was still a waiver of work-product immunity.²⁹ Similarly, courts have routinely rejected the argument that governmental entities merely investigating potential wrongdoing are not “adverse” for purposes of waiver.³⁰

In contrast to waiver of the attorney-client privilege, the waiver of work-product immunity will generally be limited to the materials actually disclosed.³¹ The case law related to waiver, particularly in the context of governmental investigations is rapidly evolving with conflicting cases throughout the nation. However, a number of district courts have held that a broader or subject matter waiver of work-product immunity occurs when:

[I]t would be inconsistent with the purposes of the work product privilege to limit the waiver to the actual documents disclosed [...for example,] when the facts relevant to a narrow issue are in dispute and have been disclosed in such a way that it would be unfair to deny the other party access to other facts relevant to the same subject matter.³²

As noted by one court, for instance, complete subject matter waiver of work product has been found where a party deliberately

disclosed work product in order to gain a “tactical advantage.”³³

Applying similar reasoning, other courts have found subject-matter waiver only if “facts relevant to a particular, narrow subject matter have been disclosed in circumstances in which it would be unfair to deny the other party an opportunity to discover other relevant facts with respect to that subject matter.”³⁴ Similarly, in cases when the party making the disclosure uses the disclosed

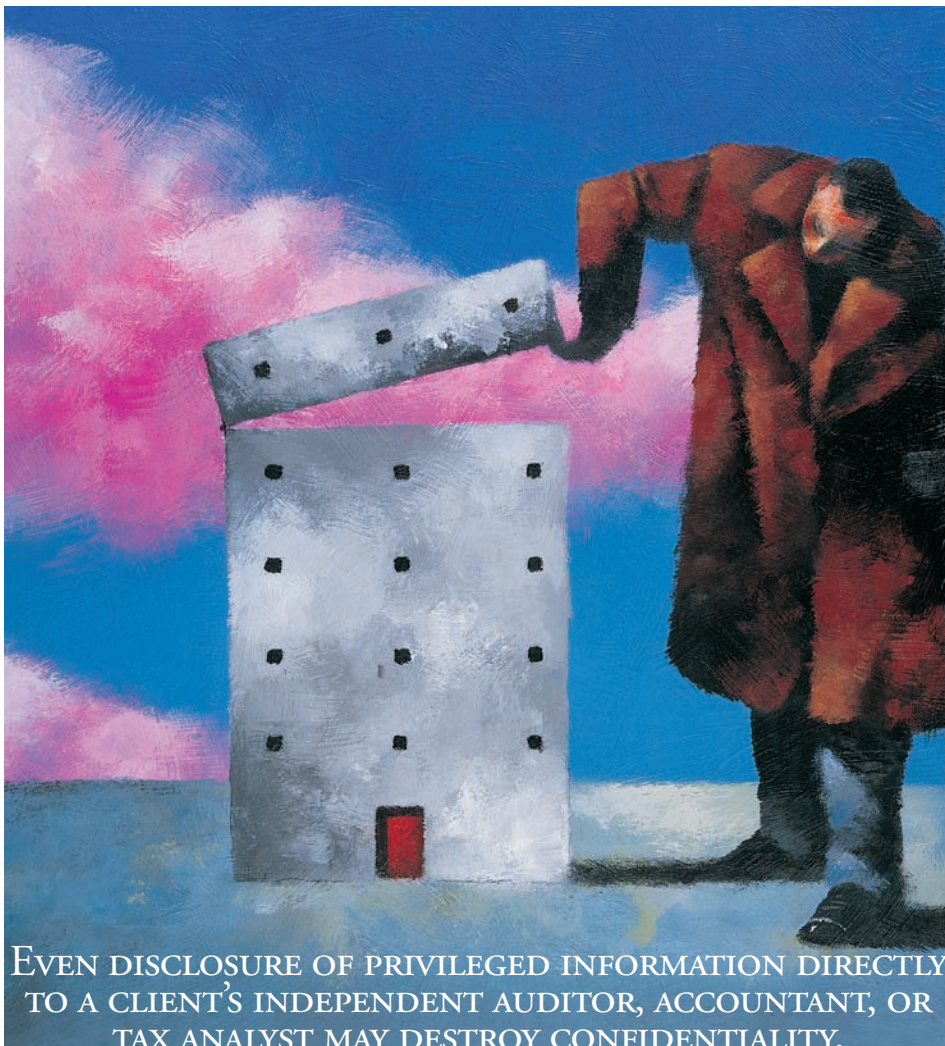
MOST COURTS HAVE RECOGNIZED THAT INTERNAL CORPORATE INVESTIGATIONS ARE CONDUCTED IN ANTI- CIPATION OF LITIGATION AND THUS ENJOY WORK- PRODUCT PROTECTION.

matter to its advantage in some way, then the opposing party should have the option of using other documents dealing with the same subject matter that may cast a different light on the issue.³⁵

SELF-CRITICAL ANALYSIS PRIVILEGE

Less frequently, corporations seek protection by claiming a self-critical evaluation privilege. The self-critical analysis privilege is a relatively recent common law development, finding its origins approximately thirty years ago in a case involving medical peer review procedures.³⁶ Although enjoying initial acceptance and limited expansion, currently the self-critical analysis privilege is not widely accepted and is not uniformly applied.

The development of this privilege has primarily remained at the federal level. Although some state courts recognize the self-critical analysis privilege, the majority have either refused to recognize the privilege or have not addressed the issue.³⁷ While there remain a number of federal district courts which at least recognize the possible existence of the doctrine, today there are only a few circuits which have embraced the



EVEN DISCLOSURE OF PRIVILEGED INFORMATION DIRECTLY TO A CLIENT'S INDEPENDENT AUDITOR, ACCOUNTANT, OR TAX ANALYST MAY DESTROY CONFIDENTIALITY.

self-critical analysis privilege. The Ninth Circuit is among the minority which has continued to recognize the privilege and in *Dowling v. American Hawaii Cruises, Inc.*, articulated the most often cited criteria that must be established by the party seeking protection.³⁸ First, the information must result from a critical self-analysis undertaken by the party seeking protection; second, the public must have a strong interest in preserving the free flow of information respecting the subject matter; third, the information must be of the type that the free flow would cease if the privilege is not recognized. Lastly, any document produced as a result of the self-critical analysis must be produced in the expectation of confidentiality, and it must actually have been kept confidential.³⁹

Even within those limited courts which recognize the privilege, these criteria are strictly applied, and the scope has been consistently narrowed.⁴⁰ For example, examin-

ing the first prong of this four part test, one district court has explained that "the touchstone of self-critical analysis is that it is an 'in house' review undertaken primarily, if not exclusively, for the purpose of internal

**IF OUTSIDE COUNSEL IS
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quality control."⁴¹ The same court explained that where documents had also been prepared in order to defend a lawsuit and perhaps to "marshal evidence to present to the media in an effort to ease any public concern," the privilege was wholly inapplicable because there was no meaningful risk of

chilling the flow of information.⁴² Instead, the court suggested that the work-product doctrine "applies the appropriate framework."⁴³

Whether asserting the privilege pursuant to statute or the common law privilege of self-critical evaluation, those documents which are prepared primarily for the purposes of in-house evaluation and compliance with regulatory programs stand the best chance of attaining privileged status. Any attempt by a corporation to characterize the fruits of an investigation as being motivated primarily by anything other than the anticipation of litigation, however, could have a negative impact on the ability to assert the work-product privilege, which is the broader and more established privilege.⁴⁴

MINIMIZING RISK

As the duties of in-house counsel expand, the risk associated with their sometimes amorphous role grows. Reducing any ambiguity greatly enhances the potential for preserving privileges. Investigations conducted purely by in-house counsel increase the risk of inadvertent waiver. In the case of potentially serious allegations or where objectivity is crucial, outside counsel working closely with corporate counsel may be the wisest choice. If outside counsel is retained, a well-drafted engagement letter should clearly identify the purpose of seeking legal advice relating to potential litigation. To further earmark investigations as privileged — and certainly in cases where outside counsel is not involved — the board or high-ranking management should formally request legal advice from in-house counsel. Regardless, both in-house and outside counsel should separate legal advice from business advice wherever feasible. Attorney-client communications should be clearly labeled, and confidential exchanges should be labeled as such.

Although the investigation may incorporate an internal team made up of non-lawyers, the team should be clearly identified and include only those necessary to complete a thorough investigation. All responsibilities and communications should be

channeled through counsel. Furthermore, written communications and email should be minimized with strict instructions regarding distribution. Information gathered from or by third-parties for investigatory purposes should be gathered at the request of counsel. Drafts should be kept at a minimum and should be clearly labeled. Inadvertent mistakes made early in the investigation, though innocent, may not be able to be undone. Taking these basic steps at the initiation of an investigation will go far in laying the groundwork for a successful assertion of privilege in the future.

¹ “[H]iring lawyers to do consultants’ work does not bring a privilege into play,” *Burden Weeks v. Welch*, 319 F.3d 897, 899 (7th Cir. 2003); see also, *U.S. v. Evans*, 113 F.3d 1457, 1463 (7th Cir. 1997).

² *Upjohn Co. v. U.S.*, 449 U.S. 383, 390, 101 S. Ct. 677, 66 L. Ed.2d 584 (1981).

³ *Hodges, Grant & Kaufmann v. U.S.*, 768 F.2d 719, 721 (5th Cir.1985).

⁴ See *Ferko v. Nat’l Ass’n For Stock Car Auto Racing, Inc.*, 218 F.R.D. 125, 134 (E.D. Tex.2003).

⁵ *Evans*, 113. at 1464.

⁶ *In re Auclair*, 961 F.2d 65, 69 (5th Cir.1992); *Ferko*, 218 F.R.D. at 134.

⁷ *Republic of Philippines v. Westinghouse Elec. Corp.*, 132 F.R.D. 384, 390 (D.N.J. 1990).

⁸ See *U.S. v. El Paso Co.*, 682 F.2d 530, 539 (5th Cir.1982); *Ferko*, 218 F.R.D. at 134-35.

⁹ See, e.g., *Westinghouse*, 951 F.2d at 1424.

¹⁰ *In re Columbia/HCA Healthcare*, 293 F.3d 289 (6th Cir. 2002), quoting *In re M & L Business Machine Company, Inc.*, 161 B.R. 689, 696 (D. Col. 1993).

¹¹ 572 F.2d 596, 611 (8th Cir. 1977).

¹² *Id.*

¹³ See *Permian Corp. v. U.S.*, 665 F.2d 1214, 1220 (D.C. Cir.1981); *U.S. v. Mass. Inst. of Tech.*, 129 F.3d 681, 686 (1st Cir. 1997); *Westinghouse Elec. Corp. v. Republic of Philippines*, 951 F.2d 1414, 1424-25 (3rd Cir. 1991); *In re Columbia/HCA Healthcare Corp Billing Practices Litigation*, 293 F.3d 289 (6th Cir. 2002).

¹⁴ *Genentech, Inc., v. U.S. Int’l Trade Comm’n*, 122 F.3d 1409, 1417 (Fed. Cir. 1997); *In re John Doe Corp.*, 675 F.2d 482, 489 (2d Cir. 1982); *In re Martin Marietta Corp.*, 856 F.2d 619, 623-24 (4th Cir. 1988).

¹⁵ *In re Syncor ERISA Litig.*, 229 F.R.D. 636, 646 (C.D. Cal. 2005). More importantly, the court found that neither the attorney-client privilege nor the work-product doctrine applied to some of the documents in question “since those documents were created with the intent to disclose them to the Government, if necessary, to benefit Syncor in any governmental investigation; thus, they were never privileged.” *Id.* at 645 (citations omitted).

¹⁶ Rice, *Attorney-Client Privilege in the United States*, Second Edition at §9:79, pp. 357-359 (West Group, 1999).

¹⁷ *Id.* at 360-361; see also *U.S. v. Rakes*, 136 F.3d 1, 5 (1st Cir. 1998) (the restriction against selective waiver is a matter of public policy). Proposed Federal Rule of Evidence 502, which was passed by the Senate in February 2008, would limit subject matter waiver in the event that a party discloses information covered by attorney-client privilege or attorney work-product doctrine, particularly if disclosure is inadvertent. While prior drafts of Proposed Rule 502 provided for selective waiver where communications or information is disclosed to governmental entities, that provision was stricken in the face of significant opposition.

¹⁸ *In re Antitrust Grand Jury*, 805 F.2d at 163, quoting *United States v. Nobles*, 422 U.S. 225, 238 n. 11, 95 S. Ct. 2160, 2170 n. 11, 45 L.Ed.2d 141 (1975).

¹⁹ Fed. R. Civ. P. 26(b)(3); *In re Grand Jury Proceedings*, 601 F.2d 162, 171 (5th Cir. 1979).

²⁰ *El Paso*, 682 F.2d at 542.

²¹ *Ferko*, 218 F.R.D. at 136, citing *Dunn v. State Farm Fire & Cas. Co.*, 927 F.2d 869, 875 (5th Cir.1991).

²² *Upjohn Co. v. U.S.*, 449 U.S. 383, 398-403 (1981).

²³ *U.S. v. Gulf Oil Corp.*, 760 F.2d 292 (Emer. Ct. App. 1985).

²⁴ *Picard Chemical, Inc., Profit Sharing Plan v. Perrigo Co.*, 951 F. Supp. 679, 689 (W.D. Mich. 1996), citing *In re Grand Jury*, 106 F.R.D. 255, 257 (D.N.H. 1985); *Handgards*, 413 F. Supp. at 929. See also *Permian*, 665 F.2d at 1219 (“We conclude, then, that while the mere showing of a voluntary disclosure to a third person will generally suffice to show waiver of the attorney-client privilege, it should not suffice in itself for waiver of the work-product privilege.”); *Freeport-McMoran Sulphur, LLC v. Mike Mullen Energy*, 2004 WL 1237450, *8 (E.D. La. June 2, 2004); *In re Broadcom Corp. Securities Litigation*, 2005 WL 1403513 *3 (C.D. Cal.), citing *Handgards, Inc., v. Johnson & Johnson*, 413 F. Supp. 926, 929 (N.D. Cal. 1976); *Key v. U.S. Bancorp Disability Income Plan*, 1988 WL 114929 *3 (D. Or. Oct.27, 1988).

²⁵ *In re Antitrust Grand Jury*, 805 F.2d at 163.

²⁶ See, e.g., *Toledo Edison Co. v. Technologies, Ind.*, 847 F.2d 335, 339-40 (6th Cir. 1988).

²⁷ *In re Antitrust Grand Jury*, 805 F.2d at 163-64 (citations omitted). See, e.g., *In re Qwest Commc’ns Int’l*, 450 F.3d 1179, 1186 (10th Cir. 2006); *In re EchoStar Commc’ns Corp.*, 448 F.3d 1294, 1302 (Fed.Cir.2006); *Tenn. Laborers Health & Welfare Fund v. Columbia/HCA Healthcare Corp.*, 293 F.3d 289, 294 (6th Cir. 2002); *Baker v. General Motors Corp.*, 209 F.3d 1051, 1054 (8th Cir.2000); *Better Gov’t Bureau v. McGraw*, 106 F.3d 582, 607 (4th Cir. 1997); *Sporck v. Peil*, 759 F.2d 312, 316 (3d Cir. 1985).

²⁸ *In re Columbia/HCA*, 293 F.3d at 306 (“Other than the fact that the initial waiver must be to an ‘adversary,’ there is no compelling reason for differentiating waiver of work product from waiver of attorney-client privilege.”).

²⁹ *Brady*, 238 F.R.D. 444-45.

³⁰ *U.S. v. Bergonzi*, 216 F.R.D. 487 (N.D. Cal. 2003).

³¹ *Brady*, 238 F.R.D. at 444. See *Varel v. Banc One Capital Partners, Inc.*, 1997 WL 86457, at *9 (N.D. Tex. 1997).

³² *S.E.C. v. Brady*, 238 F.R.D. 429, 444 (N.D. Tex. 2006)(citing *Varel*, 1997 WL 86457 at *3). See also *Brady*, 238 F.R.D. at 444 (citing *U.S. v. Nobles*, 422 U.S. 225, 228, 95 S. Ct. 2160, 45 L.Ed.2d 141 (1975)); *In re United Mine Workers*, 159 F.R.D. 307, 310-12 (D.D.C.1994).

³³ *Varel v. Banc One Capital Partners, Inc.*, 1997 WL 86457 at *9, citing *United States v. Nobles*, 422 U.S. 225, 228, 95 S. Ct. 2160, 45 L.Ed.2d 141 (1975); *In re United Mine Workers*, 159 F.R.D. at 310-12, citing cases.

³⁴ *Hercules, Inc., v. Exxon Corp.*, 434 F. Supp. 136 (D. Del. 1977).

³⁵ *In re Grand Jury Subpoena*, 341 F.3d 331, 336-37 (4th Cir. 2003)(finding the party waived the attorney-client privilege with regard to the entire subject matter of the disclosure).

³⁶ *Bredice v. Doctor’s Hospital*, 50 F.R.D. 249 (D.D.C. 1970), aff’d, 479 F.2d 920 (D.C. Cir. 1973).

³⁷ See, e.g., *Wells Dairy, Inc., v. Am. Industrial Refrigeration*, 690 N.W.2d 38 (Iowa 2004)(“We decline to judicially extend the self-critical analysis privilege . . .”); *Payton v New Jersey Turnpike Auth.*, 691 A2d 321 (N.J. 1997)(the self-critical analysis privilege does not exist in the common law); *Univ. of Kentucky v. Courier-Journal & Louisville Times Co.*, 830 SW2d 373 (Ky. 1992); *Scroggins v. Uniden Corp. of Am.*, 506 NE2d 83 (Ind. App. 1987) (Indiana courts only recognize statutory privileges, thus no common-law privilege for self-critical analysis exists); *Southern Bell Tel. & Tel. Co. v. Beard*, 597 So2d 873 (Fla. App. 1992) (all privileges in Florida are statutory, thus no common-law privilege for self-critical analysis exists); *Combined Communications Corp., Inc., v. Public Service Co. of Colo.*, 865 P2d 893 (Colo. App. 1993) (stating that self-critical analysis privilege does not exist in Colorado, although applied self-critical analysis to facts of case and held that it did not apply); *Cloud v. Superior Ct.*, 50 Cal. App. 4th 1552 (1996) (self-critical analysis privilege not in evidence code, and therefore does not exist in California); *Grimes v. DSC Communications Corp.*, 724 A2d 561 (Del. Ch. 1998); *Harris-Lewis v. Mudge*, 1999 WL 98589 (Mass. Super. 1999); *Office of Consumer Counsel v. Dept. of Pub. Util. Control*, 665 A2d 921 (Conn. Super. 1994); *Lamitie v. Emerson Elec. Co.-White Rodgers Div.*, 142 AD 2d 293 (N.Y. App. 1988).

³⁸ *Dowling v. American Hawaii Cruises, Inc.*, 971 F.2d 423, 425-426 (9th Cir. 1992).

³⁹ *Id.* But see *Union Pac. R.R. v. Mower*, 219 F.3d 1069, 1076 (9th Cir. 2000) (stating that the Ninth Circuit has never adopted the privilege).

⁴⁰ See *Ludwig v. Pilkington N. Am., Inc.*, 2004 WL 1898238 at *1-2 (N.D. Ill. 2004), reviewing cases.

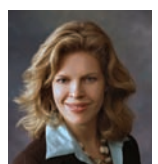
⁴¹ *In re Air Crash Near Cali., Colombia on December 20, 1995*, 959 F. Supp. 1529 (S.D. Fla. 1997).

⁴² *Id.*

⁴³ *Id.* at 1533.

⁴⁴ See *Lawndale Restoration v. Accordia of Illinois*, 853 N.E.2d 791 (Ill. App. 2006) (finding that because the party seeking the privilege first claimed the documents were prepared for the purposes of self evaluation, then those documents were not entitled to the work-product privilege as they were not prepared in anticipation of litigation).

WRITTEN by AMY M. PEPKE



Risk Management Prior to Approval for New Drugs

A SUMMARY OF FDA'S
GUIDANCE FOR INDUSTRY: PREMARKETING RISK ASSESSMENT

“We’ve been served” are words that no one wants to hear, especially when it concerns a new product. There are steps, however, that can be taken prior to launch that may help alleviate some concern and mitigate some exposure. The United States Department of Health and Human Services, Food and Drug Administration, and Center for Drug Evaluation and Research (collectively referred to as “FDA”) published in March 2005 a *Guidance for Industry: Pre-marketing Risk Assessment*. In it, FDA sets out several nonbinding recommendations

for assessing risks associated with new medicines. Although adherence is not required, it generally is quite helpful to be able to show a jury that you followed the practices recommended by FDA prior to submitting your New Drug Application (“NDA”).

I. INTRODUCTION

Risk management involves essentially two processes: risk assessment and risk minimization. Management of risk is an evolving function that continues throughout the lifecycle of the product but, naturally, should

be initiated during development. It begins with evaluating the new medicine’s risk/benefit ratio. Once risks and benefits are separately identified, tools may be designed to lower the risks and preserve, or even elevate, the benefits. After implementing those tools, the sponsor must determine whether they are effective. In other words, the first step should be repeated: re-evaluate the risk/benefit ratio to determine any improvement. Finally, based on the follow-up evaluation, the sponsor should adjust the tools as appropriate (and, again, evaluate the ratio).



MANAGEMENT OF *risk* IS AN *evolving* FUNCTION THAT CONTINUES *throughout* THE
LIFECYCLE *of the* PRODUCT BUT, NATURALLY, SHOULD BE *initiated* DURING *development*.

IT *begins* WITH EVALUATING THE NEW MEDICINE’S *risk/benefit* RATIO.



RISK

BENEFIT

While this process should be conducted prior to marketing the medicine in order to secure an acceptable risk/benefit ratio, it should continue after approval. New safety concerns always appear after approval — when larger and more diverse populations are exposed for longer periods of time. As such, the ratio may change, which in turn, may require the implementation of new risk management tools. Risk assessment and minimization is a never-ending process.

Sponsors are required by FDA's regulations to assess risk and attempt to minimize it during development and after approval. FDA pointed out in the *Guidance*, however, that these regulations “establish requirements for *routine* risk assessment and risk minimization.”¹ Perhaps due in part to recent withdrawals, FDA noted that the *Guidance's* recommendations focus on the non-routine — the unusual type of risk or the unusual level of risk.

II. RISK ASSESSMENT

So, what is meant by “risk assessment,” and how is it accomplished? In a nutshell, “assessment” means “identification.” The sponsor must identify the nature of the risk associated with the medicine. What is the frequency of the risk? How often does the risk occur? When does it occur? In which populations does it occur? Additionally, part of the nature of the risk is its severity. Is it life-threatening, or will its effects be felt for life? Again, although this process must continue throughout the product's lifecycle, an adequate premarketing assessment is crucial for at least two reasons: First, FDA requires it prior to approval. Second, a jury

requires it prior to a defense verdict.

Deciding whether a risk assessment is “adequate” — specifically during Phase 3 studies — depends on the amount of information gathered, how the information is presented and analyzed, and the nature of the information. Adequate risk assessment is a matter of quantity and quality. Quantity is the number of patients studied. Quality is the design of the clinical trials to include appropriate (broad, diverse) patient populations, consideration of the appropriate reactions in the populations, and reasonable analysis of the results.

III. GATHERING THE INFORMATION

Before an assessment begins, there must be something to assess. Information must be generated. But, as FDA notes, “[p]roviding detailed guidance on what constitutes an adequate safety database for all products is impossible.”² In other words, the specific drug will dictate the necessary contents of the safety database. Prior to approval, FDA considers known risks and unanswered questions versus demonstrated benefits. Thus, in addition to gathering information about efficacy, it behooves sponsors to design clinical trials so as to maximize the amount of safety information. For instance, if preclinical data suggests a potential problem, a trial should be designed to target that problem. Or, if related drugs already on the market have generated suspicious post-market safety information, a trial to address those suspicions should be designed. FDA addresses four main areas to guide sponsors with respect to developing an adequate safety database.

A. POPULATION SIZE MATTERS

New safety concerns always arise after approval because the medicine generally is used by more people, for longer periods of time, with different medical histories, and with different concomitant drug use. Even the largest clinical trial simply cannot mimic real world use. However, the larger the pre-approval database and the more comprehensive the information in that database, the better. Certain factors might dictate when additional efforts should be made:

- The therapy is novel
- The effects of the proposed medicine are already safely available
- The proposed population is especially vulnerable
- The proposed duration of use is long-term

Generally, smaller safety databases may be appropriate when the disease being treated is life-threatening and there is no adequate alternative. In such situations, it is more acceptable to have less certainty concerning safety because the disease itself is so serious. The converse is true as well: Use larger databases for not-so-serious illnesses. Additionally, safety signals gathered from preclinical data also may warrant a larger trial. If concerns are raised and no in-house consensus formed, FDA suggests discussing the matter with the appropriate review division.

Although FDA does not offer much guidance with respect to the appropriate size of the safety database for new medicines developed for acute use, the agency specifically recommends 1,500 patients for products



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ADEQUATE *risk* assessment IS A MATTER OF *quantity* AND *quality*.



SPONSORS ALSO MUST *ensure* THAT THEY TEST THE MEDICINE IN A *sufficiently diverse*, YET ADEQUATELY *representative*, POPULATION. THE *safety database*, TO THE EXTENT *feasible* AND *ethical*, SHOULD MIMIC *real-world* USE. A *wide* POPULATION SPECTRUM *allows* FOR SAFETY INFORMATION *to be* DEVELOPED FROM *individuals* LIKE THE ELDERLY, THOSE WITH CONCOMITANT *disease states*, OR PERSONS INGESTING *concomitant drugs*.

intended for use six months or longer (cumulative or continuous treatment). Three to six hundred should be exposed for six months, and at least one hundred should be exposed for a year. In addition to exposure time, sponsors should design trials to include different dosing regimens, including doses above the amount sought for marketing.

As always, certain signals may exist that should prompt sponsors to propose larger trials. These may include: indications that the medicine is associated with adverse events that develop later or that increase in frequency or severity; serious adverse events may have been observed in earlier trials; an adequate alternative may exist; the overall benefit achieved from the medicine is small; or the condition sought to be treated has a high rate of mortality or morbidity. A larger database may be necessary to distinguish between the baseline rate and that seen with the medicine. Larger databases likewise may be appropriate when the intended population is healthy (i.e., vaccines).

B. DESIGN MATTERS

Once the sponsor determines the size of the safety database, several other considerations come into play. Oftentimes, the total database is comprised of multiple clinical trials. In such situations, it is imperative to coordinate terminology (so that investigators from each trial describe the same events similarly and the statistical rates of adverse events are not masked by differing lingo) and methods of assessment (so that investigators from each trial actually record similar events).

Sponsors also must ensure that they test the medicine in a sufficiently diverse, yet adequately representative, population. The safety database, to the extent feasible and ethical, should mimic real-world use. A wide population spectrum allows for safety information to be developed from individuals like the elderly, those with concomitant disease states, or persons ingesting concomitant drugs. In fact, clinical trials could be designed to specifically target interactions that may occur with expected concomitant drug use or expected concomitant disease states or even common concomitant dietary supplements.

There may also be instances when sponsors should consider designing trials to generate comparative safety information. In other words, it may be advantageous to compare the new medicine to an active control. For instance, if the class of drugs is such that a high rate of adverse events is expected, then a direct comparison may demonstrate that the new drug does not have a higher rate than the class. There may be certain scenarios where it is unethical to use a placebo instead of a comparator. And, of course, where the sponsor intends to claim better safety or efficacy, the sponsor should have the data from a direct comparison to back up that claim.

Finally, Phase 3 trials should incorporate differing dosing regimens. This is especially true when Phase 2 trials have not established a dose level. Data gathered from differing dose responses may be quite helpful in establishing both safety and efficacy or in demonstrating that exceeding the recom-

mended dose raises the risk without raising the benefit. FDA recommends that sponsors meet with the review division at the completion of Phase 2 to discuss studying dose levels.

IV. SPECIAL CONSIDERATIONS

Specific concerns can help tailor the type of assessment strategies sponsors should employ, the type of data that should be sought. For instance, if the product has an unusually long half-life, trials with differing doses may generate helpful information. If an expected adverse event is not likely to be reported by the patients, the investigators may need instructions to pay special attention to certain facts or to make certain inquiries of the patients. Sponsors may wish to retain patient samples (blood, tissue) from Phase 3 for later examination if signals warrant.

Data from trials also can be used to assess medication errors — errors caused by similar names or similar packaging. Errors may occur from the presentation of the product (i.e., if the medicine should be diluted prior to use but is presented in a form capable of direct ingestion prior to dilution). Analysis of medication errors and their causes should be assessed and addressed in the premarket stage. Sponsors are encouraged to use experts, direct observation during trials, interviews of consumers and pharmacists, and focus groups to determine how best to minimize these risks.

Although FDA makes few specific across-the-board recommendations in this *Guidance*, the agency specifically sets out a list of



FDA PRESENTS *several* RECOMMENDATIONS TO SPONSORS *concerning steps*
THAT SHOULD BE TAKEN TO MAKE AN ADEQUATE *premarketing risk assessment* AND HOW
TO *present* THAT ASSESSMENT IN THE NDA. ABIDING BY FDA'S RECOMMENDATIONS *or* CREATING
A *thorough* AUDIT TRAIL OTHERWISE GENERALLY WILL BE HELPFUL IN *not only* OBTAINING
AN *approval letter* BUT ALSO IN OBTAINING A *defense verdict*.

certain adverse events that should be assessed in NDAs for small molecule drugs: QTc prolongation, liver toxicity, nephrotoxicity, bone marrow toxicity, drug interactions, polymorphic metabolism.³ Most of these adverse events arose in a constellation of withdrawn drugs. Sponsors and FDA alike suffer when withdrawal becomes a reality, so if analysis of specific adverse events can lessen the likelihood of a withdrawal, it should be performed.

V. PRESENTING THE INFORMATION

Most Phase 3 studies are directed towards efficacy. FDA's point with this Guidance, however, is that safety should not be relegated to a back seat. In one sense, sponsors should place a big net under their Phase 3 trials to catch all of the safety data available. One way to ensure accurate identification of safety signals is to ensure that investigators describe and code adverse events consistently. Throughout Phase 3, sponsors should use one dictionary and one coding convention. Additionally, sponsors should perform audits prior to analysis of the safety database to determine the extent of any variability with respect to coding. Acknowledging that product development may be years in duration, subsequent versions of dictionaries and coding conventions should be avoided as much as possible. However, the same version should be used for analysis and for proposed labeling.

FDA recommends that sponsors prospectively develop definitions and group expected adverse event terms. All such definitions and groupings, of course, must be adequately

explained in the NDA so that the reviewers clearly understand the information. Sponsors also should avoid characterizing syndromes and withdrawals from trials with single terms. Further explanation is required. Was the withdrawal due to a safety concern or simply because the patient moved from the area? Sponsors should take adequate follow-up measures to ascertain specific information.

Temporal associations must be critically considered as well and accurately reported. This includes the time between exposure and the adverse event but also involves the total duration of the adverse event itself. Analyzing changes in both over time (i.e., long-term intermittent use leads to shorter duration of AE) is crucial to a full understanding of the total safety profile. Study of concomitant drug use also should be considered temporally. Does a concomitant drug decrease the length of time between exposure and AE? Or does a concomitant therapy increase the actual length of the AE?

The use of pooled data can be problematic as well when sponsors consider how to report the information gleaned from pooled trials. For instance, if a single trial detected a serious adverse event but the total pooled analysis lessened the risk below statistical significance, is it proper to ignore the single trial? It depends. Sometimes, pooled analysis protects against too much weight being given to chance happenings. At the same time, if the single trial is superior in design or if it considered a distinct population, it may be worthwhile for the sponsor to

separately report the findings. Factors to consider when deciding whether to pool data include any differences in duration or dose and distinct differences in population groups. FDA specifically recommends "[w]hen there is clinical heterogeneity among trials with regard to the safety outcome of interest [...], sponsors should present risk information that details the range of results observed in the individual studies, rather than producing a summary value from a pooled analysis."⁴

VI. CONCLUSION

FDA presents several recommendations to sponsors concerning steps that should be taken to make an adequate premarketing risk assessment and how to present that assessment in the NDA. Abiding by FDA's recommendations or creating a thorough audit trail otherwise generally will be helpful in not only obtaining an approval letter but also in obtaining a defense verdict.

¹ *Guidance*, at 4. (Emphasis in original.)

² *Guidance*, at 5.

³ *Guidance*, at 16.

⁴ *Guidance*, at 22.



WRITTEN BY KARI SUTHERLAND



WHAT STATES HAVE STATUTORY LIMITATIONS ON DAMAGES IN PERSONAL INJURY OR WRONGFUL DEATH ACTIONS?

THE FOLLOWING STATES HAVE PLACED LIMITS ON EITHER NON-ECONOMIC DAMAGES, THE TOTAL AMOUNT RECOVERABLE AGAINST A HEALTHCARE PROVIDER OR INSTITUTION, OR PUNITIVE DAMAGES IN PERSONAL INJURY OR WRONGFUL DEATH ACTIONS:

Alaska: ALASKA STAT. §09.55.549 (2007) limits total non-economic damages based on wrongful death or personal injury to \$250,000. If the damages include loss of consortium, the total recoverable damages are \$400,000.

Arkansas: ARK. CODE ANN. §16-55-208 (2007): In calculating the punitive damages, plaintiff may receive no more than the greater of \$250,000 or three times the amount of compensatory damages, not to exceed \$1 million (adjusted for inflation).

California: CA. CIV. CODE §3333.2 (2007) limits non-economic damages to \$250,000. This cap has been interpreted to extend to past and future non-economic damages reduced to a lump sum. *Salgado v. County of Los Angeles*, 967 P.2d 585 (1998).

Colorado: COLO. REV. ST. §13-64-302 (2007) limits all damages against healthcare providers to \$1 million and non-economic damages to \$250,000.

Florida: FLA. ST. §766.207 (2007) limits non-economic damages to \$250,000.

Georgia: GA. CODE ANN. §51-12-5.1 (2007) limits punitive damages to \$250,000 except in cases where the defendant acted intentionally or under the influence of drugs or alcohol, and here no limitations on punitive damages exist. Under §51-13-1, non-economic damages are limited to \$350,000 per medical provider or a single medical facility; if there is more than one medical facility, the total damages against multiple facilities may not exceed \$700,000.

Hawaii: HAW. REV. STAT. §663-8.7 (2007) caps pain and suffering damages at \$375,000.

Idaho: IDAHO CODE ANN. §6-1603 (2007) places a maximum \$250,000 limitation on non-economic damages (adjusted for inflation). Under §6-1604, punitive damages are limited to the greater of \$250,000 or three times the amount of compensatory damages awarded.

Indiana: IND. CODE §34-18-14-3 (2007) limits the total recovery of damages in wrongful death actions to \$1.25 million and the total portion of damages recoverable from a healthcare provider to \$250,000 if the act of malpractice occurs after June 30, 1999. Under IND. CODE §34-51-3-4 (2007), the plaintiff may recover maximum punitive damages of the greater of three times the amount of compensatory damages or \$50,000.

Kansas: KAN. STAT. ANN. §60-3701 (2007) limits exemplary and punitive damages to the lesser of \$5 million or defendant's highest gross annual income as calculated in the previous five years.

Louisiana: LA. REV. STAT. ANN. §40:1299.42 (2007) placed a statutory limitation on all medical damages recoverable for physical injury or wrongful death to \$500,000. *But see Arrington v. Galen-Med, Inc.*, 970 So.2d 540 (La. Cr. App. 2007) (constitutional challenge pending).

Maine: ME. REV. STAT. ANN. tit. 18-A, §2-804 (1997) caps non-economic damages for wrongful death at \$150,000, and punitive damages are limited to \$75,000.

Maryland: MD. CODE ANN., Cts. & Jud. Proc. §11-108 (1997) limits non-economic damages for any personal injury cause of action for medical malpractice to \$710,000 (increasing by \$15,000 every October 1). The statute applies to wrongful death cases as well as personal injury, with the total damages recovered by all beneficiaries limited to 150% of the cap.

Massachusetts: MASS. GEN. LAWS Ch. 231, §60H (2007) limits punitive damages to \$500,000 except for certain situations including permanent bodily loss or impairment or substantial disfigurement.

Michigan: MICH. COM. LAWS §600.1483 (2007) caps non-economic damages recoverable in a medical malpractice action at \$280,000 for all the plaintiffs unless a specific situation is present (brain or spinal injury, permanent cognitive impairment, etc.).

Mississippi: MISS. CODE ANN. §11-1-60 (2007) limits any non-economic damages received in a suit filed after September 1, 2004, to \$1 million; any suit filed before September 1, 2004, will have non-economic damages limited to \$500,000. MISS. CODE ANN. §11-1-65 (2007) caps punitive damages on a sliding-scale method, with the cap decreasing as defendant's net worth decreases.

Missouri: MO. REV. STAT. §538.210 (1988) provides a statutory limit, adjusted every January 1, on a claimant's recovery of non-economic damages in any medical malpractice action.

Montana: MONT. CODE ANN. §25-9-411 (2007) caps non-economic damages per plaintiff at \$250,000 based on a single incident of malpractice against one or more healthcare providers. MONT. CODE ANN. §27-1-220 (2007) limits punitive damages to \$10 million or 3% of the defendant's net worth, whichever is less; however, this limitation does not apply in class action lawsuits.

Nevada: NEV. REV. STAT. §41A.035 (2007) caps non-economic damages at \$350,000 in injury or wrongful death actions against a healthcare provider. NEV. REV. STAT. §42.005 (2007) limits exemplary and punitive damages to three times the amount of recovered compensatory damages if those damages are greater than \$100,000, or if the compensatory damages are less than \$100,000, the exemplary and punitive damages awarded is capped at \$300,000.

New Jersey: N.J. STAT. ANN. §2A:15-5.14 (2007) limits the amount of punitive damages recoverable to either five times the amount of awarded compensatory damages or \$350,000, whichever is greater.

New Mexico: N.M. STAT. §41-5-6 (2007) limits the aggregate recoverable amount for all persons incident to injury or death as a result of malpractice to \$600,000. This amount, however, does not include punitive damages and medical care and related benefits. An individual healthcare provider's liability is limited to \$200,000.

North Carolina: N.C. GEN. STAT. §1D-25 (2007) caps punitive damages at the greater of \$250,000 or three times the amount of compensatory damages.

North Dakota: N.D. CENT. CODE §32-42-02 (2007) places total limitations of \$500,000 on punitive damages awards in physical injury or wrongful death actions against healthcare providers, regardless of the number of defendants or causes of action. N.D. CENT. CODE §26.1-14-11 (2007) places additional limitations concerning insured parties: If the insured has coverage with a limit of at least \$500,000, then the insured is not liable for damages in excess of these limits.

Ohio: OHIO REV. CODE ANN. §2323.43 (2008) limits non-economic damages to the greater of \$250,000 or three times the amount of economic loss. The statute also places a total cap of \$350,000 for each plaintiff or \$500,000 for each occurrence.

Oklahoma: OKLA. STAT. §1-1708.1F (2007) caps non-economic damages in medical malpractice actions, except wrongful death actions, to \$300,000, regardless of the number of defendants or number of actions brought.

Pennsylvania: 40 PA. STAT. ANN. §1303.505 (2007) limits punitive damages against a physician to 200% of compensatory damages, except in cases of intentional misconduct.

South Carolina: S.C. CODE ANN. §15-32-220 (2007) limits non-economic damages to \$350,000 per claimant for claims against a single healthcare provider. If the claim is against multiple healthcare providers, non-economic damages are limited to a total of \$1,050,000.

South Dakota: S.D. CODIFIED LAWS §21-3-11 (2007) limits non-economic damages in medical malpractice actions to \$500,000.

Texas: TEX. CIV. PRAC. & REM. CODE ANN. §74.301 (2007) limits non-economic damages in medical malpractice claims against healthcare providers and institutions to a total of \$250,000 per claimant, regardless of the number of actions asserted or the number of healthcare providers/physicians named. TEX. CIV. PRAC. & REM. §74.303 (2007) limits both economic and non-economic damages, including exemplary damages, to a total \$500,000, adjusted for inflation, with the addition of any necessary medical or custodial care costs in wrongful death actions. TEX. CIV. PRAC. & REM. CODE ANN. §41.008 (2007) limits exemplary damages to greater of: (1) two times the amount of economic damages plus an amount equal to non-economic damages; or, (2) \$200,000.

Utah: UTAH CODE ANN. §78-14-7.1 (2007) caps non-economic damages in medical malpractice actions at \$250,000.

Virginia: VA. CODE ANN. §8.01-581.15 (2008) places a cap on all damages in medical malpractice cases. For actions accruing before August 1, 1999, the cap is \$1 million; for actions accruing between August 1, 1999, and July 1, 2000, the cap is \$1.5 million; and for actions accruing after that date, the cap is increased annually every July 1 by \$50,000; for 2007, the increase is \$75,000; and the final increase will be \$75,000 on July 1, 2008 (bringing the cap to \$1.95 million).

West Virginia: W. VA. CODE §55-7B-8 (1994) limits non-economic damages to \$1 million in a medical malpractice action brought against a healthcare provider.

Wisconsin: WIS. STAT. ANN. §893.55 (1997) limits non-economic damages in any medical malpractice case, except wrongful death actions, from all healthcare providers to \$350,000, adjusted annually for inflation. WIS. STAT. ANN. §895.04 (1997) limits non-economic damages in wrongful death actions to \$350,000 for the death of an adult and \$500,000 for the death of a minor.

The following states have attempted to limit damages. In each case, the legislation was struck down when the state supreme court found it to be unconstitutional:

Alabama: ALA. CODE §6-5-547 (2007) provides an absolute limit to wrongful death actions against a healthcare provider to \$1 million. In *Mutual Assurance, Inc., v. Schulte*, 970 So.2d 292, 293 (Ala. 2007), however, the Supreme Court of Alabama held this provision violated the right to a jury trial as provided in the Alabama Constitution.

Illinois: Although 735 ILL. COMP. ST. 5/2-1115.1 (1997) limited non-economic damages, the Illinois Supreme Court held this provision arbitrary and not rationally related to the legislative interest in reducing state-wide tort litigation costs.¹ The Court also found the damages limitation violated the separation of powers doctrine by undercutting the judiciary's responsibility to reduce excessive judgments and by unduly expanding the remitter doctrine.²

New Hampshire: N.H. REV. STAT. ANN. §507-C:7 (2007) placed a limit of \$250,000 on non-economic damages; however, the Supreme Court of New Hampshire held this limitation unconstitutional in *Carson v. Maurer*, 424 A.2d 825 (N.H. 1980). The court found the limitation violated equal protection guarantees because it precluded only the most seriously injured victims of medical negligence from receiving full damages for their injuries.

Oregon: OR. REV. STAT. §31.710 (2007) was enacted to place a \$500,000 monetary cap on non-economic damages recoverable under tort actions; however, in *Lakin v. Senco Products, Inc.*, 987 P.2d 463 (Or. 1999), the Supreme Court of Oregon found this cap unconstitutional because it infringed on factual issues left to the jury and thus violated the right to a trial by jury as guaranteed by the Oregon Constitution.

Washington: WASH. REV. CODE ANN. §4.56.250 (1988) placed a limitation on non-economic damages; however, in *Soffe v. Fireboard Corp.*, 771 P.2d 711 (Wa. 1980), the Supreme Court of Washington held that the statute was an unconstitutional violation of the right to trial by jury.

The following states have placed no limitations on damages:

Arizona
Connecticut
Delaware
Iowa
Kentucky
Minnesota
Nebraska
New York
Tennessee
Vermont
Wyoming

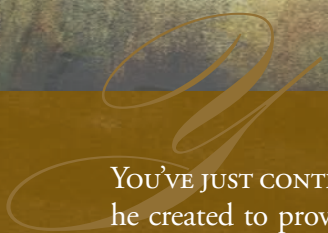
¹ *Best v. Taylor Machine Works*, 689 N.E.2d 1057 (Ill. 1997).

² *Id.* at 1076-80.

The background of the entire page is a stylized sunburst pattern in shades of blue and yellow, radiating from the top center. At the bottom, there are three sunflowers with yellow petals and brown centers, growing from a dark brown base. The title 'TRUST THROUGH TRANSPARENCY' is written in a large, bold, serif font, with the letters in a brownish-gold color that matches the sunflowers.

TRUST THROUGH TRANSPARENCY

**PROPOSED LEGISLATION REQUIRING PHYSICIAN PAYMENT
DISCLOSURE FOR MEDICAL DEVICE MANUFACTURERS.**

A decorative swirl in a brownish-gold color, matching the text and sunflowers, is located to the left of the paragraph.

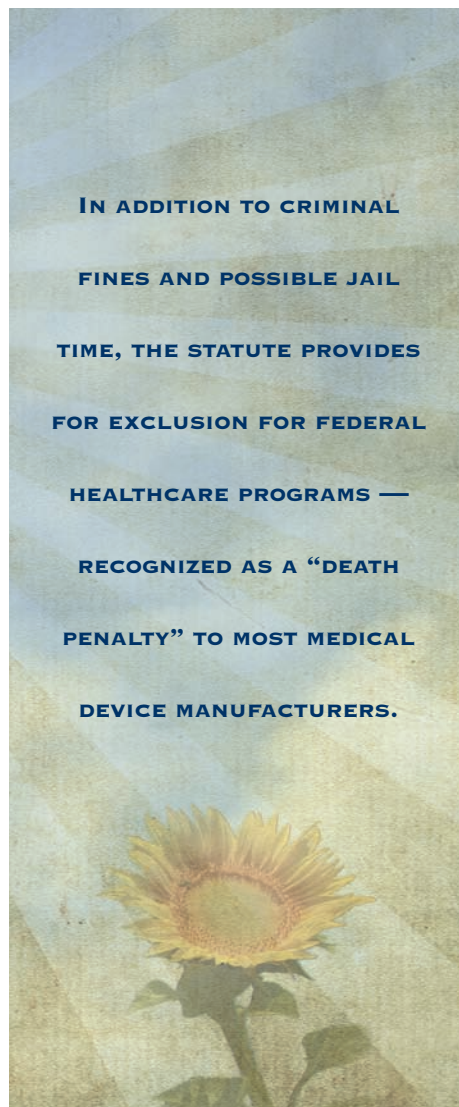
You've JUST CONTRACTED WITH A PROMINENT SURGEON to develop and market a device that he created to provide better care to his patients. Of course, your agreement provides that your company will provide compensation to that surgeon for the years of toil he spent refining his invention, whether through a lump sum payment or continuing royalty payments. As a result of this transaction, does your company have any requirement to publicize your arrangement with the surgeon? Not yet, but it may soon.

Currently, four states and the District of Columbia have laws requiring the disclosure of *pharmaceutical* company payments to physicians.¹ An additional seven states proposed similar disclosure laws in 2007.² Notably, none of the existing statutes require medical device manufacturers to report payments to physicians. Although certain public interest groups claim “there is no basis for this distinction,”³ those responsible for regulating the industry recognize that medical device manufacturers are unique from pharmaceutical companies, in that they have greater reliance on physician experience and feedback to develop better treatments for patients.⁴ Moreover, it is essential that physicians receive education and training because the effectiveness of a device often depends on a physician’s skill in using it.

That is not to say that royalty payments, consulting arrangements, paid education and travel, or other gifts to physicians from medical device manufacturers have gone unnoticed by the government. The Federal Government already uses a variety of criminal, civil, and administrative enforcement mechanisms to discourage financial arrangements that distort physicians’ professional judgment.

The Senate is currently considering adding another arrow to the government’s quiver. In September 2007, U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) introduced legislation to require manufacturers of pharmaceutical drugs, devices, and biologics to disclose the amount of money they give to doctors through payments, gifts, honoraria, travel, and other means. On February 27, 2008, the Senate Special Committee on Aging held a hearing with the ominous title “Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry.” Representative Peter DeFazio (D-OR) introduced a companion bill in the House of Representatives on March 13, 2008. The Subcommittee hopes to see the legislation included in a Medicare bill considered by the Senate this year.

This article briefly discusses the existing enforcement statutes in this area and the proposed legislation and industry recom-



mendations. As the proposed legislation is still in its formative stages, both the Senate and the House continue to encourage industry input.

EXISTING STATUTES USED BY THE FEDERAL GOVERNMENT TO PENALIZE FINANCIAL ARRANGEMENTS BETWEEN MEDICAL DEVICE MANUFACTURERS AND PHYSICIANS

The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) and the Department of Justice currently allocate substantial resources to the investigation and prosecution of medical device companies who engage in illegal schemes disguised as consulting arrangements. The False Claims Act (FCA), the federal anti-kickback statute, and the Civil Monetary Penalties (CMP) Law are the primary enforcement mechanisms through which the government addresses

what it deems to be illegal and unethical industry-physician financial relationships. Each has unique benefits to the government.

Under the FCA, the government may obtain substantial penalties against a person who knowingly submits or causes the submission of false or fraudulent claims to the federal government.⁵ The federal anti-kickback statute makes it a *criminal* offense to knowingly and willfully offer or pay remuneration to induce the referral of federal healthcare program business. The statute also criminalizes the knowing and willful solicitation or receipt of remuneration in exchange for such referrals.⁶ In addition to criminal fines and possible jail time, the statute provides for exclusion from federal healthcare programs — recognized as a “death penalty” to most medical device manufacturers.⁷

Finally, the OIG may also pursue violations of the anti-kickback statute under a provision of the CMP Law.⁸ The civil penalty is treble damages (three times the illegal remuneration), a \$50,000 fine per violation (offer, payment, solicitation, or receipt of remuneration), plus possible exclusion from participation in federal healthcare programs. Through the CMP, the OIG can pursue heavy penalties for anti-kickback violations that it proves with a simple preponderance of the evidence, a standard much easier to satisfy than the criminal standard of beyond a reasonable doubt. Moreover, cases are tried before an HHS administrative law judge, and the rules of evidence are relaxed to permit the admission of hearsay.

In recent years, the government has used each of the statutes listed above to address alleged illegal remuneration to physicians from medical device companies. For instance, in September 2007, Zimmer Inc., DePuy Orthopaedics Inc., Biomet Inc., and Smith & Nephew Inc. entered into civil settlement agreements with the government collectively totaling \$311 million to resolve allegations that the companies provided illegal inducements to physicians in the form of sham consulting agreements, lavish trips, and other perks. To avoid criminal prosecution, the companies each also entered into

an eighteen-month Deferred Prosecution Agreement (DPA) with the United States Attorney's Office.

In July 2006, Medtronic agreed to pay \$40 million to resolve allegations under the FCA that Medtronic offered kickbacks to spine surgeons to induce the doctors to choose devices marketed by a subsidiary. Medtronic also entered into a five-year Corporate Integrity Agreement (CIA) with the OIG requiring the company to put into place compliance systems as well as be subject to monitoring by an independent review organization.

In July 2007, Advance Neuromodulation Systems Inc. paid \$2.95 million in a CMP settlement and entered into a three year CIA with the OIG to resolve allegations that it paid certain physicians \$5,000 for every five new patients tested with an ANS product where the physicians provided no significant clinical value to the company.

These recent enforcement actions demonstrate that the government is committed to ferreting out physician payment schemes that it thinks improperly influence medical decision making. However, the OIG acknowledges that "it would be both inappropriate and impractical to rely solely on government enforcement to address an issue of this complexity."⁹ Not surprisingly, the OIG backs disclosure legislation as an additional tool to reduce the risks raised by financial relationships between companies and physicians.

PROPOSED PHYSICIAN PAYMENT SUNSHINE ACT

In introducing the proposed legislation, the sponsoring senators recognized that ethical relationships between surgeons and device innovators are critical to the collective mission of improving patient outcomes; however, they also decried the sometime corrosive influence financial incentives can have on physicians. In the medical device context, physicians are largely, if not solely, responsible for selecting the appropriate medical device — which often costs thousands of dollars — to be used on a patient. Through the legislation, the Special Committee on Aging hopes that subjecting industry-

physician financial relationships to reporting requirements will result in greater transparency and promote integrity. Senator Grassley believes the proposed legislation "fosters accountability by empowering consumers and other watchdogs."

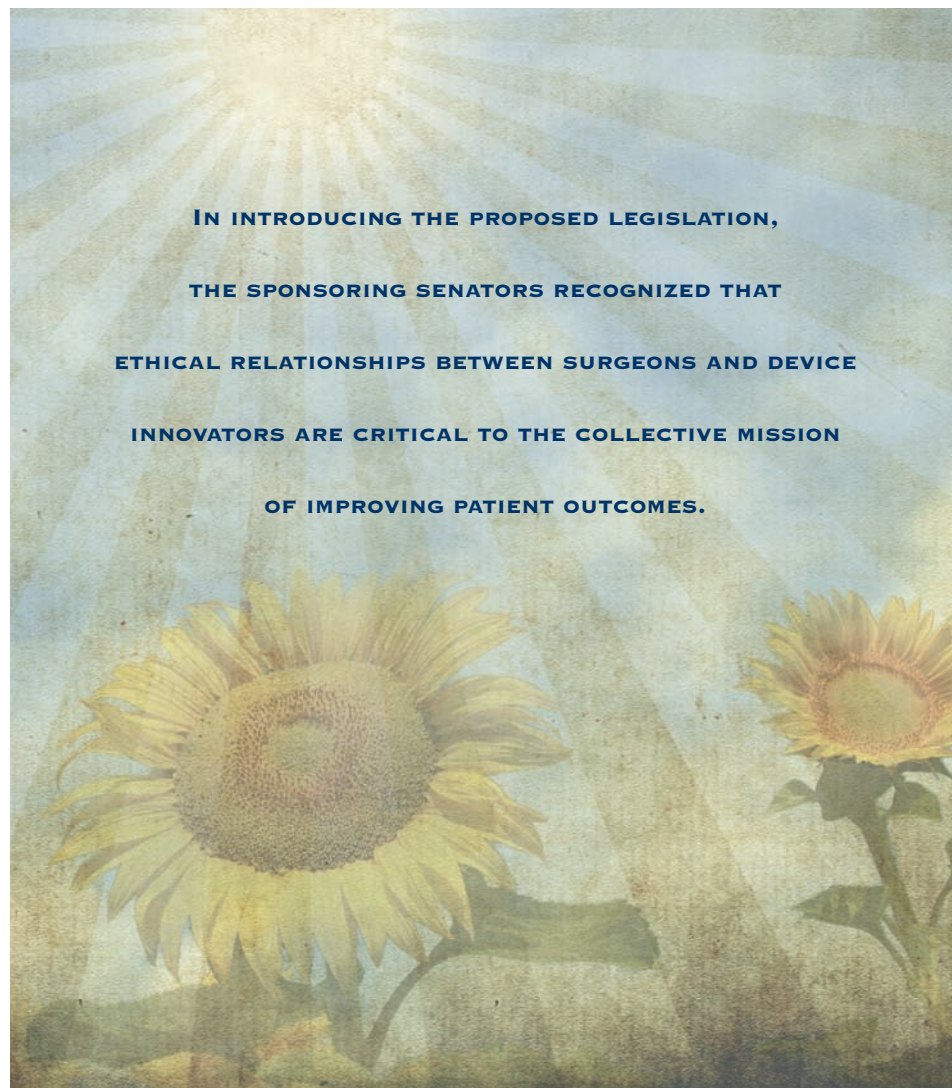
ORIGINAL LEGISLATION

The proposed legislation, S. 2029, as originally introduced in September 2007, requires manufacturers of drugs, devices, or medical supplies to submit both quarterly electronic reports and an annual

ment (payment or transfer of value includes any compensation, gift, honorarium, speaking fee, consulting fee, travel, discount, cash rebate, or services); and

- the medical issue or condition that is the basis for the transfer.

This information would then be available to the public through a website that is "easily searchable, downloadable, and understandable."¹⁰ Failure to comply with the statute could result in civil money penalties ranging from \$10,000 to \$100,000 for each act of



summary report to the Secretary of HHS identifying any payment or transfer of value over \$25 to any physician or physician's group including:

- name of physician or entity;
- value of payment;
- date of payment;
- a description of the nature of the pay-

noncompliance. The original bill applied only to companies with annual gross revenues that exceed \$100 million.

During the February hearings, the Special Committee on Aging heard testimony from representatives from OIG, The Association for Ethics in Spine Surgery, Applied Medical Resource Corporation, Styker Corporation,

Zimmer Holdings Inc., and Advanced Medical Technology Association (“AdvaMed”). All parties recognized that there had been “excesses” in the past and endorsed some form of disclosure legislation resulting in greater transparency of physician-industry collaborations. Industry representatives requested specific changes to help achieve the appropriate balance between innovation and disclosure. In addition to the testimony at the hearings, many corporations submitted written remarks and suggestions for improvements to the proposed legislation. The primary requested revisions are discussed below.

Expressly Preempt State Reporting Requirements

Most parties agree that any federal disclosure legislation should expressly preempt state reporting requirements to avoid multiple inconsistent collection and disclosure systems. As previously noted, four states and the District of Columbia already require some form of disclosure reporting for pharmaceutical manufacturers. Proposed legislation is pending in other jurisdictions that would require disclosure reporting for device manufacturers as well. In the absence of an express preemption provision, medical device manufacturers could be subject to multiple reporting systems creating heavy administrative costs. Moreover, multiple data collections in varying formats could prove confusing to consumers.

Last fall, Congress included an express preemption provision in the portion of the FDA Amendments Act requiring registration of drug and medical device clinical trials into a central database. Like the clinical trials database, express preemption in the Physician Payment Sunshine Act would create a central repository for information patients can easily access.

Allow Companies to Provide Context for Payments

As defined in the original proposed legislation, payments to physicians can take many forms ranging from royalties to paid travel. If a physician is involved in the development of a product, she may receive large

royalty payments from a medical device manufacturer for her role in the creation of the product. Similarly, a physician heavily involved in a clinical trial may receive substantial compensation even though she is paid at fair market value. To avoid the implication that any large payment to a physician is suspect, medical device manufacturers should be afforded the opportunity to provide the proper context for any given payment. To further clarify the purpose of certain payments, some manufacturers propose clearly separating out payments related to clinical research.

Require Compliance by Physician-owned Manufacturers, Distributors, and Group Purchasing Organizations

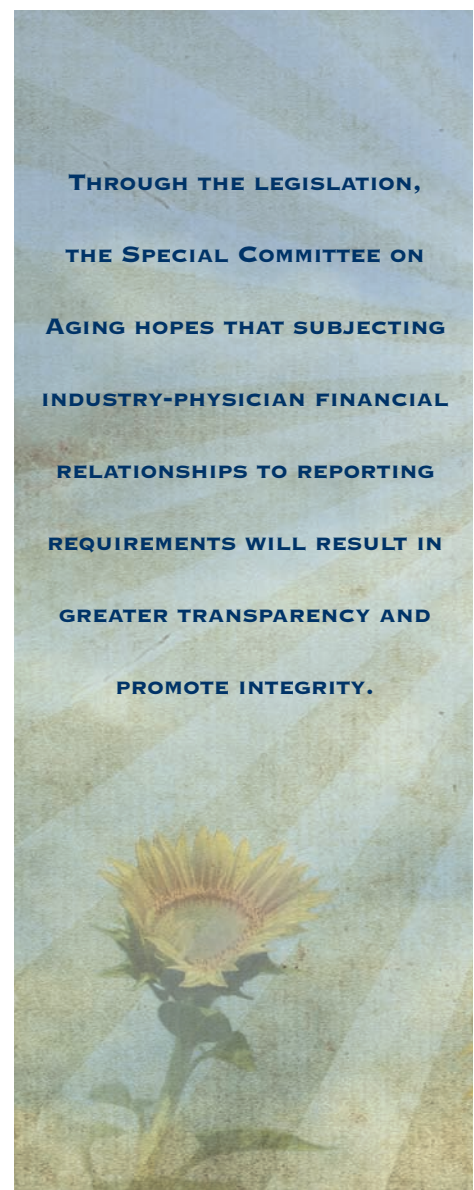
Physician ownership of medical device manufacturers and related businesses is a growing trend in the medical device sector. The OIG has closely scrutinized these relationships under the fraud and abuse laws because of “the strong potential for improper inducements between and among physician investors, the entities, device vendors, and device purchasers.”¹¹ In addition to OIG, AdvaMed also supports the inclusion of these groups in the legislation, regardless of whether such a company meets the revenue threshold originally included in the bill: “Patients should be informed about the practices of companies in which physicians have both an equity ownership interest and who are also major revenue generators for the company.”¹²

Protect Proprietary Information through Delayed Reporting

Consistent with the recently enacted clinical trials database, information about a company’s products under development through a product development agreement or a clinical trial should be disclosed only after a product is approved or cleared by the FDA or the clinical trial information is required to be posted online. This addition would protect proprietary information from competitors and help further and reward innovation.

Cap the Amount of Potential Penalties

As AdvaMed points out, under the origi-



nal legislation, accounting errors made by a manufacturer could quickly add up to millions of dollars in fines annually. Rather than decrease the amount for any single violation, AdvaMed and others in the industry recommended an annual cap on fines under the statute.

Threshold for Compliance?

Controversy remains as to whether or not smaller device manufacturers should be exempt. The first iteration of the bill required disclosures only by companies with more than \$100 million dollars in annual revenue. At hearing, Chad F. Phipps, Senior Vice President and General Counsel for Zimmer Holdings Inc. made it clear that the legislation should provide for “transparency across the board” by applying to all manufacturers

regardless of annual income. Senator Bob Corker (R-TN) agreed, stating: “Being able to abuse your way to a certain level and then have to comply in a different way doesn’t make a lot of sense.”¹³

In contrast, AdvaMed voiced the concern that smaller medical device companies may lack the resources to meet the administrative requirements set forth in the bill. Rather than the original \$100 million dollars in annual revenue threshold, AdvaMed advocates the exemption of companies that make payments to physicians of less than \$250,000 annually.

REVISED LEGISLATION

All of the revisions noted, with the exception of the threshold for compliance, have been included in the revised summary of S. 2029. Although the revisions are not included in the version of the bill available on *Thomas.gov*, the summary can be viewed as part of the Special Committee on Aging’s May 13, 2008, press release.¹⁴ According to the policy advisor with the Special Committee on Aging, although the senators will not reintroduce the legislation with the revised provisions, they will push for inclusion of those revisions as the bill works its way through the full Senate. In key part, the revised summary provides for:

- Reporting on an annual basis beginning March 31, 2011;
- Annual caps on monetary penalties for failure to report;
- Proper context for payments;
- Appeal and correction process;
- Delayed reporting for product development agreements and clinical trials;
- Express preemption of state reporting requirements;
- Application to all manufacturers regardless of annual revenue.

The following companies have written Senator Grassley confirming their support for the revised legislation and applauding the increase in transparency: Eli Lilly and Company; AstraZeneca Pharmaceuticals LP; and Merck & Co. Inc. In addition, two key trade organizations, PhRMA and AdvaMed

have endorsed the current version of the proposed legislation. Eli Lilly and Company hopes the legislation will be “an important step in building public trust in and understanding of the relationships between pharmaceutical and device industries and physicians.”¹⁵

CONCLUSION

To some extent, the transparency sought by this legislation already exists. With the OIG actively pursuing enforcement actions against pharmaceutical and medical device manufacturers involving illegal financial incentives for physicians, many companies already voluntarily publish certain financial gifts. For instance, Eli Lilly and Company reports all educational grants and charitable contributions.¹⁶ Similarly, AstraZeneca makes public their medical education grants and contributions to non-profit organizations. Other companies, such as Zimmer Holdings Inc., post the majority of information contemplated by the bill on its website pursuant to the DPA. Finally, OIG is considering requiring the disclosure requirements that are currently part of the DPA to be included in future CIAs with device and pharmaceutical companies.

Nevertheless, if the proposed bill is enacted this fall, it will impose an additional administrative burden on the medical device industry. As reflected by the revisions included in the summary of S. 2029, the Special Committee on Aging has, to date, been responsive to suggested changes from the industry that minimize the administrative burden while continuing to achieve the sought after transparency. When the bill reaches the full Senate, medical device companies and their advocates should continue monitoring the bill’s progress and offer constructive input when needed to ensure the revisions discussed in this article are included in the final bill.

New Hampshire, New York, Oregon, and Washington in 2007. Although some are carried over into the 2008 legislative session for consideration, none have passed to date. See National Conference on State Legislatures. “2007 Prescription Drug State Legislation,” February 8, 2008. Available at <<http://www.ncsl.org/programs/health/drugbill07.htm>>; National Conference on State Legislatures. “2008 Prescription Drug State Legislation,” May 28, 2008. Available at <<http://www.ncsl.org/programs/health/drugbill08.htm>>.

³ Peter Lurie, Public Citizen’s Health Research Group, et al. “Testimony on State Laws Requiring Disclosures of Pharmaceutical Company Payments to Physicians (HRG Publication #1817).” June 27, 2007. Available at <http://www.citizen.org/publications/print_release.cfm?ID=7531>.

⁴ For instance, Senator Kohl recognized that the financial relationships between the medical device industry and surgeons and physicians “can play an important role in product innovation.” Opening Statement of Senator Herb Kohl. Special Committee on Aging Hearing. “Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry.” February 27, 2008.

⁵ See 31 U.S.C. §§3729-3733.

⁶ See 28 U.S.C. §1320a-7b(b).

⁷ In his testimony before the Senate subcommittee, Chad F. Phipps, Senior Counsel and Secretary of Zimmer Holdings Inc., stated that forced withdrawal from federal healthcare reimbursement is “in effect a death penalty for a company such as ours.”

⁸ See 28 U.S.C. §1320a-7a(a)(7).

⁹ Written testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs, Special Committee on Aging Hearing. “Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry.” February 27, 2008.

¹⁰ S. 2029 §1128G(d)

¹¹ OIG Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industry, October 6, 2006. Available at <[http://oig.hhs.gov/fraud/docs/alertsandbulletins/guidancemedicaldevice%20\(2\).pdf](http://oig.hhs.gov/fraud/docs/alertsandbulletins/guidancemedicaldevice%20(2).pdf)>.

¹² Attachment to written testimony of Christopher L. White, Executive Vice President, General Counsel and Secretary of AdvaMed, Special Committee on Aging Hearing. “Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry.” February 27, 2008.

¹³ Oral testimony from Special Committee on Aging Hearing. “Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry.” February 27, 2008. Available for download at <http://aging.senate.gov/hearing_detail.cfm?id=293677&>.

¹⁴ Available at <http://aging.senate.gov/hearing_detail.cfm?id=297721&>.

¹⁵ Correspondence from John C. Lechleiter, Ph.D., President and CEO of Eli Lilly and Company to The Honorable Charles Grassley, May 12, 2008. Available at <<http://aging.senate.gov/record.cfm?id=297721>>.

¹⁶ <www.lillygrantoffice.com>.

¹ Maine, Minnesota, Vermont, West Virginia, and the District of Columbia require disclosure of certain pharmaceutical company payments to physicians. Me. Rev. Stat. Ann. Tit. 22 §2698-A; Minn. Stat. Ann. §151.47; Vt. Stat. Ann. Tit. 33 §2005; W. Va. Code ann. §5A-3C-13; D.C. Code Ann. §48-833.

² Some version of disclosure law was proposed by the legislature in Massachusetts, Mississippi, Nebraska,

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