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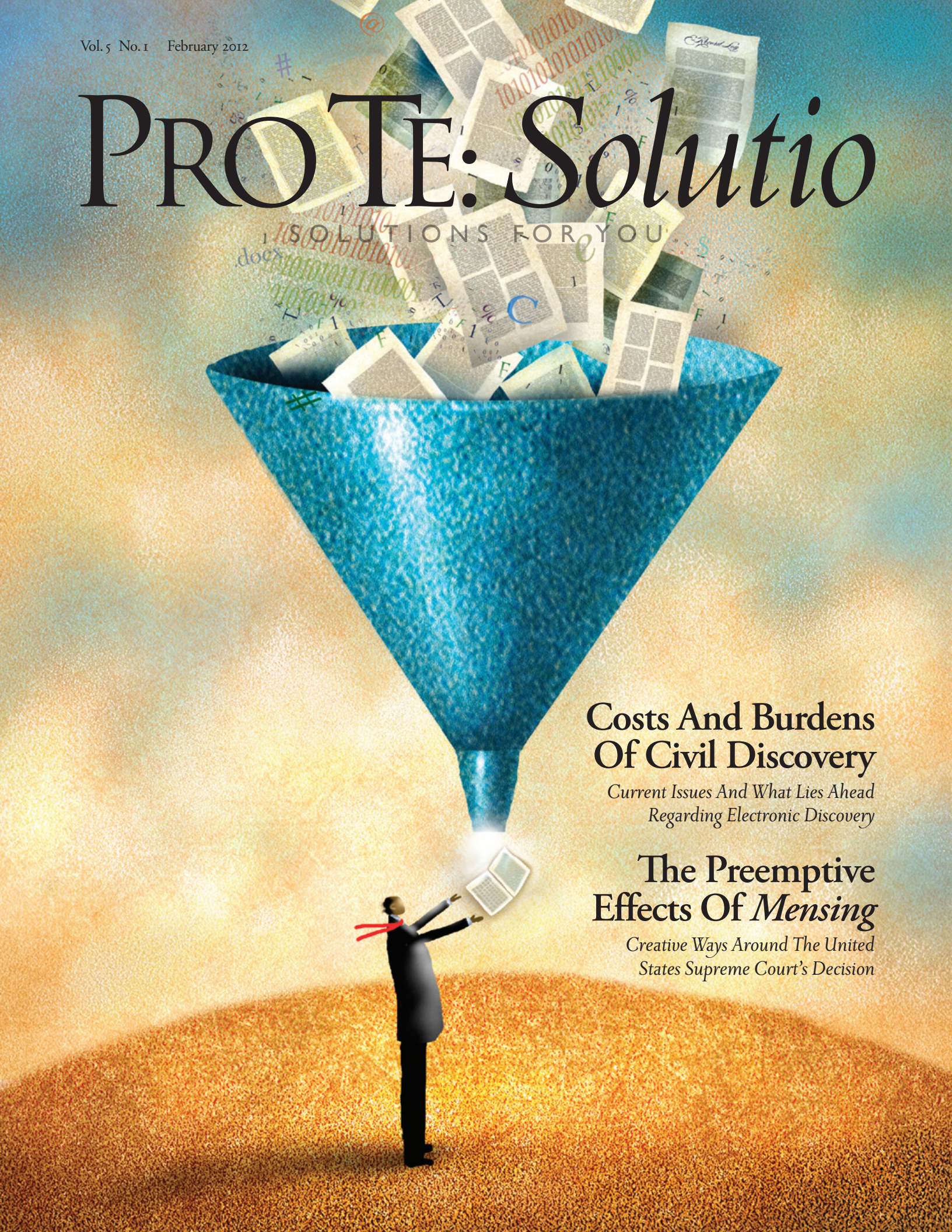
PRO TE: *Solutio*

SOLUTIONS FOR YOU



Costs And Burdens Of Civil Discovery

Current Issues And What Lies Ahead Regarding Electronic Discovery

The Preemptive Effects Of *Mensing*

Creative Ways Around The United States Supreme Court's Decision

Dear Client:

In case law and on the blogosphere, everyone is talking about e-discovery. *The Costs and Burdens of Civil Discovery* presents the current issues in discovery and offers a peek into the future with a summary of a recent Congressional hearing into proposed changes to the Federal Rules of Civil Procedure concerning e-discovery.

Few issues are as important to those in the pharmaceutical industry as the reporting of adverse events to the FDA. *"The Final Rule": FDA's Safety Reporting Requirements for Investigational New Drug Applications* summarizes the new rule issued last year.

Any company that manufactures generic drugs is well aware of *Pliva v. Mensing*, the 2011 Supreme Court case that found preemption of state law failure-to-warn claims against generic manufacturers. After that decision, some plaintiffs voluntarily dismissed their cases against generic manufacturers. Some plaintiffs' attorneys, however, are trying to avoid the broad implications of that decision. *Mensing: Preemption or Not? Plaintiffs' Creative Ways Around the Decision* discusses some of those attempts.

And in this issue, we have another one of our very comprehensive state surveys — this time as pertains to state laws regarding protective orders and confidential documents. In this issue, you will find that information for the first twenty-six states and the District of Columbia. The remaining twenty-four states will be covered in the next issue of *Pro Te Solutio*.

We know that keeping abreast of the latest legal issues in the pharmaceutical and medical device field is a challenge you face every day. We hope this issue will be helpful to you in meeting that challenge.

Christy D. Jones
Co-Chair — Litigation

Charles F. Johnson
Co-Chair —
Business and Corporate Healthcare

Pro Te: *Solutio*

Vol. 5 No. 1 February 2012

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 Christy Jones and Charles Johnson, as well as any of the attorneys listed on the last page of this publication.

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THE COSTS & BURDENS OF CIVIL DISCOVERY

Current Issues And What Lies Ahead

Introduction

It is no secret that the rising costs of discovery, due in large part to the volume of electronic data produced today, has become a hot topic in recent years. A survey of Fortune 200 companies found that, in 2008, the 36 responding companies spent a total of $4.1 billion on litigation in the United States alone, a figure which did not include judgments, settlements, or internal costs to store and retrieve electronic information.[1] Furthermore, on average, for each dollar of global profit earned in 2008, companies spent 16 to 24 cents on litigation in the U.S.[2] For the years 2006 through 2008, the companies paid an average per-case discovery cost of $621,880 to $2,993,567.[3]

Companies at the high end of this study reported costs ranging from $2,354,868 to $9,759,900 per case.[4] What do these numbers mean, you may ask? In short, it means that some feel that the current system is not working. The failure of our system to require precise pleadings and limit the scope of discovery leads to companies being forced to over-preserve electronic information, which, in turn, gets passed on to the consumer and affects the U.S. economy in a negative way. Fortunately, these issues have been recognized by the United States Judicial Conference

Rules Committee (hereafter "Judicial Conference") who, through the Advisory Committee on Civil Rules (hereafter "Civil Rules Advisory Committee"), has undertaken an initiative to study the Federal Rules of Civil Procedure. As part of its responsibility under the Rules Enabling Act, the Judicial Conference is charged with recommending amendments which promote simplicity, fairness, and just determination of litigation in Federal Courts.[5] In addition to action by the Judicial Conference, the U.S. House of Representatives has begun to monitor these issues as well. This article will give a brief background on some of the issues with the current system and will summarize the December 13, 2011, "Costs and Burdens of Civil Discovery" hearing conducted by the House Judiciary Subcommittee on the Constitution.

Issues With the Current System

In 2006, the Federal Rules of Civil Procedure were amended to address the ever-growing area of electronic discovery. Unfortunately, these amendments did very little to combat the increasing costs and inefficiencies that arise when dealing with electronically stored information. In May 2010, the Judicial Conference Standing Committee on the Rules of Practice and Procedure (hereafter "Advisory Committee on Civil Rules") held a two-day conference at Duke University Law School to begin looking into the issues that plague the current system. Numerous white papers from national organizations were submitted to the committee from both sides, those who believe a change in the rules is needed and those who think the current system is working. The side seeking amendments to the rules suggest the reforms are needed in four main areas: (1) a heightened pleading requirement; (2) a limit on discovery; (3) clearer rules on preservation and spoliation; and (4) more cost splitting between the parties.[6] For proponents of amending the rules, some of the suggested changes are:

• Pleadings — Proposed rule changes in this area would amend the current Rule 8 standard of mere notice pleading and require the heightened plausibility pleading standards enunciated in *Twombly* and *Iqbal*. Specifically, by revising this rule to heighten the pleading standard to that in *Twombly* and *Iqbal*, the doctrinal confusion that has often plagued lower courts will be eliminated. This change will also allow for a consistent standard to be applied across all civil cases, as some types of cases currently adhere to this standard.[7]

• Discovery — Suggested rule amendments would narrow the scope of discovery to claims and defenses in the litigation and would require that discovery requests be in proportion to the stakes and needs of the litigation.[8] Rule 26 would be amended in several ways to narrow the scope of discovery, including the exemption of certain categories of electronically stored information unless there is a showing of "substantial need and good cause."[9] Rule 34 would also be amended to limit the number of requests for production to no more than 25, limit the number of custodians to 10, and limit the time period for which discoverable electronic information is available to the requesting party for no more than two years prior to the date of the complaint.[10] These amendments would reduce the volume of information and evidence subject to discovery, provide a clearer standard of relevance, lessen the likelihood of litigation on discovery issues, and limit overall the costs of discovery.[11]

• Preservation/Spoliation — The proposed amendment to Rule 37(c) would permit spoliation sanctions only when willful conduct was carried out for the purpose of depriving another party's use of the destroyed evidence, if that destruction results in actual prejudice to the other party.[12] By amending this rule, the inconsistency of requirements established by various courts would be alleviated.[13] Proponents of amending the rules of preservation feel that it should also be addressed in Rule 26. A new Proposed Rule 26(h) would memorialize the duty to preserve and specifically limit the types of electronically stored information that would fall under this duty.[14]

• Cost Allocation — The suggested amendment for Rule 26 regarding cost allocation would require each party to pay the cost of the discovery it seeks.[15] According to its proponents, a requester-pays rule will encourage parties to focus the scope of their discovery requests to evidence that is reasonably calculated to lead to relevant information, as opposed to being allowed to seek broad categories of information.[16] This focus, in turn, would force litigants to analyze the merits of their case, rather than trying to force a settlement based on the excessive costs of discovery.

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Opponents of amending the Federal Rules of Civil Procedure argue that it is far too soon to amend rules that were promulgated in 2006. They argue that the current data is too flawed, inconsistent, and inconclusive and that we should give the current rules a chance to work before making amendments.[17] In addition, opponents of amending the rules to achieve bright-line guidance feel that it will lead to an increase in the litigation related to discovery and will result in unfairness to some litigants as they could be deprived of their day in court because of the nonexistence of evidence key to their case.[18] As with any argument, there is data and statistics to support both sides.

December 13th Hearing — "The Costs and Burdens of Civil Discovery"

On December 13, 2011, the House Judiciary Subcommittee on the Constitution convened a hearing titled the "Costs and Burdens of Civil Discovery" to address whether the Federal Rules of Civil Procedure need to be amended regarding the rules governing discovery, particularly the rules regarding preservation and electronic discovery. This was the first hearing of this type since the Federal Rules of Civil Procedure were last amended in 2006, a hearing which some felt was long overdue.

The hearing opened with Committee Chairman Trent Franks (R-Arizona) stating that the hearing was needed to "identify rules and regulations that impose undue costs and burdens and destroy American jobs."[19] Franks added that the current rules "appear to fall short" of encouraging a "just, speedy, and inexpensive" resolution to disputes as envisioned by the Federal Rules of Civil Procedure.[20] He stated that the current system encourages parties to bury each other in requests for data of dubious evidentiary value and that, under the current rules, the "vague standards and harsh sanctions leave parties no choice but to preserve excessive amounts of data" leading to excessive costs and burdens being placed on companies forced to preserve the data.[21] Franks concluded by arguing that rule changes must be made to combat the rising costs of discovery.

After Franks' opening statement, Rep. Jerrold Nadler (D-New York) acknowledged that electronic data discovery poses new challenges and burdens, but that discovery of electronic data "has proven particularly valuable in uncovering critical evidence and improving accountability."[22] He further urged that we should not lose sight of the tremendous benefits of discovery when weighing the costs and burdens. Nadler briefly described two examples of large-scale cases where massive discovery played a critical role. He read briefly from a Department of Justice submission stating that, without concrete empirical data, changes to the rules should not be made. Nadler finished his statement by reading a letter submitted by the Civil Rules Advisory Committee, which urged the subcommittee to "allow the Rules Committee to continue their consideration of these issues through the thorough, deliberate, and time-tested procedure Congress created in the Rules Enabling Act."[23]

Upon the completion of Nadler's statement, Rep. John Conyers (D-Michigan) voiced his skepticism about the motives behind the hearing, stating that "one-tenth of one percent of federal cases involve the level of discovery costs that are the subject of the hearing, which suggests this hearing may be based on some corporation insistence that they be heard about this matter, rather than a genuine need for rules changes."[24] He also inquired to Franks as to why no members of the Judicial Conference Advisory Committee had been invited to testify at the hearing. Franks replied that some judges on the Advisory Committee believed that it was more appropriate for that committee to convey its stance by letter, to which Conyers replied "perhaps their letter wasn't as persuasive as they had hoped," as Franks had chosen to continue the hearing anyway.[25]

After the opening statements were given, four witnesses were introduced: Rebecca Love Kourlis, executive director of the Institute for the Advancement of the American Legal System at the University of Denver and former Colorado Supreme Court Justice; William H. J. Hubbard, assistant professor of law at the University of Chicago Law School; William P. Butterfield, partner at Hausfeld LLP; and Thomas H. Hill, associate general counsel for environmental litigation and legal policy at General Electric Corporation. Each witness was asked to submit a truth in testimony written statement and were given five minutes each to summarize their positions.

The first witness to testify was Justice Kourlis, who stated ultimately that, as it is today, "the civil justice system in the United States is too expensive and too complex."[26] She went on to say that lawsuits take too long and cost too much and that the current discovery process does not lend itself to the "just, speedy, and inexpensive" system envisioned by the Federal Rules of Civil Procedure.[27] Kourlis stated that the electronic age has affected both plaintiffs and defendants alike and that the cost of discovery is frequently not proportional to the dispute at issue. In fact, Justice Kourlis pointed out that the costs of e-discovery are not only affecting large cases and defendants but cases of all sizes, plaintiffs and defendants alike. She cited a survey stating that most attorneys will not take a case unless there is a minimum $100,000 at issue.[28] She testified further that fewer cases are reaching trials on the merits and that the result is settlements due to the increasing costs of discovery. Justice Kourlis believes that the solution to fixing problems with the current system is multi-faceted — with rule changes, more effective case management by judges, and more cooperation between attorneys in the discovery process all playing a role. The rule changes, however, are the first step as they prevent a case-by-case and courtroom-by-courtroom discovery system that is present now.[29]

Professor William H. J. Hubbard was the next witness. The focus of Professor Hubbard's testimony was the excessive cost of discovery and preservation under the current rules. He stated that, although discovery for the average federal civil case costs around $12,000, these costs have a "long tail."[30] Professor Hubbard cited a study in which the top

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five percent of cases, in terms of discovery costs, accounts for 60 percent of all litigation costs in federal courts. These cases have discovery costs going into the hundreds of thousands of dollars. As for preservation, Professor Hubbard testified that the "long tail" phenomenon is present as well. He stated that because parties are required to alter their normal business activities even before a lawsuit is filed, many unnecessary costs are incurred.[31] Moreover, many of the costs associated with preservation are for cases that never go to litigation. For these reasons, the current rules are not working. In closing, Professor Hubbard stated that a change is needed and that "clear federal rules should help to reduce the ambiguity and overbreadth of current case law and to reduce the costs of civil litigation to society."[32]

The committee then heard testimony from William Butterfield. Mr. Butterfield, the lone witness calling for no change in the rules, stated that discovery costs are generally proportional to the stakes in the litigation and to change the rules "for a few thousand" of the 300,000 cases filed in federal court per year would pose a "substantial risk" to the civil justice system.[33] Mr. Butterfield argued that the proponents of rule changes are choosing to focus on the outliers (the cases in the "long tail" discussed by Professor Hubbard) and that discovery in those cases will always be expensive, with or without rule changes.[34] Mr. Butterfield then addressed the issue of over-preservation. He cited a study that showed in only 1/15th of one percent of cases were sanctions sought for spoliation. In those cases, the offending party was only sanctioned half of the time. Mr. Butterfield also cautioned that some of the proposed rule changes, such as the one that would trigger the duty to preserve only upon the filing of a complaint, would have adverse consequences. In his example, people would rush to file lawsuits before evaluating all options available, and this shift would drive up the costs of litigation due to the fact there would be more lawsuits, not reduced costs. He also cautioned that a rule such as this one would encourage the destruction of evidence in cases where a lawsuit has not yet been filed but it is likely that one will be.[35]

The final witness to testify was Thomas Hill. Mr. Hill began his testimony by stating that, in these tough economic times, companies are wasting millions of dollars on preservation, and the current system yields minimal discovery benefit to courts, litigants, or juries. Under the current system, companies are forced to preserve information for claims that may never materialize, and companies are given little guidance on the scope of their preservation duties. Mr. Hill cited two real-world

examples of GE being forced to over-preserve. The first case Mr. Hill described is one where GE has reasonably anticipated litigation and the breadth of the legal hold is relatively narrow, with 96 custodians. Although no case has been filed, GE has spent $5.4 million to date in fees for preserving the 16 million pages of data produced by these custodians. This figure does not include money spent for legal review of the documents.[36] The second example of over-preservation that Mr. Hill cites is a case where the amount in dispute is $4 million, yet GE has spent $6 million on discovery to date. He focuses on the fact that since courts rarely impose cost shifting, plaintiffs have little motivation to narrow the focus of discovery. Hill stated that this creates a "perverse incentive" to leverage dispute resolution on the economics rather than the merits of a claim. In concluding his testimony, Mr. Hill stated, "With clearer rules, including a narrower scope to avoid this waste, the discovery process will be faster, more fair, litigants can have the disputes resolved on the merits, and the savings can be used to create jobs, invest in the future, and benefit the U.S. economy."[37]

After the conclusion of the witness testimony, Representatives Franks, Nadler, Conyers, and Bobby Scott were all allowed five minutes each to ask questions of the witnesses. It was confirmed that all witnesses had communicated their positions and recommendations to the Civil Rules Advisory Committee. It was agreed that Congress would do nothing at this time but would report to the Civil Rules Advisory Committee its findings from the hearing. Rep. Conyers even suggested the possibility of scheduling another hearing when the Civil Rules Advisory Committee reports its findings. In some of his final comments, Chairman Franks indicated that he was "hopeful" and even "optimistic" that the Civil Rules Advisory Committee would come forward with ideas and proposed changes to the rules.[38]

What to Look For Next

Because Congress chose to take no action at the hearing, it will await the findings of the Civil Rules Advisory Committee before taking any further action. The parties are hopeful that report will be released in March 2012. At that time, any recommendations that the Advisory Committee makes will go to the Judicial Conference, which will meet in September 2012. The Judicial Conference will then make its recommendations for changes to the Supreme Court by the end of 2012, and the Court will approve or amend the rules as it sees fit. The new proposed rules will then go to Congress for review in June 2013 for approval. Congress has six months to approve or suggest changes to the proposed rules. If approved, the rules will go into effect by 2014. Given the length of time the Civil Rules Advisory Committee has been studying this issue, and the fact that the House Judiciary Subcommittee on the Constitution has begun to take a look at the rules as well, this will no doubt be a hot topic to watch in 2012 to see how the future of discovery under the Federal Rules of Civil Procedure is impacted.

The suggested amendment for Rule 26 regarding cost allocation would require each party to pay the cost of the discovery it seeks.

[1] Lawyers for Civil Justice, DRI — The Voice of the Defense Bar, Federation of Defense & Corporate Counsel, International Association of Defense Counsel, *Comment: Supplementing the White Paper Submitted to the 2010 Litigation Conference*, (June 8, 2010).

[2] *Id.* at 3.

[3] *Id.* at 4.

[4] *Id.*

[5] Lawyers for Civil Justice, DRI — The Voice of the Defense Bar, Federation of Defense & Corporate Counsel, International Association of Defense Counsel, *White Paper: Reshaping the Rules of Civil Procedure for the 21st Century, The Need for Clear, Concise, and Meaningful Amendments to Key Rules of Civil Procedure*, (May 2, 2010).

[6] *See generally Supplementing the White Paper Submitted to the 2010 Litigation Conference* at 9-13.

[7] *Id.* at 9-10.

[8] Lawyers for Civil Justice, *Statement Submitted to the U.S. House of Representatives Committee on the Judiciary Subcommittee on the Constitution Hearing: The Costs and Burdens of Civil Procedure*, (Dec. 13, 2011).

[9] Lawyers for Civil Justice, *A Prescription for Stronger Discovery Medicine: The Danger of Tinkering Change and the Need for Meaningful Action*, (Aug. 18, 2011) (comment submitted to the Civil Rules Advisory Committee).

[10] *Id.* at 2.

[11] *Id.*

[12] *See Supplementing the White Paper Submitted to the 2010 Litigation Conference* at 12.

[13] *Id.*

[14] *See White Paper: Reshaping the Rules of Civil Procedure for the 21st Century* at 36-37.

[15] *See* LCJ *Statement Submitted to the U.S. House of Representatives Committee on the Judiciary Subcommittee on the Constitution Hearing* at 3.

[16] *See Supplementing the White Paper Submitted to the 2010 Litigation Conference* at 12-13.

[17] Milberg LLP and Hausfeld LLP, *E-Discovery Today: The Fault Lies Not in Our Rules*, 2011 Fed. Cts. L. Rev. 4 (Feb. 2011).

[18] Letter to The Honorable David G. Campbell from Milberg LLP and Hausfeld LLP, Nov. 6, 2011 at 2.

[19] United States, 112th Cong., 1st sess., House Committee on the Judiciary, Subcommittee on the Constitution, *The Costs and Burdens of Civil Discovery, Hearing*, 13 Dec. 2011, Web video, *available at* <http://judiciary.house.gov/hearings/hear_12132011_2.html> (last accessed Dec. 20, 2012).

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.*

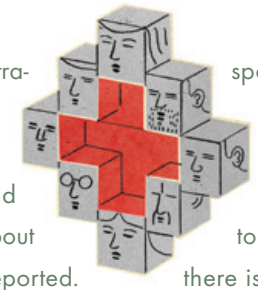
[37] *Id.*

[38] *Id.*

Written by
Rockney S. Taveau

THE FINAL RULE

FDA'S SAFETY REPORTING REQUIREMENTS FOR INVESTIGATIONAL NEW DRUG APPLICATIONS



ON MARCH 28, 2011, the U.S. Food and Drug Administration (FDA) issued its "final rule" about new safety reporting requirements for pharmaceutical manufacturers involved with clinical trials.[1] The rule lays out clear definitions and standards to help ensure that critical safety information about an investigational new drug is accurately and rapidly reported. The purpose of adverse event reporting is to enable FDA to develop a meaningful safety profile of the drug.[2] In an effort to identify real threats to human safety, FDA issued the final rule not only to obtain the pertinent information but also to lessen the "irrelevant" information sponsors were submitting.[3] As FDA recognized, irrelevant information is a "drain on resources for FDA, investigators, and institutional review boards," and it does not "meaningfully contribute" to FDA's reporting efforts.[4] According to FDA, over-reporting of serious adverse events for which there is little reason to believe that the drug caused the event complicated and delayed FDA's ability to detect a safety signal.[5] FDA claims that its final rule will provide more effective surveillance by improving the quality of safety reports and better protect people participating in clinical trials of drugs.[6]

New Reporting Requirements

An Investigational New Drug Application (IND) is the vehicle through which a pharmaceutical manufacturer (sponsor) advances drug development through clinical trials. Because the drugs being tested are investigational and their adverse effects on people are not completely known, appropriate safety reporting is an important part of the clinical trial process. This reporting is done by the sponsor submitting an IND safety report.[7] The final rule requires that certain safety information that previously had not been required to be reported to FDA now be submitted within 15 days of becoming aware of an occurrence. These reports include:

- findings from clinical or epidemiological studies that suggest a significant risk to study participants;
- serious suspected adverse reactions that occur at a rate higher than expected;
- serious adverse events from bioavailability studies which determine what percentage and at what rate a drug is absorbed by the bloodstream; and
- serious adverse events from bioequivalence studies which determine whether a generic drug has the same bioavailability as the brand name drug.

The Adverse Event

An adverse event is an "untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related."[8] The final rule defines new terms that help clarify when an adverse event should be rapidly reported to FDA.[9] The four types of events include: (1) life-threatening adverse event (or suspicion thereof); (2) serious adverse event (or suspicion thereof); (3) suspected adverse reaction; and (4) unexpected adverse event.[10] The final rule requires expedited reporting (within 15 days) of an adverse event "only when there is a reasonable possibility that the drug caused the adverse event."[11] The adverse events that must be reported within 15 days of discovery are those that are "both 'serious' and 'unexpected'" and also a "suspected adverse reaction."[12] This requirement has been called an "intermediate level of suspicion" because even if no causal relationship has been proven but there is reason to believe it might exist, the event should be reported.[13] In an effort to clarify the identification of a causal connection, the final rule provides for sponsors to better understand when rapid reporting of an adverse report is necessary.[14] For example, a serious adverse event is when a participant develops "drug dependency" or an "allergic bronchospasm" which may or may not result in hospitalization.[15]

Sponsors must identify all previously submitted safety reports regarding a similar suspected adverse reaction at the time a 15-day report is submitted. Sponsors must also submit an analysis of the significance of this report in light of other similar reports.[16] In some instances, the final rule requires reporting in the aggregate as compared to a control group, rather than a report of a single adverse event, so that the adverse event reporting will have more context.[17] FDA has provided some guidance documents for methods of interpreting pooled data, but recognizes that it is impossible to completely avoid "noise" in the reporting system.

So what is exempt from rapid reporting requirements? In an FDA-issued reporting guide, FDA listed a few events that need not be reported: (1) death or serious injury that were "likely to have been manifestations of the underlying disease;" (2) events that "commonly occurred in the study population independent of drug exposure;" and (3) events "that were study endpoints," meaning that "the study was evaluating whether the drug reduced the rate of these events."[18]

Effect on the Blind Study

When the rule was in the proposed stage, it seemed to require that a blind clinical study be "broken" while the causal connection is identified. FDA recognized that the risk could "compromise the integrity of well-regulated clinical investigations, lead to fewer patients completing a trial, necessitate larger patient enrollment, and lengthen the timeline for new product development, possibly leading to higher costs for marketed drugs."[19] Sponsors immediately raised concerns about breaking the trial, arguing that it would ruin the results of the study.[20]

In response to these comments, FDA noted that "where the serious, unexpected, suspected adverse reaction must be reported expeditiously, the agency expects the blind to be broken."[21] This is not to say that a study designed with a specific endpoint, such as heart attack or stroke, should generally be

broken upon the event happening if the event was disclosed in the study protocol.[22] Accordingly, FDA made changes in the final rule that allow for alternative reporting methods which do not require breaking the blind when proposed by the sponsor and accepted by FDA.[23] In this protocol, the sponsor must disclose any serious adverse events for which the blind will not be broken and plans for alternative reporting and further observation.[24] FDA's acceptance of such plans will hinge on whether "patient safety can be assured without breaking the blind."[25]

Concerns and Solutions

The rule would appear to make clear a sponsor's reporting requirements about which types of adverse events need to be reported to FDA and how they are to be reported. In essence, a pharmaceutical company will have to decide, based on FDA rules, which cases need to be reported on an individual basis and which adverse events needs to be reported on an aggregate basis. Pharmaceutical manufacturers are also faced with the reality that any approved drug may be the subject of future litigation. A decision by a pharmaceutical manufacturer that it need not report certain adverse events (or not report them within 15 days) can have long-lasting implications in lawsuits. One should assume that a plaintiff's attorneys will request and scour adverse events and whether they were reported to FDA. Similarly, one should assume that they will look at whether adverse events were reported in an expedited manner, if required.

The FDA itself has some suggestions as to how a pharmaceutical manufacturer can comply with the rules. It suggests that "sponsors should have processes in place to periodically review and analyze their entire safety database, not only for IND safety reporting purposes, but also to update investigator brochures with newest safety information."[26] Additionally, sponsors should consider having a system, with clear protocols in place, to ensure that all decisions as to which "adverse events" are not reported are fully documented, as well as to the reasoning behind the decisions. A similar protocol as to who decides which reports need to be made within 15 days will also helpful. Everyone involved in the clinical study should be given the information necessary to make sure that these protocols are followed. Since each 15-day adverse event has to be accompanied by other similar adverse events and an analysis of that information, the sponsor may find that having a database that can be quickly accessed to determine other similar adverse events will make following the requirements of the rule easier to follow.

Conclusion

Although sponsors may believe the rule will make the process of bringing new drugs to market slower and more burdensome, the goal is just the opposite. Reviewing and evaluating uninformative individual safety reports places a tremendous burden on FDA's resources without an accompanying benefit. By reducing the current number of uninformative individual safety reports, sponsors, FDA, investigators, and institutional review boards can focus more time and resources on safety issues that affect patients and, ultimately, public health.

THE FDA ITSELF HAS SOME SUGGESTIONS as to how a pharmaceutical manufacturer can comply with the rules. It suggests that "sponsors should have processes in place to periodically review and analyze their entire safety database, not only for IND safety reporting purposes, but also to update investigator brochures with newest safety information."

[1] FDA. Q&A: Final Rule: New Safety Reporting Requirements for Investigational New Drug Applications (INDs). Last updated Sept. 28, 2010. Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226365.htm>. Last accessed Feb. 16, 2012.

[2] 75 FR 59936.

[3] *Id.*

[4] Draft Guidance for Industry and Investigators Safety Reporting Requirements for INDS Studies, Sept. 2010, p. 3. The recommendations in such guidances are nonbinding but contain the FDA's thoughts and comments as to the topics that are the subject of the guidance.

[5] Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans 75 FR 59935, 59936.

[6] *Id.* Another stated goal is to harmonize the regulations with recommendations by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and by the World Health Organization's Council for International Organizations of Medical Sciences (CIOMS), and which have been adopted by the European Union (EU).

[7] FDA. Q&A: Final Rule: New Safety Reporting Requirements for Investigational New Drug Applications (INDs). Last updated Sept. 28, 2010. Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226365.htm>. Last accessed Feb. 16, 2012.

[8] 21 C.F.R. § 312.32(a).

[9] *Id.*

[10] 21 C.F.R. § 312.32.

[11] *Id.*

[12] 21 C.F.R 312.32 (c)(1).

[13] *Id.*

[14] 21 C.F.R. § 312.32.

[15] *Id.*

[16] 21 CFR § 312.32 (c).

[17] FDA. Final Rule: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans. 2010 WL 3997257, *3. Last updated June 10, 2011. Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm>. Last accessed Feb. 16, 2012.

[18] *Id.*

[19] 75 FR at 59940.

[20] 75 FR at 59947.

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] 75 FR at 59947.

[26] *Id.*

Written *by*
Chad Hutchinson

PART 1: A FEDERAL SURVEY ON PROTECTING CONFIDENTIAL INFORMATION

Obtaining a protective order may seem at first a pedantic concern, another litigation *t* to be crossed or an *i* to be dotted. But pharmaceutical, medical device, biotech, and other companies spend tens of millions of dollars researching and developing new products, and the release of trade secrets or other confidential commercial information in litigation (particularly when competitors are part of the litigation circus) could lead down a "*Palsgraf*-ian"[1] path of woes so horrible that I will not illustrate. Instead, I will remind you of the power of keeping trade secrets confidential. How many people in the world know the formula for Coke?

The standard practice in any product liability action is to secure a protective order before the production of company documents. The protective order serves to safeguard the disclosure of confidential information.[2] Federal Rule of Civil Procedure 26(c) controls the issuance of a protective order in federal proceedings and provides that a "party" or "any person from whom discovery is sought" may obtain a protective order in the court where the action is pending to protect disclosure of "trade secret or other confidential research, development, or commercial information" and for other enumerated grounds.[3]

With the advent of electronic filing in federal courts, confusion has arisen on how to file secret information. The red-inked stamp of "top secret" is a thing of spy novels, and litigators in some federal districts may not have the luxury of squirreling away confidential documents in an envelope, sealing the envelope with a healthy shot of super glue, and hand-delivering the envelope marked "under seal" to the court clerk.

Advances in electronic filing technology require new ways "to seal and protect." A good number of federal courts have issued local rules on how to handle this. The following provides the first half of a survey on how federal district courts across the United States handle the filing of confidential information. This article surveys district courts in Alabama through Montana.

Alabama: The United States District Courts for the Northern and Middle Districts of Alabama do not have specific local rules on the filing of documents under seal, although the middle district does require the redaction of personal identifiers under Local Rule 5.2. The United States District Court for the Southern District of Alabama has enacted Local Rule 5.1(d), which requires that a request to deem information confidential be submitted in the form of a motion, not in the form of a letter.

Alaska: The United States District of Alabama has enacted Local Rule 5.4(a)(4), which requires "[a]n order authorizing filing a document under seal in a protective order or in connection with a non-dispositive motion will not be considered or construed as authorization to file the document under seal in connection with a dispositive motion, hearing, or trial, unless: [A] specifically so stated in the order; and [B] the order sets forth the compelling reasons justifying sealing the document."

Arizona: The United States District Court of Arizona has enacted Local Rule 5.6, entitled "Sealing of Court Records in Unsealed Civil Actions." Local Rule 5.6 provides that: "No document may be filed under seal in an unsealed case except pursuant to an order by the Court as set forth in subpart (b) of this Rule." Subpart (b) states that "the Court may order the sealing of any document pursuant to a motion, stipulation, or the Court's own motion. *The Court generally will not enter an order that gives advance authorization to file documents under seal that are designated for such treatment by parties under a protective order or confidentiality agreement.* Any motion or stipulation to file a document under seal must set forth a clear statement of the facts and legal authority justifying the filing of the document under seal and must append (as a separate attachment) a proposed order granting the motion […]." Local Rule 5.6 (b) — Emphasis added. "Unless otherwise ordered by the Court, if a party wishes to file a document that has been designated as confidential by another party pursuant to a protective order […], the submitting party must confer with the designating party about the need to file the document (or proposed filing) under seal and whether the parties can agree on a stipulation seeking to have the document (or proposed filing) filed under seal […]." Local Rule 5.6 (d).

Arkansas: The United States District Court of Arkansas does not have a specific local rule on filing confidential documents. Local Rule 26.1, however, requires the disclosure of protective orders as part of the Rule 26(f) report.

California: The United States District Courts for all of the districts in California have enacted specific local rules on protective orders. The recent case of *Young v. Axa Art Ins. Corp.*, slip op., 2010 WL 3895173 (C.D. Cal. Sept. 30, 2010), illustrates the reasons why a district court may reject a stipulated protective order under applicable local rules.

In reviewing the requirements of Fed. R. Civ. P. 26 and the applicable local rules, the court in *Young v. Axa Art Ins. Corp.*, found that the protective order was not narrowly tailored and was overbroad. "It is not sufficient to define the protected material as any Disclosure or Discovery Material that is designated as 'Confidential' or 'Highly Confidential — Attorneys' Eyes Only'" where the designation "Confidential" applies to information

(regardless of how generated, stored, or maintained) or tangible things that contain non-public, confidential, private, proprietary, or commercially or personally sensitive information that requires the protections provided in this stipulation; and the designation "Highly Confidential — Attorneys' Eyes Only" applies to information or items extremely sensitive "Confidential Information or Items" whose disclosure to another party or non-party would create a substantial risk of serious injury that could not be avoided by less restrictive means. *Id.*

Second, the court rejected the procedure the parties propose for resolving disputes regarding the designation of confidential information. "Such disputes must strictly comply with the Central District's Local Rule 37. If a party seeks judicial intervention regarding any discovery challenge, both parties must timely file a written joint stipulation containing all issues in dispute. C.D. Cal. R. 37-2, 37-2.1. The form and preparation of this stipulation are expressly laid out in Local Rules 37-2.1 and 37-2.2. […] The Court will not consider the dispute unless the stipulation or a declaration from the moving party describing how the opposing party failed to cooperate in formulating the stipulation is timely filed." *See* C.D. Cal.. 37-2.4.

Third, the court rejected the procedure the parties proposed for filing protected materials. "The parties propose that material filed in this action be designated by counsel as, 'filed under seal pursuant to a protective order [...] and issued by the United States District Court of the Central District of California […].' However, this designation might suggest that the Court has made a determination about whether particular material fits within the categories described by a Protective entered in this case. If the parties wish to designate material as confidential, they may mark documents 'confidential' but should not indicate that the Court has also reached a decision about the nature of the documents." The court reiterated that "the parties must comply with the Central District's Local Rule 79 when filing all protected material. No document will be filed under seal without prior approval of the Court. C.D. Cal. R. 79-5.1. To obtain approval, the moving party must submit a written application and proposed order to the presiding judge along with the document submitted for filing." *Id.*

Finally, the court found that protective order did not establish the "requisite good cause" and required that "any revised stipulated protective order submitted to the Court, the parties must include a statement demonstrating good cause for entry of a protective order pertaining to the documents or information described in the order. The documents to be protected shall be specifically described and identified. The paragraph containing the statement of good cause should be preceded by the phrase: 'GOOD CAUSE STATEMENT.' The parties shall articulate, for each document or category of documents they seek to protect, the specific prejudice or harm that will result if no protective order is entered."

Colorado: The United State District Court of Colorado recognizes a "'constitutional obligation' to determine whether sealing a paper filed in a case […] is warranted." D.C. Col. L. Civ. R. 7.2A. Consistent with this obligation, "[a] stipulated protective order or a confidentiality agreement executed by the parties, standing alone, will not suffice for sealing a paper or closing a court proceeding to the public, will not substitute for the showing required by D.C. Colo. L. Civ. R 7.2C, and will not be binding on the court." *Id.* at 7.2B. "Any document that a party asserts should not be part of the public record pursuant to a protective order or a confidentiality agreement shall be filed as a sealed document. The document shall be sealed for 14 days. If no motion to seal is filed within 14 days, the document shall be automatically unsealed." *Id.* "Any motion to seal shall address the nature of the material, the private interest that outweighs the right of public access, the clearly defined and serious injury that would result if relief not granted, and why a less restrictive alternative is not practicable." *Id.* at 7.2C. The filing of a motion for protective order stays discovery. *Id.* at 30.2A.

Connecticut: The United State District Court of Connecticut provides procedures for the filing of sealed proceedings and documents. Under Local Rule 5(e)(3), "[n]o judicial document shall be filed under seal, except upon entry of an order of the Court either acting *sua sponte* or specifically granting a request to seal that document. Any such order sealing a judicial document shall include particularized findings demonstrating that sealing is supported by clear and compelling reasons and is narrowly tailored to serve those reasons. A statute mandating or permitting the non-disclosure of a class of documents (e.g., personnel files, health care records or records of administrative proceedings) provides sufficient authority to support an order sealing such documents. […] No document shall be sealed merely by stipulation of the parties. A confidentiality order or protective order entered by the Court to govern discovery shall not quality as an order to seal documents for purposes of this rule. Any document filed under seal in the absence of a Court order to seal is subject to unsealing without prior notice to the parties […]." The motion to file confidential documents shall be called a "Motion to Seal" and include a description of the documents. *Id.* at 5(e)(5). Further, the party filing a document that could be publicly available shall redact personal identifiers. *Id.* at 5(e)(8).

Delaware: In the United States District Court of Delaware, "[d]ocuments placed under seal must be filed in accordance with CM/ECF Procedures, unless otherwise ordered by the Court." Local Rule 5.1.3.

District of Columbia: Local Rule LcvR5.1(j) governs the sealing of documents in the United States District Court of Columbia. This rule provides in pertinent part that:

(1) Absent statutory authority, no cases or documents may be sealed without an order from the Court. Any pleading filed with the intention of being sealed shall be accompanied by a motion to seal. The document will be treated as sealed, pending the outcome of the ruling on the motion. Failure to file a motion to seal will result in the pleading being placed in the public record.

(2) Unless otherwise ordered or otherwise specifically provided in these

Local Rules, all documents submitted for a confidential *in camera* inspection by the Court, which are the subject of a Protective Order, which are subject to an existing order that they be sealed, or which are the subject of a motion for such orders, shall be submitted to the Clerk securely sealed in an envelope/box needed to accommodate the documents. The envelope/box containing such documents shall contain a conspicuous notation that carries "DOCUMENT UNDER SEAL" or "DOCUMENTS SUBJECT TO PROTECTIVE ORDER," or the equivalent.

(3) The face of the envelope/box shall also contain the case number, the title of the Court, a descriptive title of the document and the case caption unless such information is to be, or has been included among the information ordered sealed. The face of the envelope/box shall also contain the date of any order, or the reference to any statute permitting the item sealed […].

Florida: The United States District Courts for the Northern, Middle, and Southern Districts of Florida have enacted their own local rules. While the Northern District does not have a specific rule on motions to seal, the Middle and Southern districts do. For example, Local Rule 1.09 of the United States District Court for the Middle District of Florida provides that "[u]nless filing under seal is authorized by statute, rule, or order, a party seeking to file under seal any paper or other matter in any civil case shall file and serve a motion, the title of which includes the words 'Motion to Seal' and which includes (i) an identification and description of each item proposed for sealing; (ii) the reason that filing each item is necessary; (iii) the reason that sealing each item is necessary; (iv) the reason that a means other than sealing is unavailable or unsatisfactory to preserve the interest advanced by the movant in support of the seal; (v) a statement of the proposed duration of the seal; and (vi) a memorandum of legal authority supporting the seal." Local Rule 1.09.

Likewise, Local Rule 5.3(a) of the United States District Court for the Southern District of Florida provides that "[u]nless otherwise provided by law, Court rule, or Court order, proceedings in the United States District Court are public, and Court filings are matters of public record. Where not so provided, a party seeking to file matters under seal shall follow the procedures prescribed by this Local Rule. Pursuant to Section 5A of the CM/ECF Administrative Procedures, attorneys are prohibited from filing sealed documents electronically." Local Rule 5.3(b) sets forth the procedures for filing under seal. The Discovery Practices Handbook for this district warns that "counsel should be aware that the mere filing of a motion for a protective order does not, absent an order of the Court granting the motion, excuse the moving party from complying with the discovery requested or scheduled." See Discovery Practices Handbook, VI "Motions to Compel or Protective Order."

Georgia: Neither the United States District Court for the Northern District of Georgia nor the Southern District of Georgia has enacted local rules on filing documents under seal.

Hawaii: The United States District Court of Hawaii has enacted Local Rule 83.12, which governs the sealing of information filed with the court. This court requires more than a stipulation or blanket protective order before a party may designate matters filed under seal.

Idaho: The United States District Court of Idaho has enacted Local Civil Rule 5.3, which sets for the procedure for filing sealed documents. Among other things, the party must file a motion, supporting memorandum, and proposed order.

Illinois: The United States District Court of the Northern District of Illinois has enacted Local Rules 5.8 and 26.2, which set forth procedures for filing materials under seal. The Southern District of Illinois does not have any specific local rules addressing these issues.

Indiana: The United States District Court for the Northern and Southern Districts of Indiana have enacted Local Rule 5.3, which provides procedures for filing documents under seal.

Iowa: The United States District Court for the Northern and Southern Districts of Iowa have enacted Local Rule 5(c) and 5.2, which provides the method for filing sealed documents and prohibits the electronic filing of a proposed order containing personal identifiers.

Kansas: The United States District Court of Kansas implemented Local Rule 5.4.6, which provides the procedures for filing documents under seal. Under Local Rule 26.2, the "filing of a motion for a protective order pursuant to Fed. R. Civ. P. 26(c) or 30(d) stays the discovery at which the motion is directed pending order of the court."

Kentucky: The United States District Courts for the Eastern and Western Districts of Kentucky do not have local rules on filing documents under seal.

Louisiana: The United States District Court for the Eastern District of Louisiana has enacted Local Rule 5.6, which sets forth procedures for filing documents under seals. Requirements include a motion, non-confidential memorandum, and proposed order. Under Local Rule 5.7.06, the United States District Court for the Western District of Louisiana provides that documents ordered to be placed under seal "may be filed conventionally or electronically."

Maine: The United States District Court for Maine has enacted Local Rule 7A, which provides the procedures for filing sealed documents and pleading. "To obtain an order allowing one or more documents or pleadings to be sealed, a party shall electronically file on ECF a motion to seal together with the separate document(s) or pleading(s) sought to be sealed. The motion shall propose specific findings as to the need for sealing and the duration the document(s) should be sealed. The motion shall include a statement

whether there is agreement of the parties to the sealing. The ECF system will generate and send a Notice of Electronic Filing (NEF) to counsel of record notifying them of the filing, but counsel will be unable to view the document. If service is required, all counsel must be served in a manner other than through ECF." Local Rule 7A(a).

Rule 7A includes the following exception:

"No motion or order is required for the filing of a redacted document or a document under seal that is already subject to an existing protective order or that is included within a category of pleadings and documents deemed sealed or authorized to be filed *ex parte* pursuant to a federal statute, the federal rules of procedure, or the local rules of this court. Any filing of a document which had been previously authorized shall reference the prior authority for such filing." Local Rule 7A(e).

Maryland: The United States District Court of Maryland sets forth procedures for sealing documents in Local Rule 11: "Any motion seeking the sealing of pleadings, motions, exhibits, or other documents to be filed in the Court record shall include (a) proposed reasons supported by specific factual representations to justify the sealing and (b) an explanation why alternatives to sealing would not provide sufficient protection. The Court will not rule upon the motion until at least fourteen (14) days after it is entered on the public docket to permit the filing of objections by interested parties. Materials that are the subject of the motion shall remain temporarily sealed pending a ruling by the Court. If the motion is denied, the party making the filing will be given an opportunity to withdraw the materials. Upon termination of the action, sealed materials will be disposed of in accordance with L.R. 113." L.R. 11.

Massachusetts: The United States District Court of Massachusetts has enacted Local Rule 7.2, which controls "impounded and confidential materials." Local Rule 7.2 provides, in pertinent part:

(a) Whenever a party files a motion to impound, the motion shall contain a statement of the earliest date on which the impounding order may be lifted, or a statement, supported by good cause, that the material should be impounded until further order of the court. The motion shall contain suggested custody arrangements for the post-impoundment period.

(b) The clerk shall attach a copy of the order to the envelope or other container holding the impounded material.

(c) If the impoundment order provides a cut-off date but no arrangements for custody, the clerk (without further notice to the court or the parties) shall place the material in the public information file upon expiration of the impoundment period. If the order provides for post-impoundment custody by counsel or the parties, the materials must be retrieved immediately upon expiration of the order, or the clerk (without further notice to the court or the parties) shall place the material in the public file.

(d) Motions for impoundment must be filed and ruled upon prior to submission of the actual material sought to be impounded, unless the court orders otherwise.

(e) The court will not enter blanket orders that counsel for a party may at any time file material with the clerk, marked confidential, with instructions that the clerk withhold the material from public inspection. A motion for impoundment must be presented each time a document or group of documents is to be filed.

Michigan: The United States District Courts for the Eastern and Western Districts of Michigan have enacted local rules on civil material filed under seal. In the Eastern District, Local Rules 5.3 and 26.4 control. In the Western District, Local Rule 10.6 sets forth the procedures for filing documents under seal.

Minnesota: The United States District Court for Minnesota has enacted Local Rule 79.1, which sets out the procedures for the custody and disposition of records, exhibits, and documents under seal. The court has also provided forms for such orders.

Mississippi: The United States District Court for the Northern and Southern Districts of Mississippi have enacted Local Rule 5.2, which identifies the requirements and responsibilities of counsel and parties to protect personal and sensitive information. Local Rule 79 sets forth the procedures for filing documents under seal.

Missouri: The United States District Court for the Eastern District of Missouri has enacted Local Rule 83-12.05 on pleadings and documents filed under seal. In Local Rule 26.1, the United States District Court for the Western District of Missouri requires parties to identify protective orders as part of the discovery plan, but no specific procedures are provided for the filing of confidential documents.

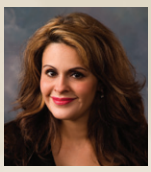
Montana: The United States District Court of Montana has enacted Local 1.8, which provides procedures for the filing and service of sealed documents.

The second part of this survey will be in the next edition of *Pro Te: Solutio*.

[1] *Palsgraf v. Long Island R. Co.*, 162 N.E. 99 (N.Y. 1928).

[2] Fed. R. Civ. P. 26 (e).

[3] *Id.*



Written *by*
Anita Modak-Truran

MENSING: PREEMPTION OR NOT?

Plaintiffs' Creative Ways Around The Decision

THE UNITED STATES SUPREME COURT'S DECISION in *Pliva v. Mensing*, 131 S.Ct.[1], in which the Court held that state law failure-to-warn claims involving generic prescription drugs were preempted, had a dramatic effect on failure-to-warn claims against generic manufacturers. Hundreds of cases were voluntarily dismissed following *Mensing*, and even where plaintiffs attempted to avoid the preemptive effects of *Mensing*, courts have generally held that the broad scope of the *Mensing* decision precludes virtually all failure-to-warn claims against generic manufacturers. There have, however, been a few cases where courts declined to dismiss cases at the 12(b)(6) stage, and plaintiffs are pushing various theories to avoid the effects of *Mensing*. This article discusses recent decisions in which courts did not dismiss failure-to-warn claims against generic manufacturers and the theories that plaintiffs are using to support those efforts.

In *Mensing*, the Court rested its finding of preemption on the requirement that a generic drug manufacturer is required to ensure that its label is the "same as" the brand name's drug. The Court specifically rejected arguments that a generic manufacturer could use the changes-being-effected (CBE) process to amend its label, or that a generic manufacturer could utilize Dear Doctor letters to disseminate "substantial new warning information."[2] The FDA asserted that generic manufacturers could petition the FDA for changes to the label, but the Court rejected this argument, finding that the possibility that the FDA might have accepted the generic manufacturer's proposal was not enough to satisfy the requirements under state law failure-to-warn claims, thus triggering preemption. *Mensing* thus left very little — if any — room for exceptions, and it is against this background that plaintiffs have mounted an effort to avoid *Mensing* preemption.

Brasley-Thrash v. Teva Pharms. involved a plaintiff's effort to amend a complaint to avoid the effects of *Mensing* by adding a claim that the generic manufacturer of metoclopramide should have sent out a Dear Doctor letter notifying physicians of new changes to the brand label for Reglan.[3] The defendant opposed the plaintiff's motion under *Mensing*, but in a short decision, the court permitted the amendment and denied the defendant's motion. The court held that the defendants had not shown that the claims were preempted because there was not a clear indication that FDA approval would have been required for the generic manufacturers to send out a Dear Doctor letter addressing the new changes to the branded label. The defendants argued that 21 U.S.C. § 355-1(i) prohibited an Abbreviated New Drug Application (ANDA) holder from undertaking any communication plan, including Dear Healthcare Provider (DHCP)

letters that apply to the brand.[4] Without deciding whether this provision applied as the defendants argued, the court noted that the statutory provisions did not go into effect until 2008, while the events in question in the case happened before then. As a result, this decision does not foreclose the possibility that 21 U.S.C. § 355-1(i) prohibits an ANDA holder from sending out a DHCP letter. This decision also failed to address the argument espoused by the FDA in *Mensing* that generic drug manufacturers could *not* send out a Dear Doctor letter in the absence of the branded label doing so, because such a letter could imply a therapeutic difference between the brand and the generic, thus becoming impermissibly misleading under 21 C.F.R. § 314.50(b)(3) — the FDA may withdraw approval of a generic drug if the "labeling of the drug […] is false or misleading in any particular." Nonetheless, the decision to permit the amendment in *Brasley-Thrash* will likely trigger copycat claims in other jurisdictions.

Keck v. Endoscopy Center also addressed the use of Dear Doctor letters updating physicians of labeling changes, but here, the plaintiffs creatively used a hypothetical Dear Doctor letter during corporate representative depositions in an effort to avoid the effects of *Mensing*.[5] This decision stemmed from a plaintiff's motion that *Mensing* did not prevent the plaintiffs from arguing to a jury that certain generic manufacturers of propofol should have sent a Dear Doctor letter that was "consistent with and not contrary to" the existing labeling. To advance their argument, the plaintiffs created a draft Dear Doctor letter and presented it to a corporate representative during his deposition. Using the proposed Dear Doctor letter, the plaintiffs were able to get the witness to agree that the language in their proposed letter was "consistent with and not contrary" to the existing label.[6] They then argued that, since their proposed letter was consistent with the label, *Mensing* did not prevent the company from sending such a letter.

After openly noting its disagreement with the majority decision in *Mensing*, the *Keck* court noted that the Supreme Court's decision held only that federal law did not permit a generic manufacturer to issue "additional warnings through Dear Doctor letters." Since the defendant witness had agreed that the warning in the plaintiff's proposed Dear Doctor letter was "consistent with and not contrary to" the existing labeling, the court concluded it was not an "additional warning" and thus was not preempted by *Mensing*. Nonetheless, the court limited its holding by stating that it did not conclude whether the plaintiffs had any remaining failure-to-warn cause of action and that it was not determining whether the defendants had any duty to send a Dear Doctor letter that was "consistent with and not contrary to" the drug's existing label. These qualifications underscore the tenuous grounds for this decision. It seems unlikely that the Supreme Court's holding that federal law preempted the use of Dear Doctor letters to send "additional warnings" would not include a Dear Doctor letter reiterating warnings in an existing label. In other words, this decision appears to represent much more of a stretch than the opinion in *Brasley-Thrasher*, and on its face appears to be at odds with the Supreme Court's decision in *Mensing*.

> *Mensing* left very little — if any — room for exceptions, and it is against this background that plaintiffs have mounted an effort to avoid *Mensing* preemption.

Fisher v. Pelstring addressed the timing of changes to a generic label after changes to the branded drug's label.[7] In Fisher, the court denied a *Mensing*-based motion to dismiss on the grounds that the generic manufacturer did not promptly amend the label on its generic metoclopramide after the branded manufacturer amended its label. The court reasoned that the "same as" requirement that provided the foundation for the Supreme Court's decision in *Mensing* would not be satisfied if the generic manufacturer failed to promptly amend its label following changes to the brand's label. Although very technical, *Fisher* may be a persevering exception to *Mensing*, in that a significant lag between changes to the brand label and the generic label will provide a window in which plaintiffs may claim that the generic label was not "the same as" the branded label, thus potentially defeating preemption. Defenses to such arguments should include efforts to confirm that the prescriber relied on and was aware of the changes to the branded label rather than the generic label, prescriber awareness of any accompanying changes to the PDR, and emphasizing the fact that prescribers generally keep up with the brand, rather than generic label.

In re: Reglan/Metoclopramide Litigation[8] involved motions to dismiss approximately 2,000 claims against generic metoclopramide manufacturers pursuant to *Mensing*. Although the court noted that, since *Mensing*, many courts have summarily dismissed failure-to-warn claims against generic manufacturers, it pointed out that courts had recognized some exceptions to *Mensing* and cited the opinions discussed above. In denying the defendants' motions to dismiss, the court did not reach the conclusion that there was no preemption under *Mensing*. Rather, it indicated that factual disputes needed to be resolved and that the court would consider preemption defenses at the summary judgment stage. This decision therefore suggests, at least in mass-tort cases, that *Mensing* may not be a complete shield that can be used to trigger the early dismissal of failure-to-warn cases. Plaintiffs may be able to "plead-around" *Mensing* (particularly in state courts), triggering discovery and delaying a court's consideration of preemption defenses until the summary judgment stage.

Although there are not yet any reported decisions addressing this issue, one can also expect to see arguments about the effects of *Mensing* where the branded drug is no longer on the market and the FDA has deemed the market-leading generic to be the reference listed drug (RLD). This is a common situation with older drugs where, after the

introduction of several generics, the brand is no longer sold. In a citizen's petition to the FDA seeking regulatory changes that would limit the scope of *Mensing*, Public Citizen took the position that, upon the exit of the branded manufacturer from the market, the generic manufacturer deemed the RLD by the FDA would have responsibility for the label and would not benefit from the preemptive effect of *Mensing*.[9] Opposition to this position included several arguments. First, in a recent draft guidance document addressing required safety labeling changes, the FDA distinguishes between NDA holders and an ANDA without a marketed NDA RLD. Second, in the process of determining whether an NDA holder has withdrawn a product for reasons of safety and efficacy, the FDA has repeatedly stated that "[a]pproved ANDAs that refer to the NDAs […] are unaffected by the discontinued marketing of the products subject to those NDAs […]. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling."[10] Finally, if accepted, the unilateral denomination by the FDA of one generic manufacturer as the RLD would cause that manufacturer to be unable to avail itself of the preemptive effects of *Mensing* and would seemingly give any other generic manufacturers of the same drug an unfair marketplace advantage. The FDA has not yet ruled on this petition.

Overall, the Court's decision in *Mensing* is both broad-sweeping and without any obvious exception. Despite the efforts by plaintiffs to avoid *Mensing*, it appears unlikely that any significant exceptions will gain traction.

[1] *Pliva v. Mensing*, 131 S.Ct. 2567 (2011).

[2] Id. at 2575-76.

[3] *Brasley-Thrash v. Teva Pharms*. USA, Inc., 2011 WL 4025734 (S.D. Ala. Sept. 12, 2011).

[4] 21 U.S.C. § 355-1 addresses risk evaluation and mitigation strategies. Section 355-1(i) provides that, for an ANDA holder, only the FDA shall undertake any communication plan required under section 355-1(e)(3). Subsection (e)(3) provides that a communication plan may include sending letters to healthcare providers. This provision would seem to preclude the argument asserted in *Brasley-Thrash*.

[5] *Keck v. Endoscopy Center*, 2011 WL 3921690 (Nev. Dist. Aug. 19, 2011).

[6] The "consistent and not contrary to" language stems from the FDA's position in *Mensing*, where it argued that Dear Doctor letters qualify as labeling and must be consistent with and not contrary to the drug's approved labeling as required under 21 CFR § 201.100(d)(1).

[7] *Fisher v. Pelstring*, 2011 WL 4552464 (D.S.C. Sept. 30, 2011).

[8] *In re: Reglan/Metoclopramide Litigation*, No. 11090904 (Penn. Civil, First Jud. Dist., Nov. 18, 2011).

[9] *See* Docket No. FDA-2011-0675.

[10] *See*, e.g., FDA Determination that Decadron Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 74 F.R. 22,751, 22,752 (May 14, 2009).

WRITTEN *by* ERIC HUDSON

Team Members

Cara R. Baer
M. Melissa Baltz
Amanda B. Barbour
P. Ryan Beckett
Al Bright, Jr.
Michael L. Brown
Denise D. Burke
Betty L. Campbell
Donald Clark, Jr.
Kimberly S. Coggin
Charles R. Crawford
John A. "Jack" Crawford, Jr.
Laura H. Dixon
Mark A. Dreher
William M. Gage
Mark W. Garriga
Hemant Gupta
Charles C. Harrell
Michael B. Hewes
Shannon E. Hoffert
Eric E. Hudson
Chad R. Hutchinson
Donna Brown Jacobs
David P. Jaqua
Alyson Bustamante Jones
Richelle W. Kidder
Julie Watson Lampley
James J. Lawless, Jr.
Elizabeth "Liz" Moccaldi
Anita Modak-Truran
Charles F. Morrow
Ashley H. Nader
Amy M. Pepke
Orlando R. Richmond, Sr.
Benjamin W. Roberson
Scott B. Shanker
Machelle D. Shields
Bart N. Sisk
Hollie A. Smith
Adam J. Spicer
Kari L. Sutherland
Rockney S. Taveau
Ronald G. Taylor
J. Paul Varner
Thomas E. Williams

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