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SOLUTIONS FOR YOU

Compounding Pharmacies

*Will They Be Hit With Compounding Regulation
In The Wake Of The Meningitis Outbreak?*

FDA Warning Letters

*Potential Evidentiary Effects Of July 2012
FDA Regulatory Procedures Manual*





DEAR CLIENT:

What could be more timely than *Will Compounding Pharmacies Be Hit with Compounding Regulation in the Wake of Meningitis Outbreak?* This article explores the interplay between Federal and State law in regulating pharmaceuticals and explores some possibilities about what may happen in future regulations as a result of this occurrence.

FDA Warning Letters Through Finality and Beyond: Potential Evidentiary Effects of July 2012 FDA Regulatory Procedures Manual discusses this recent publication. This manual's pronouncements may change whether the Warning Letter for your product can be introduced into evidence at trial.

Congress passes a law with a deadline for federal regulation, and the deadline comes and goes. Now what happens? *Forecast for the Physician Payments Sunshine Act: Partly Cloudy* talks about that very issue.

Spoliation issues have been around as long as there has been discovery. However, the proliferation of electronic documents has added some additional questions regarding preservation of evidence. *Document Preservation Notices and the Lists of Who Receive Them: Are They Discoverable?* informs as to the case law in this area.

We hope that you will find this latest issue both informative and relevant to your business.



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PRO TE: *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 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 inside back cover of this publication.

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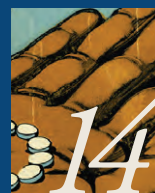
FORECAST FOR THE
PHYSICIAN PAYMENTS
SUNSHINE ACT:
PARTLY CLOUDY



DOCUMENT PRESER-
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WILL COMPOUNDING
PHARMACIES BE HIT
WITH COMPOUNDING
REGULATION?





FORECAST FOR THE PHYSICIAN PAYMENTS SUNSHINE ACT: PARTLY CLOUDY

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On August 14, 2012, four life science trade associations¹ sent a letter to Centers for Medicare and Medicaid Services (CMS) Acting Administrator, Marilyn Tavenner, encouraging the CMS to “promptly publish the final rule implementing the Physician Payments Sunshine Act, section 6002 of the Affordable Care Act of 2010, following complete and thoughtful consideration of comments submitted by stakeholders on the proposed rule.”² One wonders if the authors of the public letter were feeling a little cheeky when they requested this “prompt” action. Unless it is an IRS auditor knocking on your door, rarely is government action swift. Waiting for the final implementing rule of this Act has been like waiting for an agreement to be reached on the veracity of global warming. This article sets out some of the expectations associated with the Act.

ABOUT THE ACT

When the Patient Protection and Affordable Care Act passed in March 2010, it contained section 6002, the Physician Payments Sunshine Act (“Sunshine Act” or “Act”). The law requires medical device and pharmaceutical manufacturers, among others, to report to Health and Human Services (HHS) any “payment or transfer of value” made to teaching hospitals or to physicians.³ Information must be included about the amount and date of the payment, how payment was effectuated, and the type of payment (e.g., consulting fee, gift). These entities also must submit information regarding the ownership or investment interests held by physicians

or their immediate family members. The Sunshine Act sets out that manufacturers owe their first reports for the 2012 reporting period on March 31, 2013. Once this information is gathered and submitted, CMS is statutorily obligated to post the reported information on a public website and to report it annually to Congress and each state. According to CMS, the Sunshine Act “will provide important transparency [...]”⁴

SPECIAL FORUM

The deadline to draft final regulations implementing the Act was October 1, 2011, and HHS passed that burden to CMS.⁵ On March 24, 2011, CMS held a Special Open

Door Forum — teleconference only — to discuss the Act and its parameters. The agenda for the forum set out six areas where CMS requested input:⁶

1. Should CMS broaden the scope of “forms of payment”? The Act specifically lists what payment forms must be reported: “cash or cash equivalent; in-kind items or services; stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.”⁷ CMS wanted input on whether it should require reporting of additional types of “payments” and, if so, which ones and why.

2. Should CMS broaden the scope of “nature of payment”? Again, the Act

delineates fourteen “natures of payment.” These consist of “consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food, travel (including specified destinations), education, research, charitable contribution, royalty or license, current or prospective ownership or investment interest, direct compensation for serving as faculty or speaker for a medical education program, and grant.” CMS requested input as to whether it should consider additional natures and why.⁸

3. Should CMS broaden the reporting categories? Besides the “forms” and “natures” of payments, CMS advised that additional informational categories could be required.

4. Should CMS broaden the reporting requirement of ownership or investment interest? Although the Act already requires reporting of ownership interests by physicians *and their immediate family members*, CMS inquired whether it should require more information on this topic and why.

5. Should CMS broaden its disclosure to consumers? The Act sets out that data gathered on forms of payments, natures of payment, and ownership interests be publicly posted. CMS wanted to know what other types of “background information on industry-physician relationships” it could provide to consumers.⁹

6. Reporting. CMS queried in which electronic form the data should be submitted and how reporting errors could best be rectified.

The theme of the two-hour forum seemed to focus on how wide a net to cast rather than actually *how* to cast it. Meanwhile, October 1, 2011, came and went without any implementing regulations. The deadline did not pass by unnoticed, however, and Democratic Senators Charles E. Grassley and Herb Kohl — authors and sponsors of the Act — wrote a public letter inquiring about the delay.¹⁰ They noted that the “Act was developed after numerous investigations and hearings revealed that large sums of money were going to physicians for sometimes questionable purposes.”¹¹ Mr. Grassley and Mr. Kohl also noted, however, that manufacturers were supposed to

have “adequate time to comply” and that is why the October 1, 2011, deadline had been established. Stating the obvious, the senators wrote that the “deadline for establishing procedures has passed and there has not been, to our knowledge, adequate consultation with either industry representatives or consumer advocates.”¹² They also noted their concern that this “lack of timely guidance” would prove “burdensome and costly.”¹³

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HOPE SPRINGS
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PROPOSED RULE

Whether due to pressure brought to bear or something else, finally, on December 19, 2011, CMS published a proposed rule¹⁴ implementing the Sunshine Act.¹⁵ The 93-page rule sets out, among *many* other things, that covered entities can incur civil monetary penalties for the failure to comply with the reporting requirements (capped at \$150,000 annually for unintentional omissions and capped at \$1,000,000 for intentional omissions). Despite that admonition, and despite the fact that the Act itself requires reporting for 2012 by March 31, 2013, CMS issued a press release just a few days before the formal publication of the rule proposing that data collection not begin until the issuance of final regulations.¹⁶

In the sixty-day comment period following publication of the proposed rule, more than 300 comments made their way to CMS.

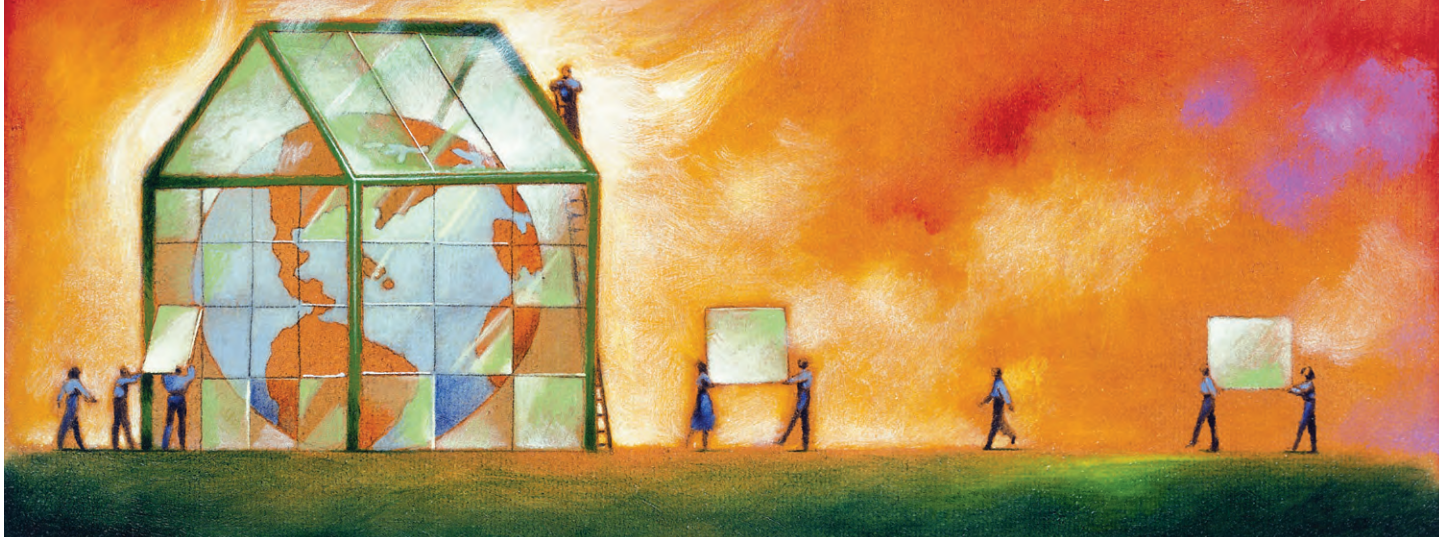
In May 2012, CMS — apparently still overwhelmed by the task before it, as well as by the concerns expressed by manufacturers and physicians — attempted to soothe those impacted entities by noting that it remained “committed to addressing the valuable input received during the comment period, and to ensuring the accuracy of the data collected.”¹⁷ CMS further offered some leeway by noting that it would not require data collection before January 1, 2013. It also optimistically noted that it “intends to release the final rule later this year.”¹⁸

ROUNDTABLE

On September 12, 2012, the United States Senate Special Committee on Aging held a roundtable to discuss the Act.¹⁹ Per Mr. Kohl, they convened the roundtable to discuss “how best to make the Sunshine law a reality and to ensure that CMS is listening to the questions and concerns these groups [meaning industry, physicians, patient advocates] are bringing to the table.”²⁰ Senators Grassley and Kohl expressed frustration at the inability of CMS to provide a timetable for implementation. According to Mr. Grassley, CMS’s response was “incomplete and very uninformative. There was no explanation for the delay and no indication of an expected completion date.”²¹ When pressed further for details as to when a final rule could be expected, CMS’s Niall Brennan responded, “Certainly we do hope to get the final rule out as soon as possible and hope to build in an appropriate period of time for manufacturers and covered recipients to get ready to collect the data, and we certainly hope that some of that data collection would occur in 2013.”²²

Hope springs eternal. Yet here we are in October 2012, and we still await a final rule. And the clock is ticking. At this time it is anyone’s guess when the final rule will be issued. What is a manufacturer to do? As even Senator Grassley noted at the roundtable, manufacturers cannot just go to Best Buy to purchase the software necessary to collect, record, and report the required data.²³ Further, even if manufacturers attempt to make efforts now to comply

According to CMS, the Sunshine Act “will provide important transparency.”



with the Act, which some are doing, what if they guess wrong on what will ultimately be required? It is no small wonder that industry associations are antsy about having a final rule in place “promptly.” For now, manufacturers can only wonder and wait.



¹ Advanced Medical Technology Association (AdvaMed), Biotechnology Industry Organization (BIO), Medical Imaging & Technology Alliance (MITA), and Pharmaceutical Research and Manufacturers of America (PhRMA).

² See <<http://www.bio.org/sites/default/files/Trade%20Association%20Sunshine%20Letter%20to%20CMS%20Aug%202014%202012%20FINAL.pdf>>.

³ Excluded from the reporting requirements are certain “payments” such as product samples, dividends, or rebates. A question for a later article (or court opinion) concerns the preemption effect of the Sunshine Act on those states’ laws that set different disclosure requirements. See, e.g., West Virginia Code 5A-3C-13 (disclosure of advertising costs); District of Columbia Code 48-833.01 (disclosure of marketing costs).

⁴ See <<http://blog.cms.gov/2012/05/03/information-on-implementation-of-the-physician-payments-sunshine-act>>.

⁵ See <<http://www.policymed.com/2011/10/physician-payment-sunshine-act-cms-misses-deadline-creating-confusion.html>>.

⁶ See <<http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/032411SODFTransparencyReports.pdf>>.

⁷ *Id.*

⁸ CMS specifically queried whether it should specify “types” of consulting in its definitions. See <<http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/032411SODFTransparencyReports.pdf>>. This could be problematic were the definition to include litigation consulting. For example, if a manufacturer consults with a non-testifying physician in litigation — a relationship generally considered confidential — the CMS final rule could overrule that confidentiality and require disclosure.

⁹ *Id.*

¹⁰ See <<http://www.grassley.senate.gov/about/upload/Grassley-Kohl-CMS.pdf>>.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ See <<https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf>>.

¹⁵ See <<http://blog.cms.gov/2012/05/03/information-on-implementation-of-the-physician-payments-sunshine-act>>.

¹⁶ See <<http://www.cms.gov/apps/media/press/release.asp?Counter=4220>>.

¹⁷ See <<http://blog.cms.gov/2012/05/03/information-on-implementation-of-the-physician-payments-sunshine-act>>.

¹⁸ *Id.*

¹⁹ See <http://aging.senate.gov/hearing_detail.cfm?id=337599&>.

²⁰ See <<http://medicaldesign.com/engineering-prototyping/regulatory/Sunshine-Act-Senate-convened-roundtable-raises-issues-calls-on-CMS-for-action-0918>>.

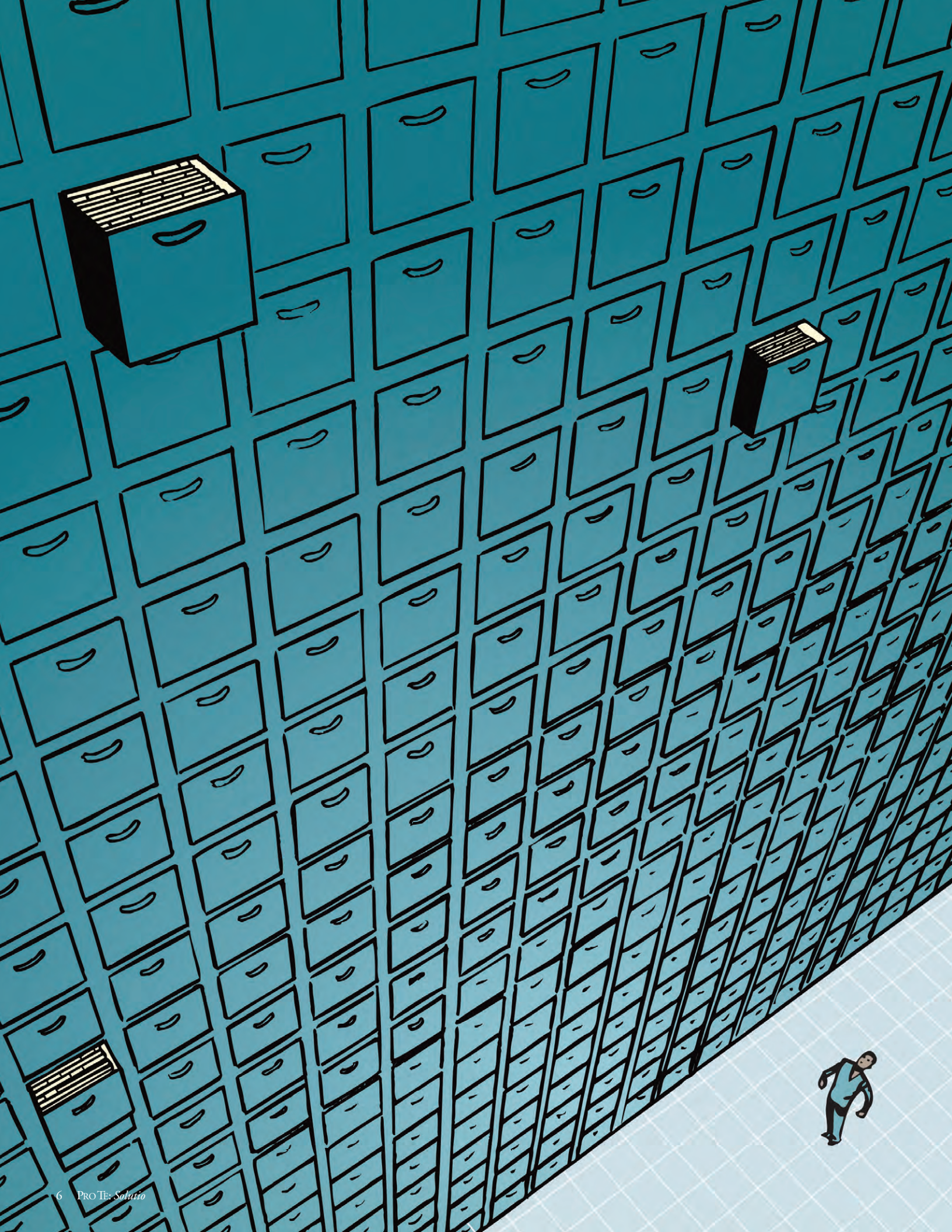
²¹ See <<http://medicaldesign.com/engineering-prototyping/regulatory/Sunshine-Act-Senate-convened-roundtable-raises-issues-calls-on-CMS-for-action-0918>>.

²² *Id.*

²³ See <<http://medicaldesign.com/engineering-prototyping/regulatory/Sunshine-Act-Senate-convened-roundtable-raises-issues-calls-on-CMS-for-action-0918>>.

WRITTEN by
KARI SUTHERLAND





DOCUMENT PRESERVATION NOTICES



AND THE LISTS OF WHO RECEIVE THEM: ARE THEY DISCOVERABLE?

SINCE THE INCEPTION OF FEDERAL RULE 26(B) governing electronic discovery, e-discovery and document production issues continue to become more complex and numerous. The most popular topics include data preservation, records retention policies, production of backup media and tapes, production of mirror images, on-site inspections, keyword searches, format of production, metadata, cost-shifting, and spoliation. Plaintiffs are continuing with their new tactic to request 30(b)(6) depositions immediately upon being allowed to serve discovery. Moreover, included in the initial Requests for Production will undoubtedly be a request for: *ALL DOCUMENTS concerning any document retention policy or policies maintained by YOU, including, but not limited to, the policies themselves and any*

communications regarding the policies and/or changes thereto. Courts have generally allowed these requests and required defendants to produce responsive documents. However, we are seeing a trend for requests that are specific to obtaining legal hold or document preservation notices, including the list of recipients, and for these requests, the decisions are not as clear.

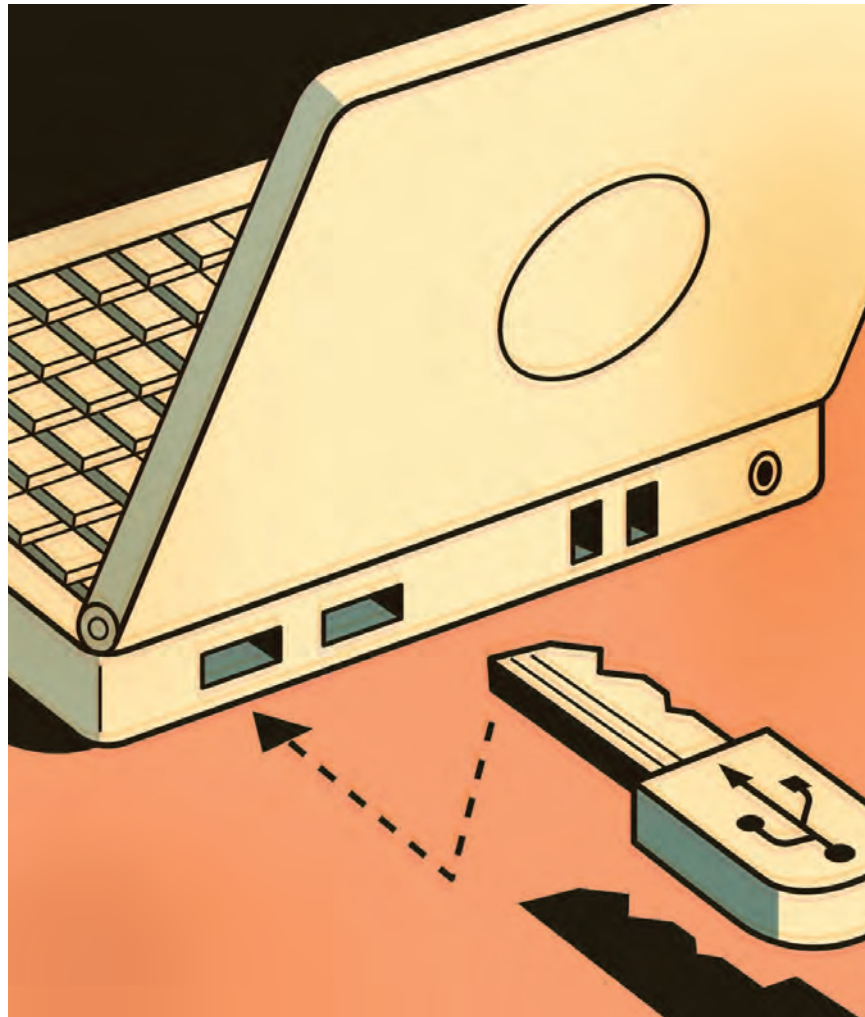
It is well-settled that, as a general matter, document preservation notices are protected from production under the attorney-client privilege and work product doctrine.¹ Also, it has been commonly held that disclosure of document preservation notices and related communications is improper unless there is first a specific finding of spoliation.² In some situations, district courts have found that although a party does not have an automatic

right to obtain copies of a defendant's litigation hold letters, it is entitled "to know which categories of electronic storage information employees were instructed to preserve and collect, and what specific actions they were instructed to undertake to that end."³

In the seminal discovery matter, *eBay Sellers Antitrust*,⁴ the court held:

eBay has made an adequate showing that the Document Preservation Notices (DPN) documents themselves include material protected under attorney-client privilege and the work product doctrine. To the extent, however, that eBay is seeking to foreclose *any* inquiry into the contents of those notices at deposition or through other means, such a position is not tenable. Although plaintiffs may not be entitled to

probe into what exactly eBay's employees were *told* by its attorneys, they are certainly entitled to know what eBay's employees are *doing* with respect to collecting and preserving Electronically Stored Information (ESI). Furthermore, because it would neither be reasonable nor practical to require or even to permit plaintiffs to depose all 600 employees, it is appropriate to permit plaintiffs to discover what those employees are *supposed* to be doing. Even though such inquiry may, indirectly, implicate communications from counsel to the employees, the focus can and should be on the *facts* of what eBay's document retention and collection policies are, rather than on any details



of the DPNs. Thus, while plaintiffs should not inquire specifically into how the DPNs were worded or to how they described the legal issues in this action, plaintiffs are entitled to know what kinds and categories of ESI eBay employees were instructed to preserve and collect, and what specific actions they were instructed to undertake to that end.⁵

In the *eBay* matter, the court further found that eBay had not shown that the identities of the approximately 600 employees receiving the DPNs were privileged or subject to work product protection. The court held that “[a]lthough the relevance of such information appears tenuous, even under the liberal standard applicable in discovery, eBay also has not shown that producing the information would be burdensome or otherwise objectionable. Accordingly, eBay shall provide a list of names and job titles of the approximately 600 employees who received DRNs.”⁶



IT IS WELL-SETTLED THAT, AS A GENERAL MATTER, DOCUMENT PRESERVATION NOTICES ARE PROTECTED FROM PRODUCTION UNDER THE ATTORNEY-CLIENT PRIVILEGE AND WORK PRODUCT DOCTRINE. ALSO, IT HAS BEEN COMMONLY HELD THAT DISCLOSURE OF DOCUMENT PRESERVATION NOTICES AND RELATED COMMUNICATIONS IS IMPROPER UNLESS THERE IS FIRST A SPECIFIC FINDING OF SPOILIATION.

Plaintiffs are succeeding in obtaining legal hold notices when claims of spoliation are made and initial thresholds of proof are cleared. Although litigation hold notices are privileged, the privilege may be lost upon a preliminary finding of spoliation.⁷ To support an order compelling production of an opponent's legal hold notice and list of notice recipients, a movant must show the loss or destruction of documents that should have been preserved.⁸ In *Tracy v. NVR, Inc.*, plaintiffs alleged that they were unlawfully denied overtime pay under the Fair Labor Standards Act (FLSA) and New York labor law. The parties disputed the point

in time at which the defendant was obligated to preserve documents relating to potential opt-in plaintiffs. The court found that “the potential evidence involved in this case [...] provides only indirect information, at best, about the kinds of activities engaged in by [potential] opt-in plaintiffs.”⁹ The court, therefore, denied plaintiffs' motion to compel, finding that plaintiffs in this case failed to make even a preliminary showing of spoliation.

A different result was reached by the court in *Major Tours, Inc. v. Colorel*. In that case, plaintiff bus companies alleged that defendant bus inspectors discriminated against African-American bus owners.¹⁰ After the defendants objected to the production of archived e-mail, the plaintiffs moved to compel the production of defendants' hold notices to convince the court that production of e-mail archives was warranted. The court found that the companies made a preliminary showing of spoliation based on

the testimony of the inspectors' employees and their 30(b)(6) witness. One defendant admitted that he did not save any e-mails, and defendants' 30(b)(6) witness testified that she did not know what a litigation hold was. Additionally, nearly two years had lapsed between the triggering of defendants' preservation obligation and the issuance of hold notices, so the court said it was reasonable to infer that some e-mails were lost. The inspectors, therefore, lost the general privilege for the hold notices, and the court ordered the inspectors to disclose the identities of all hold-notice recipients and all portions of the notices referring to preservation issues. The remaining portions of the hold notices were still subject to privilege and work-product protection.

Spoliation was also an issue in *Pension Committee*.¹¹ Thirteen plaintiffs were sanctioned for conducting "discovery in an ignorant and indifferent fashion."¹² Plaintiffs had failed to institute timely hold notices. Documents and possible evidence, therefore, were destroyed. Sanctions ranged from monetary fines to a negative-inference instruction: "Courts cannot and do not expect that any party can meet a standard of perfection. Nonetheless, the courts have a right to expect that litigants and counsel will take the necessary steps to ensure that relevant records are preserved when litigation is reasonably anticipated, and that such records are collected, reviewed, and produced to the opposing party."¹³ The court further cautioned that "parties need to anticipate and undertake document preservation with the most serious and thorough care, if for no other reason than to avoid the detour of sanctions."¹⁴

The *Pension* court criticized several plaintiffs for placing "total reliance on the employee to search and select what that employee believed to be responsive records without any supervision from Counsel."¹⁵ The court noted that "not every employee will require hands-on supervision from an attorney. However, attorney oversight of the process, including the ability to review, sample, or spot-check the collection efforts is important. The adequacy of

each search must be evaluated on a case by case basis."¹⁶

In summary, while we do not have absolute clarity on the issue of whether legal hold notices, and more importantly, the list of recipients who receive the notices, are discoverable, what is clear is that demands to obtain these items in routine discovery requests likely will increase. When drafting these notices, companies should work closely with counsel with an eye to the fact that the notice may be Exhibit A in a motion to the court to push for even more document production demands. Make sure the content and wording of the notice is something the company would feel comfortable with a jury seeing. Additionally, documenting the process of how and why certain recipients received that notice will be helpful if the case goes to trial — months, if not years, later — when memories as to the exact process used to select recipients have faded.

¹ See *Muro v. Target Corp.*, 250 F.R.D. 350, 360 (N.D. Ill. 2007) (denying plaintiff's objection to Magistrate's ruling that Target's litigation hold notices are subject to the attorney-client privilege and to work-product protection as communications of legal advice from counsel to corporate employees regarding document preservation); *Tracy v. NVR, Inc.*, No. 04-CV-6541L, 2012 WL 1067889, at *6 (W.D.N.Y. Mar. 26, 2012) (refusing to compel production of the defendant's litigation hold notice sought by plaintiff presumably as part of its assessment of whether a full-blown spoliation motion would be justified); *Turner v. Resort Condos. Int'l*, No. 03-CV-2025 (DFH), 2006 WL 1990379, at *7-8 (S.D. Ind. July 13, 2006) (accepting the defendant's assertion that its litigation hold document is privileged and denying the plaintiff's motion to compel defendant to produce its litigation hold document in discovery); see also *Gibson v. Ford Motor Co.*, 510 F.Supp.2d 1116, 1123 (N.D. Ga. 2007) (finding that defendants are not required to produce litigation hold letters because "[n]ot only is the document likely to constitute attorney work-product, but its compelled production could dissuade other businesses from issuing such instructions in the event of litigation"); *Major Tours, Inc. v. Colorel*, No. 05-3091, 2009 WL 2413631, at *2 (D.N.J. Aug. 4, 2009); *In re eBay Seller Antitrust Litig.*, No. 07-CV-01882 (RS), 2007 WL 2852364, at *2 (N.D. Cal. Oct. 2, 2007).

² See, e.g., *Oleksy v. Gen. Elec. Co.*, No. 06 C1245 1245, 2011 WL 3471016, at *6 (N.D. Ill. Aug. 8, 2011) (holding that production of litigation hold letters and documents relevant to steps taken to institute the hold is appropriate only after a showing that a party failed to preserve certain data); see also *United Medical Supply Co. v. United States*, 77 Fed. Cl. 257 (Fed. Cl. 2007) (ordering production of defendant's hold letters only after finding that the defendant spoliated evidence); *Cache La Poudre Feeds, LLC v. Land O'Lakes, Inc.*, 244 F.R.D. 614, 634 (D. Colo. 2007) (permitting plaintiff to take a Rule 30(b)(6)

deposition to explore the procedures defendants' counsel took "to identify, preserve, and produce responsive documents" after finding that defendants expunged the hard drives of several former employees after the present litigation had begun); *Zubulake v. UBS Warburg, LLC*, 229 F.R.D. 422, 425 nn. 15-16 (S.D.N.Y. 2004) (discussing the details of counsel's litigation hold communication after discovery that certain electronically stored information had not been produced); *Keir v. UnumProvident Corp.*, No. 02-CV-8781 (DLC), 2003 WL 21997747, at *6 (S.D.N.Y. Aug. 22, 2003) (allowing analysis of e-mails pertaining to defendant's preservation efforts after finding that electronic records which had been ordered preserved had been erased).

³ See *Major Tours, Inc.*, 2009 WL 2413631, at *2 (citing *In re eBay*, 2007 WL 2852364, at *2).

⁴ *In re eBay Seller Antitrust Litig.*, No. 07-CV-01882 (RS), 2007 WL 2852364 (N.D. Cal. Oct. 2, 2007).

⁵ *Id.*, at *2-3.

⁶ *Id.*

⁷ *Major Tours, Inc. v. Colorel*, 2009 WL 2413631 (D.N.J. Aug. 4, 2009).

⁸ *Tracy v. NVR, Inc.*, 2012 WL 1067889 (W.D.N.Y. March 26, 2012).

⁹ *Id.*

¹⁰ *Id.*

¹¹ On May 28, 2010, the *Pension Committee* court amended the previous opinion by clarifying the scope of a party's obligation to collect records from its employees. *Pension Committee of the University of Montreal Pension Plan v. Banc of America Securities LLC*, 685 F.Supp.2d 456 (S.D.N.Y. January 15, 2010, amended May 28, 2010); see also May 28, 2010 Order. Specifically, the Judge replaced the sentence "By contrast, the failure to obtain records from all employees (some of whom may have had only a passing encounter with the issues in the litigation), as opposed to key players, likely constitutes negligence as opposed to a higher degree of culpability" with "By contrast, the failure to obtain records from all those employees who had any involvement with the issues raised in the litigation or anticipated litigation, as opposed to key players, could constitute negligence." No longer does the opinion require collection from all employees, but rather only those with some level of involvement. Additionally, it changes the phrase "likely constitutes negligence" to "could constitute negligence" (emphasis added).

¹² *Id.* at 496.

¹³ *Id.*, at 472.

¹⁴ *Pension Committee of the Univ. of Montreal Pension Plan v. Banc of America Securities LLC*, No. 05-CIV-9016, 2010 WL 184312, at *10 (S.D.N.Y. January 15, 2010).

¹⁵ *Id.* at *12.

¹⁶ *Id.* at *12, n. 68. See also *Major Tours, Inc. v. Colorel*, No. 05-3091, 2009 WL 2413631, at *2 (D.N.J. Aug. 4, 2009). ("Despite the fact that plaintiffs typically do not have the automatic right to obtain copies of a defendant's litigation hold letters, plaintiffs are entitled to know which categories of electronic storage information employees were instructed to preserve and collect, and what specific actions they were instructed to undertake to that end.")

WRITTEN by ALYSON JONES







FDA WARNING LETTERS THROUGH FINALITY AND BEYOND:

POTENTIAL EVIDENTIARY EFFECTS OF JULY 2012
FDA REGULATORY PROCEDURES MANUAL

YOUR COMPANY RECEIVED AN FDA Warning Letter years ago. You responded and everything seemed settled. Now your company has been sued about the drug or medical device that was the subject of the letter. Is that old Warning Letter going to come back to haunt you in court?

More than five hundred FDA Warning Letters have been issued to various food, drug, and device manufacturers in 2012 alone.¹ Their substance ranges from regulatory clearance and approval, to proposed findings of promotional and misleading labeling and advertising, to adulterated and misbranded products, to a host of other issues under the Federal Food, Drug, and Cosmetic Act. Frankly, while warning and other untitled letters are routinely issued by the FDA, they do not bring good news to their recipients. Perhaps it is for this reason that Warning Letters sometimes find themselves in court — as the supposed basis for the action itself or as key evidence for one of the parties. In either instance, however, one question must be addressed: *Is the use of the Warning Letter proper?*

In July 2012, the FDA released an updated Regulatory Procedures Manual in which the agency defined and established uniform guidance and procedures for FDA Warning Letters and Untitled Letters.² At the outset of its chapter on Advisory Actions, the FDA defines Warning Letters as “the agency’s principal

means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act).³ The FDA proceeds to explain that such letters are “informal and advisory” and do “not commit FDA to taking enforcement action.”⁴ Instead, while the letters “communicate the agency’s position on a matter [...] FDA does not consider Warning Letters to be final agency action on which it can be sued.”⁵ In other words, FDA Warning Letters do not constitute a determination of rights by the agency from which legal consequences arise.

This Regulatory Procedures Manual, notably, was released just six months after the U.S. Court of Appeals for the D.C. Circuit upheld the dismissal of an action against the FDA brought by manufacturers of “ear candles”⁶ under the Administrative Procedures Act.⁷ In *Holistic Candles*, the plaintiff-appellant manufacturers sued the FDA alleging, among other things, that Warning Letters issued by the agency violated the manufacturers’ First Amendment rights and were contrary to the Act.⁸ The Warning Letters at issue advised the manufacturers that they had failed to obtain the proper approval or clearance prior to marketing the devices, that the FDA had received a number of adverse event reports related to the devices, and that the manufacturers should therefore cease marketing, promoting, or distributing the devices.⁹ Although the

manufacturers claimed the letters espoused the “FDA’s determination that ear candles are, per se, unapproved medical devices [that] cannot be sold in the United States,”¹⁰ the Court of Appeals disagreed, finding that “the Warning Letters do not constitute final agency action.”¹¹ This finding was markedly unaffected by either the presence of a Consumer Update against ear candles on the FDA’s website or by the individual statements of agency officials that the “FDA would never approve” ear candles.¹² The rationale for the opinion was as follows:

As a general matter, two conditions must be satisfied for agency action to be ‘final’: First, the action must mark the consummation of the agency’s decision-making process — it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined or from which legal consequences will flow [...]. FDA’s Warning Letters fail to satisfy either condition: they neither mark the consummation of the agency’s decision-making process nor determine the appellants’ legal rights or obligations.¹³

Chapter 4 of the FDA’s July 2012 Regulatory Procedures Manual, for all intents and purposes, adopts and memorializes the opinion of the D.C. Circuit as the position



of the FDA. In fact, in September 2012, the FDA cited the Manual repeatedly in response to a Petition for Writ of Certiorari filed by the manufacturer plaintiffs in *Holistic Candles*. The FDA reiterated the following to the United States Supreme Court:

[T]he warning letters here did not mark the consummation of FDA’s decision-making process. [...] Relatedly, the Warning Letters were not based on a formal and complete administrative record. At this stage, FDA’s statement that Petitioners violated the FDCA was not ‘final and binding’ on the agency or petitioners but rather remained ‘tentative and interlocutory’ in nature.¹⁴

These recent representations of the FDA — both in the Regulatory Procedures Manual and to the Supreme Court — solidify the FDA’s position that Warning Letters to product manufacturers, alone, or in combination

ANY SUBSTANTIVE USE OF FDA WARNING LETTERS BY A PARTY TO TRY TO PROVE THE TRUTH OF THE WARNINGS THEMSELVES ARGUABLY SHOULD BE LIMITED HEAVILY – IF NOT PROHIBITED ALTOGETHER – ABSENT SOME OTHER INDICATION OF A FINAL DETERMINATION OF RIGHTS BY THE FDA.

with other informal agency communications, are not final agency action. As a result, they do not subject the agency to judicial review.

An interesting corollary to this position, however, concerns the admissibility of FDA Warning Letters and similar communications in product liability trials against drug or device manufacturers. On their face, written FDA warnings and communications are hearsay, inadmissible to prove the truth of the warnings themselves. Nevertheless, Federal Courts routinely apply Rule 803(8) of

the Federal Rules of Evidence to determine whether governmental reports such as FDA Warning Letters should be excepted from the hearsay rule in civil actions. Under that rule, courts may admit documents or reports that contain “factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.”¹⁵

An important commonality exists between this evidentiary inquiry and the position taken by the FDA in *Holistic Candles* and its Regulatory Procedures Manual. In a nutshell, both connote a requirement of finality before FDA Warning Letters may be used against a party substantively. On one hand, Warning Letters do not constitute “final agency action” sufficient to institute an action directly against the FDA. On the other, the “informal and advisory” nature of Warning Letters, which do “not commit FDA to taking enforcement action,”¹⁶

arguably do not constitute final governmental findings with sufficient trustworthiness to be admissible under Rule 803(8)(c).

This latter rationale has supported a number of federal evidentiary opinions on governmental reports that predate both the *Holistic Candles* litigation and the July 2012 Regulatory Procedures Manual.¹⁷ For instance, in *Toole v. McClintock*, the Eleventh Circuit Court of Appeals reversed the Florida District Court and granted a new trial to the defendant manufacturer because the trial court improperly admitted a report containing the FDA's proposed findings on silicone breast implants under Rule 803(8)(c).¹⁸ The *Toole* court first noted that "the FDA report contains no findings specifically about the [...] implants at issue in this case, but rather proposes findings about implants generally."¹⁹ Furthermore:

The FDA report is not the kind of trustworthy report described in *Rule 803*. By its own terms, the FDA report contained only 'proposed' findings. The report invited public comment and forecasted the issuance of a "final" document after more study. *Rule 803* makes no exception for tentative or interim reports subject to revision and review. [...] The tentative and secondhand nature of the findings in the FDA report should have kept it out of evidence.²⁰

Similarly, in *Appleby v. Glaxo Wellcome, Inc.*, the U.S. District Court for the District of New Jersey rejected the plaintiffs' claim that "Dear Healthcare Professional" letters issued by the FDA concerning risks of the drug Lotronex[®] fell within the hearsay exception for public records and reports under Rule 803(8)(c). The *Appleby* court explained that the rule "typically does not apply to render hearsay admissible where the findings are merely proposed, tentative, or 'secondhand.'"²¹ This common element of finality — or the lack thereof — has been the deciding factor for numerous other courts in deciding whether to admit government writings of any nature under the public report's exception to the hearsay rule.²² These courts have specifically emphasized the "interim or inconclusive nature of the reports"²³ and have focused largely on whether the

reports reflected the "final determination" of the authoring agency.²⁴

The FDA's now-express categorization of Warning Letters as "tentative and interlocutory in nature"²⁵ substantially bolsters the argument that Warning Letters do not fall within the hearsay exception of Rule 803(8)(c), and as such are not admissible for substantive purposes at trial. The parallel between the FDA's declaration that Warning Letters "do

MORE THAN FIVE HUNDRED FDA WARNING LETTERS HAVE BEEN ISSUED TO VARIOUS FOOD, DRUG, AND DEVICE MANUFACTURERS IN 2012 ALONE. THEIR SUBSTANCE RANGES FROM REGULATORY CLEARANCE AND APPROVAL, TO PROPOSED FINDINGS OF PROMOTIONAL AND MISLEADING LABELING AND ADVERTISING, TO ADULTERATED AND MISBRANDED PRODUCTS, TO A HOST OF OTHER ISSUES UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

not mark the consummation of FDA's decision-making process" and Rule 803's exclusion of interim or inconclusive reports is evident. More importantly, however, that parallel may provide manufacturer defendants with new or stronger ground on which to stand when seeking the exclusion or opposing the admission of Warning Letters into evidence at trial. The same ammunition may also apply to FDA Web-based safety alerts, Dear Doctor letters, and other similar, informal public health notifications, none of which possess the prerequisite finality discussed above. This is not to suggest that plaintiffs will be prevented from using documents like these for the non-hearsay purpose of demonstrating notice or state-of-mind. Nevertheless, any substantive use of FDA Warning Letters by a party to try to prove the truth of the warnings themselves arguably should be limited heavily — if not prohibited altogether — absent some other indication of a final determination of rights by the FDA. Therefore, your litigation team should not assume that letter is admissible, and a motion to exclude it might be in order.

¹ See <<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/default.htm?Page=50>>.

² FDA, Regulatory Procedures Manual, 4-1 (July 2012).

³ FDA, Regulatory Procedures Manual, 4-2 (July 2012).

⁴ *Id.*

⁵ FDA, Regulatory Procedures Manual, 4-2 – 4-3 (July 2012).

⁶ Ear candles are hollow cones made of fabric, soaked in beeswax or paraffin, which are placed into the ear and set on fire with an open flame. They are marketed as a holistic treatment for a number of conditions, including sinus congestion, ear infection, and sleep disorders.

⁷ *Holistic Candles & Consumers Ass'n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012).

⁸ *Holistic Candles*, 664 F.3d at 942.

⁹ *Id.*

¹⁰ *Id.* at 943.

¹¹ *Id.* at 942.

¹² *Id.* at 945.

¹³ *Id.* at 943.

¹⁴ Br. of Respondents, *Holistic Candles & Consumers Ass'n v. FDA*, 2012 WL 3991471, *10, No. 11-1454 (Sept. 11, 2012).

¹⁵ Fed. R. Evid. 803(8)(c).

¹⁶ FDA, Regulatory Procedures Manual, 4-2 – 4-3 (July 2012).

¹⁷ See, e.g., *In Re Cessna 208 Series Aircraft Prod. Liab. Litig.*, 2009 U.S. Dist. LEXIS 78504, Case No. 05-md-1721 (D. Kan. Sept. 1, 2009); *Appleby v. Glaxo Wellcome, Inc.*, 2005 U.S. Dist. LEXIS 32875, Civil No. 04-0062 (D. N.J. Dec. 13, 2005); *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993), and *City of New York v. Pullman, Inc.*, 662 F.2d 910 (2d Cir. 1981).

¹⁸ *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993).

¹⁹ *Toole*, 999 F.2d at 1434.

²⁰ *Id.* at 1434-35.

²¹ *Appleby v. Glaxo Wellcome, Inc.*, 2005 U.S. Dist. LEXIS 32875, Civil No. 04-0062 (D. N.J. Dec. 13, 2005).

²² See, e.g., *United Air Lines Inc. v. Austin Travel Corp.*, 867 F.2d 737 (2d Cir. 1989); *Koonce v. Quaker Safety Prods. & Mfg. Co.*, 798 F.2d 700 (5th Cir. 1986); *Plemer v. Parsons-Gilbane*, 713 F.2d 1127 (5th Cir. 1983); *City of New York v. Pullman, Inc.*, 662 F.2d 910 (2d Cir. 1981); *In Re Cessna 208 Series Aircraft Prod. Liab. Litig.*, 2009 U.S. Dist. LEXIS 78504, Case No. 05-md-1721 (D. Kan. Sept. 1, 2009); *Gentile v. County of Suffolk*, 129 F.R.D. 435 (E.D.N.Y. 1990).

²³ *United Air Lines*, 867 F.2d at 743.

²⁴ *In Re Cessna 208 Series Aircraft Prod. Liab. Litig.*, 2009 U.S. Dist. LEXIS 78504, *22.

²⁵ *Holistic Candles*, 2012 WL 3991471 at *10.

WRITTEN by
LAURA H. DIXON







WILL COMPOUNDING PHARMACIES BE HIT WITH COMPOUNDING REGULATION IN THE WAKE OF MENINGITIS OUTBREAK?

THE OUTBREAK... *Concern first arose on September 21, 2012, when the Tennessee Department of Health notified the United States Centers for Disease Control and Prevention (CDC) of a patient with the onset of meningitis¹ approximately nineteen days after receiving an epidural steroid injection at a Tennessee ambulatory surgical center.² By October 10, 2012, the outbreak of a rare and potentially deadly form of fungal meningitis had sickened 137 people and killed twelve in ten states.³ By October 15, 2012, the total number of reported cases reached 205 in fourteen states and included fifteen deaths.⁴*

Options for treatment of this rare fungal infection are limited to two antifungal medicines with serious side effects.⁵ While these drugs fight the fungus, they can also cause serious damage to the kidneys and liver, so much so that the CDC has warned that they should not be given unless a patient's spinal fluid is clouded by infection.⁶ To further complicate matters, there is nothing that can be done preventatively for those who may have been exposed to this rare infection, and medical research provides very little guidance to doctors as they attempt to predict the ultimate outcome of this treatment regimen.⁷

The source of this severe outbreak of fungal meningitis was eventually traced to three lots of preservative-free methylprednisolone acetate (80mg/ml) produced by the New England Compounding Center (NECC) located in Framingham, Massachusetts.⁸ The CDC later determined that NECC produced and distributed a total of 17,676 vials of the potentially contaminated injections to healthcare providers and facilities in twenty-three states.⁹ In all, the CDC estimates that some 14,000 individuals received

potentially tainted steroid injections compounded by NECC.¹⁰

In response to concerns over these contaminated injections, on October 6, 2012, NECC voluntarily recalled the three lots in question, and the CDC and FDA recommended that all healthcare personnel cease use of all inventories of any product produced by NECC.¹¹ Thereafter, NECC voluntarily suspended all operations and expanded its recall to include all methylprednisolone acetate it had prepared, as well as all other drug products it had produced for intrathecal administration.¹² On October 10, 2012, a second pharmacy operation owned by the same company voluntarily ceased operations.¹³ On October 16, 2012, the FDA and local police officers raided the NECC headquarters, seizing drug samples and company records as part of the FDA's ongoing investigation into the company and its compounding practices.¹⁴

WHAT IS COMPOUNDING? Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of

an individual patient.¹⁵ This process has historically been used to prepare medications that are not commercially available or when a particular patient is unable to take a mass-produced pharmaceutical product.¹⁶

Until the 1950s, when the mass production of prescription medications truly began in earnest, it is estimated that approximately 80% of all prescription medications were compounded.¹⁷ This form of "traditional compounding" involved pharmacists only preparing compounded drugs upon the receipt of a valid prescription from a healthcare provider licensed to prescribe medication.¹⁸ However, drug compounding has become a big business over the last couple of decades. Now, it is estimated that compounded drugs represent thirty-seven million prescriptions in the United States each year, representing 3% of the \$300 billion prescription drug industry in the United States.¹⁹ Large-scale compounding pharmacies, like NECC, are often licensed to distribute their products to medical providers and clinics in all fifty states and, in many cases, are producing large quantities of these drugs.²⁰

While in the past, traditional compounding was focused on providing drugs that met the specific needs of individual patients, today it appears that large-scale drug compounding largely serves a different purpose. Physicians often cite the lower cost and widespread availability of compounded drugs as compared to brand-name drugs as the biggest advantages to utilizing compounding pharmacies.

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While in the past, traditional compounding was focused on providing drugs that met the specific needs of individual patients, today it appears that large-scale drug compounding largely serves a different purpose. Physicians often cite the lower cost and widespread availability of compounded drugs as compared to brand-name drugs as the biggest advantages to utilizing compounding pharmacies.²¹ For instance, in the case of the steroid methylprednisolone acetate being produced and distributed by NECC, the FDA approved a brand-name version of this drug developed, patented, and manufactured by Pfizer — Depo-Medrol — in 1959.²² After Pfizer's patent on Depo-Medrol expired, generic versions of the drug were widely available on the market for some time.²³ The steroid, however, became scarce in recent years after a number of generic manufacturers discontinued supplying the drug, causing the price to skyrocket from \$3.00 for a multi-dose vial to \$40.00 per vial.²⁴ Compounding pharmacies largely filled this vacuum by producing a compounded version of the drug, which costs between \$15.00 and \$20.00 for a multi-dose vial.²⁵

NOT THE FIRST TIME COMPOUNDING HAS COME UNDER FIRE... In the wake of the fungal meningitis outbreak, compounding pharmacies have come under intensifying public scrutiny and media attention. Reports show that since 2001, the FDA has issued more than forty warning letters to compounding pharmacies nationwide for issues such as producing banned compounds, distributing drugs that were adulterated or contaminated, and selling medication in improper dosages or without accurate labels.²⁶ In this same time frame, it is reported that more than two dozen deaths and scores of injuries and illnesses have been linked to medications produced

and distributed by compounding pharmacies.²⁷ For instance:

- In 2001, three people died from bacterial meningitis when a San Francisco Bay area physician injected twelve patients with a contaminated compounded drug.
- In September 2005, three people died and several others were sickened at a Virginia hospital after receiving drugs from a compounding pharmacy in Maryland.
- In March 2007, two patients in Washington and Oregon died after receiving excessive doses of an intravenous pain medication that was incorrectly measured by a compounding pharmacy in Texas.
- In March 2011, nine patients in Alabama died after receiving contaminated nutritional supplements prepared by a local compounding pharmacy.
- In March 2012, thirty-three patients in seven states developed fungal eye infections following surgery during which they were injected with contaminated drugs prepared by a Florida compounding pharmacy.²⁸

REGULATION OF COMPOUNDING PHARMACIES AND LEGAL BATTLES... Neither compounded drugs nor compounding pharmacies are discussed in any great detail anywhere in the 1938 law that authorized the FDA to regulate virtually all aspects of the manufacture, marketing, and distribution of drugs in the United States. Given the unclear application of the FDCA to the activities of compounding pharmacies, for some fifty years the FDA generally left regulation of compounding and compounding pharmacies to the states.²⁹ However, in the 1990s, the FDA became concerned that some pharmacists were manufacturing and selling drugs beyond what was traditionally understood to be the business of compounding, while continuing to avoid the requirements of the FDCA.³⁰

Therefore, in 1992, the FDA issued a Compliance Policy Guide (CPG) titled *Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies*.³¹ While this CPG explicitly recognized that “a licensed pharmacist may compound drugs extemporaneously after receipt of a valid prescription for an individual patient,” and that such activity would not be subject to the Agency’s enforcement discretion, the CPG suggested that the FDA would become more active in enforcing the requirements of the FDCA against compounding pharmacies whose activities raised concerns that they were actually acting as drug manufacturers as opposed to traditional compounders.³² Specifically the CPG contained a list of nine factors meant to guide the Agency in determining whether future enforcement actions were appropriate. These factors, which the Agency determined were suggestive of the manufacture of drugs that would subject a compounding pharmacy to the requirements of the FDCA, were as follows:

1. Soliciting business [...] to compound specific drug products [...];
2. Compounding, regularly, or in inordinate amounts, drug products that are commercially available in the marketplace and that are essentially generic copies of commercially available, FDA-approved drug products;
3. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-approved facility;
4. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements;

5. Using commercial scale manufacturing or testing equipment for compounding drug products;
6. Compounding inordinate amounts of drugs in anticipation of receiving prescriptions in relation to the amounts of drugs compounded after receiving valid prescriptions;
7. Offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale;
8. Distributing inordinate amounts of compounded products out of state; and
9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.³³

Despite a legal victory upholding the validity and effect of this CPG,³⁴ there is very little evidence that the FDA significantly increased or otherwise altered its enforcement activities vis-à-vis compounding pharmacies in the years that followed the issuance of the CPG.

Then, in 1997, the federal Food and Drug Administration Modernization Act (FDAMA) was signed into law, adding section 503A to the FDCA in an attempt to clarify the status of pharmacy compounding under the Act. The Act adopted many of the policies contained in the FDA's 1992 CPG and created legislation empowering the FDA to regulate the activities of compounding pharmacies.³⁵ The FDAMA also explicitly distinguished compounding from manufacturing of drugs and provided for certain exemptions under which compounded products would not be viewed as "new drugs" under the FDCA.³⁶

First, in order to have qualified for exemption under the FDAMA, a drug would have to be compounded by a licensed pharmacist or physician in response to a valid prescription for an identified individual patient. Or, if prepared before the receipt of such a prescription, the drug would have to be made

only in "limited quantities" and in response to a history of the licensed pharmacist's or physician's receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber.³⁷ Second, the compounded drug would have to be made from approved ingredients that met certain manufacturing and safety standards,³⁸ and the compounded drug could not have appeared on an FDA list of drug products that had been withdrawn or removed from the market because they were found to be unsafe or ineffective.³⁹ Third, the pharmacist or physician compounding the drug could not "compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that were essentially copies of a commercially available drug product."⁴⁰ Fourth, the drug product could not have been identified by the FDA as a drug product that presented demonstrable difficulties for compounding in terms of safety or effectiveness.⁴¹ Fifth, in states that had not entered into a "memorandum of understanding" with the FDA addressing the distribution of "inordinate amounts" of compounded drugs in interstate commerce, the pharmacy, pharmacist, or physician compounding the drug could not distribute compounded drugs out of state in quantities exceeding 5% of that entity's total prescription orders.⁴² Finally, the prescription must have been "unsolicited" and the pharmacy, licensed pharmacist, or licensed physician compounding the drug could "not advertise or promote the compounding of any particular drug, class of drug, or type of drug."⁴³ The pharmacy, licensed pharmacist, or licensed physician could, however, "advertise and promote the compounding service."⁴⁴

Shortly after the enactment of the FDAMA, a group of licensed pharmacists, in *Western States Med. Ctr. v. Shalala*, brought an

action specifically challenging the advertising and promotion restrictions contained in the Act's exemption provisions, claiming that these provisions constituted unconstitutional restrictions of commercial speech under the First Amendment.⁴⁵ In response, the government urged that three substantial interests underlied the FDAMA: 1) the interest in "preserv[ing] the effectiveness and integrity of the FDCA's new drug approval process and the protection of the public health that it provides; 2) the interest in "preserv[ing] the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA"; and 3) "[a]chieving the proper balance between those two independently compelling but competing interests is a substantial government interest."⁴⁶ Ultimately, the United States Supreme Court in *Western States* held that the advertising and promotional restrictions contained in the FDAMA were unconstitutional.⁴⁷ In doing so, however, the Court, in *dicta*, suggested that several means of drawing a line between compounding and large-scale manufacturing were possible, including many of the very same factors upon which the FDA relied to distinguish compounding from manufacturing in its 1992 CPG.⁴⁸ But, maybe most importantly, the Court decided that it could not review the holding of the Ninth Circuit Court of Appeals, which held that the advertising and promotional provisions of the law were not severable from the remainder of the statutory provisions because neither party petitioned for certiorari on that issue — rendering the entire statutory section relating to compounding pharmacies invalid.⁴⁹

In the wake of *Western States*, the FDA issued a revised CPG in 2002 indicating its position that the entirety of the FDAMA had been struck down and once again addressing

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Some believe that regulation should remain largely with the states, while others believe that the FDA could have acted under the authority it already has. However, it is difficult to deny that evidence to date would suggest that, at least in the case of NECC, varying state regulations combined with a lack of FDA oversight has opened the door for safety problems to arise with compounding pharmacies.

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its continuing but relatively limited role in the regulation of compounding.⁵⁰ Just as before *Western States*, going forward, the FDA would only involve itself in limited compounding drug cases involving only the most egregious activities.⁵¹

However, as issues with compounding pharmacies continued to mount, calls for stricter regulation by the federal government grew, but so did lobbying efforts by compounding pharmacists. In 2003, when an FDA oversight committee on pharmacy compounding was proposed as part of a bill on the government's Medicare health plan for the elderly, health officials voiced concerns regarding the safety and efficacy of compounded drugs.⁵² For instance, Sarah Sellers, a pharmacist who worked in compounding before joining the FDA, testified: "Professional standards for sterile compounding have not been consistently applied," and "[t]he absence of federal compounding regulations has created vulnerability in our gold standard system for pharmaceutical regulation."⁵³ Similarly, Dr. Steven Galson, also with the FDA, related how limited testing of compounded drugs found that ten out of twenty-nine compounded drug samples tested failed one or more quality tests compared to only four of 3,000 samples of drugs manufactured by drug manufacturers subject to FDA regulation.⁵⁴ Despite this testimony, intensive lobbying efforts by the compounding industry ultimately led to the downfall of the proposed legislation.⁵⁵

Then, a group of compounding pharmacists brought yet another action against the FDA which challenged the Agency's new assertions of authority in the 2002 CPG.⁵⁶ In this action, *Med. Ctr. Pharmacy v. Gonzales*, the plaintiffs sought, in part, a declaration that drugs compounded by licensed pharmacists were not "new drugs" per se under the FDCA.⁵⁷ Ultimately, the Fifth Circuit Court

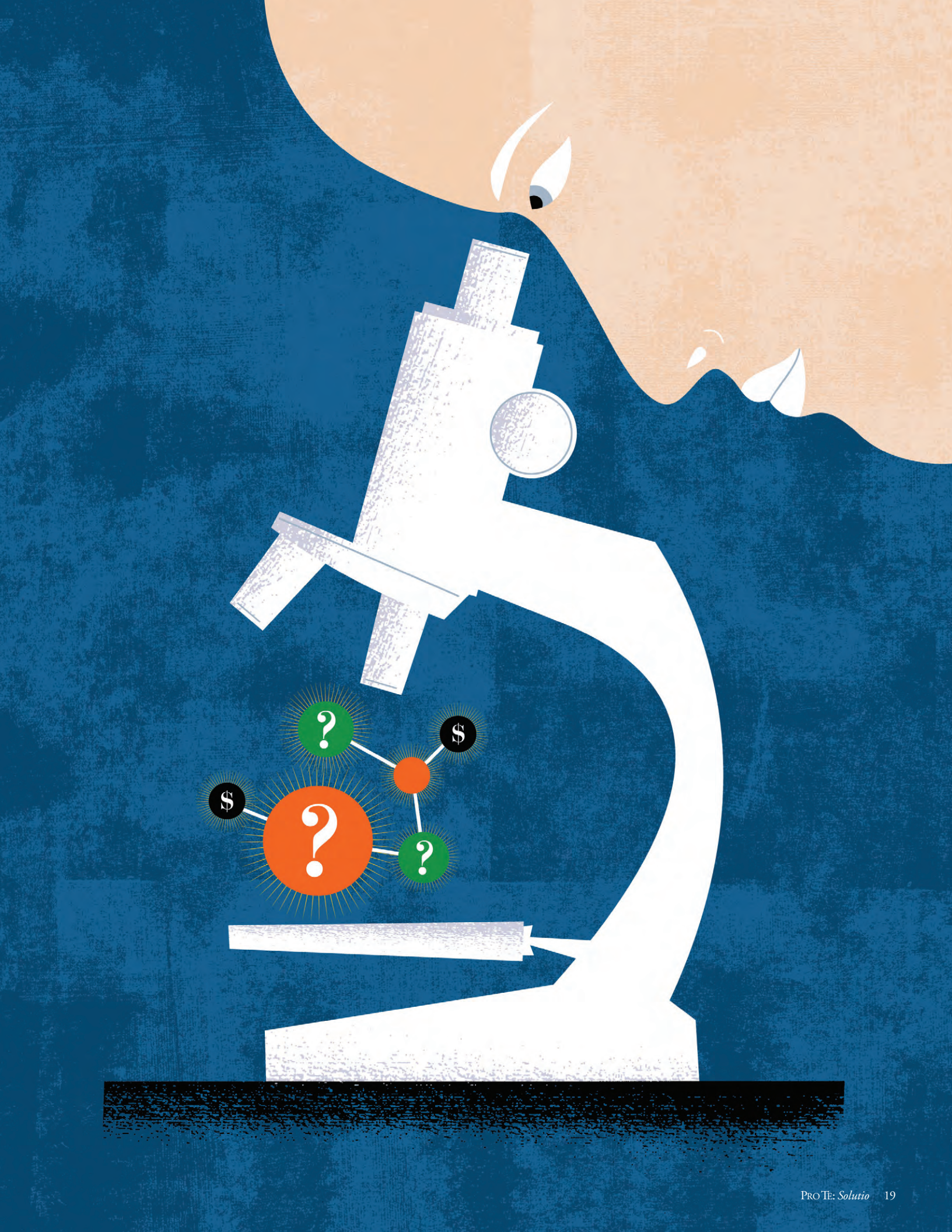
of Appeals found that compounded drugs are not uniformly exempt from the new drug approval requirements of the FDCA, but instead that the statutory scheme provides for a limited exemption from the new drug approval requirements for compounded drugs that comply with the legally valid conditions set forth in the FDAMA (which had been previously struck down in *Western States*).⁵⁸ In coming to its conclusion, the Fifth Circuit explicitly held, contrary to the Ninth Circuit in *Western States*, that the invalidated portion of FDAMA was severable, and therefore, the remaining provisions in the statute relating to compounding pharmacies remain in full force and effect.⁵⁹ Therefore, according to the Fifth Circuit, compounding pharmacies are not exempt from the requirements of the FDCA as a matter of law, but instead, as long as they meet the "traditional compounding" exemptions set forth in the FDAMA, they would remain exempt from the significant "new drug" requirements of the FDCA.⁶⁰ Despite this finding, the FDA's approach to regulating compounding pharmacies did not significantly change in the years following *Med. Ctr. Pharmacy*.

Finally, in 2007, senators from Massachusetts, Kansas, and North Carolina introduced sweeping legislation, titled *The Safe Drug Compound Act of 2007*, which again sought to give the FDA more power to regulate compounding pharmacies.⁶¹ This legislation would have given the FDA authority to inspect all retail compounding pharmacies and their records. Additionally, it would have restricted interstate distribution of compounded products by requiring pharmacists to provide detailed documentation on such orders and advising state boards to discourage distribution of inordinate amounts of interstate compounded products, while also requiring physicians to document when compounded medications were needed.⁶² Finally,

it also called on the FDA to establish federal requirements for sterile compounding.⁶³

Opponents of this proposed legislation argued that it would not be practical to regulate compounded products as new drugs and that the costs and time involved in complying with the documentation requirements would complicate the prescribing and dispensing of these drugs, thus restricting access to patients who need them.⁶⁴ They further stressed that the proposed legislation would interfere with the physician-pharmacist-patient relationship by granting the FDA authority to determine when the medications are needed.⁶⁵ Again, in the face of significant opposition by the compounding pharmacists' lobby, this bill failed.⁶⁶ Thereafter, regulation of compounding pharmacies has remained largely with the states through the present day.

WHAT HAPPENS NEXT? Opinions vary as to what could have and what should have been done to avoid the fungal meningitis outbreak that continues to spread across the country. Some believe that regulation should remain largely with the states, while others believe that the FDA could have acted under the authority it already has. However, it is difficult to deny that evidence to date would suggest that, at least in the case of NECC, varying state regulations combined with a lack of FDA oversight has opened the door for safety problems to arise with compounding pharmacies. This evidence has led to reenergized efforts in Congress to enact wide-ranging legislation to regulate compounding pharmacies. Recently, Rep. Edward Markey, D-Massachusetts, said in a statement announcing new efforts to pass federal legislation to ensure that the FDA has authority to oversee these pharmacies: "Unfortunately, compounding pharmacies are a 19th-century service operating in a 21st-century industry, and we need to update and strengthen the rules that govern



these operations so that patients can safely benefit from the unique service they offer.”⁶⁷ Similarly, Rep. Rosa DeLauro, D-Connecticut, wrote in a recent letter to the Health and Human Services Secretary, Kathleen Sebelius: “This outbreak and the corresponding recall of products from the New England Compounding Center expose dramatic gaps in our drug safety standards that create an unnecessary risk to the public health.”⁶⁸ Representative DeLauro went on to write that while “some compounding pharmacies have evolved into large-scale operations that produce sizable quantities of some drugs [...] the FDA lacks clear authority for ensuring the safety of these products and last updated its guidance for [the] industry in 2002. Because of the current vague patchwork of federal and state oversight and regulation of these pharmacies, consumers are left at risk and often unaware of the differences between these products and others.”⁶⁹

At the same time, the FDA cites conflicting court rulings as the main obstacle for change. FDA Deputy Commissioner Deborah M. Autor recently stated: “We need to come together and work together [...]. It’s really unfortunate that it takes a crisis to bring this kind of change. But that often is the case. It is in crisis that we have the opportunity to make change. I will say that enforcement in this case and in other compounding cases is complicated greatly by litigation and by a lack of clarity in the law.”⁷⁰

In the end, as doctors continue to diagnose patients across the country with fungal meningitis and as many of those patients continue to succumb to this rare condition, it remains unclear how far the federal government will be able to go in enacting sweeping regulations of the drug compounding industry. However, with the continuing onslaught of media attention and public outcry keeping this issue front and center, it seems likely that some form of federal legislation will surely follow. While successful in the past, the lobbying efforts of compounding pharmacies will likely be overmatched this time around. However, as in the past, it seems certain that the courts will have the last word on any enacted legislation. Given past history, what happens next is anyone’s guess.

¹ Meningitis is an inflammation of the membranes that envelop the brain and spinal cord, which causes people to suffer from fever, new or worsening headache, nausea, and symptoms consistent with stroke. See *Dorland’s Illustrated Medical Dictionary*, 1,004 (27th ed. 1988).

² Centers for Disease Control and Prevention, CDC Newsroom, <http://www.cdc.gov/media/releases/2012/r1004_meningitis_outbreak.html>. Last accessed October 11, 2012.

³ Centers for Disease Control and Prevention, Multistate Meningitis Outbreak Investigation, <<http://www.cdc.gov/HAI/outbreaks/meningitis.html>>. Last accessed October 11, 2012.

⁴ Bliss, J., *The Tennessean*, October 15, 2012, “Meningitis Outbreak Keeps Local, CDC Labs Busy.”

⁵ Wilemon, T., *The Tennessean*, October 11, 2012, “Meningitis Outbreak: Harmful Meds Are Sole Weapon.”

⁶ *Id.*

⁷ *Id.*

⁸ Centers for Disease Control and Prevention, Multistate Meningitis Outbreak Investigation, *supra*, note 3.

⁹ Centers for Disease Control and Prevention, CDC Newsroom, *supra*, note 2. Brown, J. & Marsteller, D., *The Tennessean*, October 12, 2012, “Meningitis Outbreak: Compounding Pharmacies Have Advantages, Pain Doctors Say.”

¹⁰ Roche, Jr., W., and Wilemon, T., *The Tennessean*, October 12, 2012, “Meningitis Outbreak: Drug Regulators Seek More Oversight on Compounding Pharmacies.”

¹¹ Centers for Disease Control and Prevention, CDC Newsroom, *supra*, note 2.

¹² *Id.*

¹³ White, J., *The Wall Street Journal*, October 11, 2012, “Meningitis Case Count Rises to 170, Putting a Fast-Growing Industry on the Spot.”

¹⁴ Smith, E., *The Boston Herald*, October 17, 2012, “Feds Raid Pharmacy in Outbreak.”

¹⁵ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002).

¹⁶ *Id.* at 361.

¹⁷ Lam, Carol, *Pharmacy Compounding – Regulatory Issues*, <<http://regulatory.usc.edu/Journal.htm>> (last visited October 16, 2012).

¹⁸ *Id.*

¹⁹ White, J., *supra*, note 13; Cohen, E.; Dellorto, D.; and Hudson, W., *CNN*, October 10, 2012, “Meningitis Outbreak Highlights Failed Oversight Efforts.”

²⁰ Cohen, et al., *supra*, note 19.

²¹ Brown, et al., *supra*, note 9.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ Eisler, P., *USA Today*, October 12, 2012, “Deaths, Infections Tied to ‘Compounding’ Drugs.”

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Western States Med. Ctr.*, *supra*, note 15, at 362.

³⁰ *Id.*

³¹ *Professionals and Patients for Customized Care v. Shalala*, 847 F.Supp. 1359, 1362 (S.D. Tex. 1994).

³² *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 593–4 (5th Cir. 1995).

³³ *Id.* at 597.

³⁴ See generally *Professionals and Patients for Customized Care*, *supra*, note 32.

³⁵ *W. States Med. Ctr.*, *supra*, note 15, at 364.

³⁶ *Id.* at 363.

³⁷ *Id.* at 364 (citing 21 U.S.C. § 353a(a)).

³⁸ *Id.* (citing 21 U.S.C. § 353a(b)(1)(A)-(B)).

³⁹ *Id.* (citing 21 U.S.C. § 353a(b)(1)(C)).

⁴⁰ *Id.* (citing 21 U.S.C. § 353a(b)(1)(D)).

⁴¹ *Id.* (citing 21 U.S.C. § 353a(b)(3)(A)).

⁴² *Id.* (citing 21 U.S.C. § 353a(b)(3)(B)).

⁴³ *Id.* (citing 21 U.S.C. § 353a(a)).

⁴⁴ *Id.* at 364–65 (citing 21 U.S.C. § 353a(c)).

⁴⁵ *Western States Med. Ctr. v. Shalala*, 69 F.Supp.2d 1288 (D. Nev. 1999).

⁴⁶ *Western States Med. Ctr.*, *supra*, note 15, at 368.

⁴⁷ *Id.* at 377.

⁴⁸ *Id.* at 372.

⁴⁹ *Id.* at 366.

⁵⁰ *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 391 (5th Cir. 2008).

⁵¹ See, e.g., *In re Establishment Inspection of: Wedgewood Village Pharmacy, Inc.*, 270 F.Supp2d 525 (D.N.J. 2003).

⁵² Begley, S., *Reuters*, October 16, 2012, “Insight: How Compounding Pharmacies Rallied Patients to Fight Regulation.”

⁵³ Cohen, et al., *supra*, note 18; Begley, S., *supra*, note 52.

⁵⁴ Begley, *supra*, note 52.

⁵⁵ *Id.*

⁵⁶ See *Med. Ctr. Pharmacy v. Gonzales*, 451 F.Supp.2d 854 (W.D. Tex. 2006).

⁵⁷ *Id.* at 856.

⁵⁸ *Med. Ctr. Pharmacy v. Mukasey*, *supra*, note 50, at 394.

⁵⁹ *Id.* at 401.

⁶⁰ *Id.* at 405.

⁶¹ Lam, *supra*, note 17.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*; Begley, *supra*, note 52.

⁶⁷ Cohen, et al., *supra*, note 18.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ Roche, et al., *supra*, note 10.





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