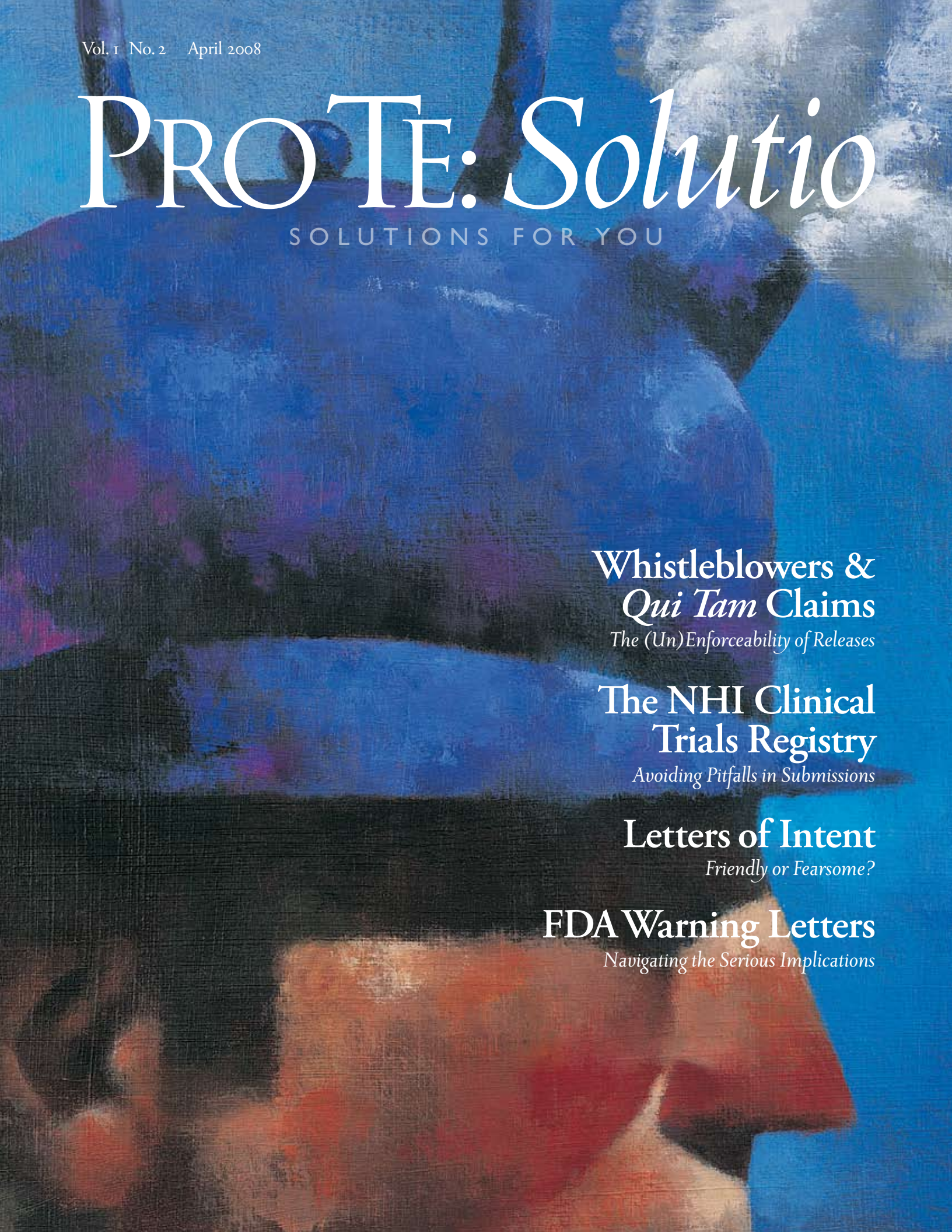
Vol. 1 No. 2 April 2008

PRO TE: *Solutio*

SOLUTIONS FOR YOU



Whistleblowers & *Qui Tam* Claims

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Dear Clients:

Welcome to our second quarterly issue of *Pro Te: Solutio* (Solutions For You), designed exclusively for Butler Snow Pharmaceutical, Medical Device, and Healthcare Industry clients.

Through this publication and our working relationships with clients like you, we seek to provide information that helps you solve, or avoid altogether, industry problems. Because your input and insights on this publication can help us be even more effective on your behalf, we welcome your feedback and suggestions. Please contact us by phone or email and let us know what you think.

The industry to which you've dedicated your resources and your future is growing more complicated and demanding every year. In this issue of *Pro Te: Solutio*, we're focusing on corporate submission and response matters with the FDA and the potential for legal liabilities as well as employee release agreements in regard to the FCA (False Claims Act).

Even though these topics range from interactions with a powerful Federal agency to negotiations with a present or past employee, the objective is the same: minimize your risks and avoid litigation. Within this issue you'll also find valuable information and specific case references on initiating *ex parte* contacts between a plaintiff's non-party treating physician and defense counsel. And in the business arena is an article on the importance of letters of intent prior to finalizing transactions.

As always, our Pharmaceutical, Medical Device, and Healthcare Industry Group hopes to provide you with practical insights based on Butler Snow's experience. Our ultimate goal? To make a difference for those dedicated to making a difference in the lives of others.

Christy D. Jones
Co-Chair — Litigation

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

Pro Te: *Solutio*

Vol. 1 No. 2 April 2008

Sharing Solutions

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

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

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

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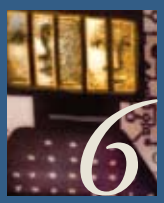

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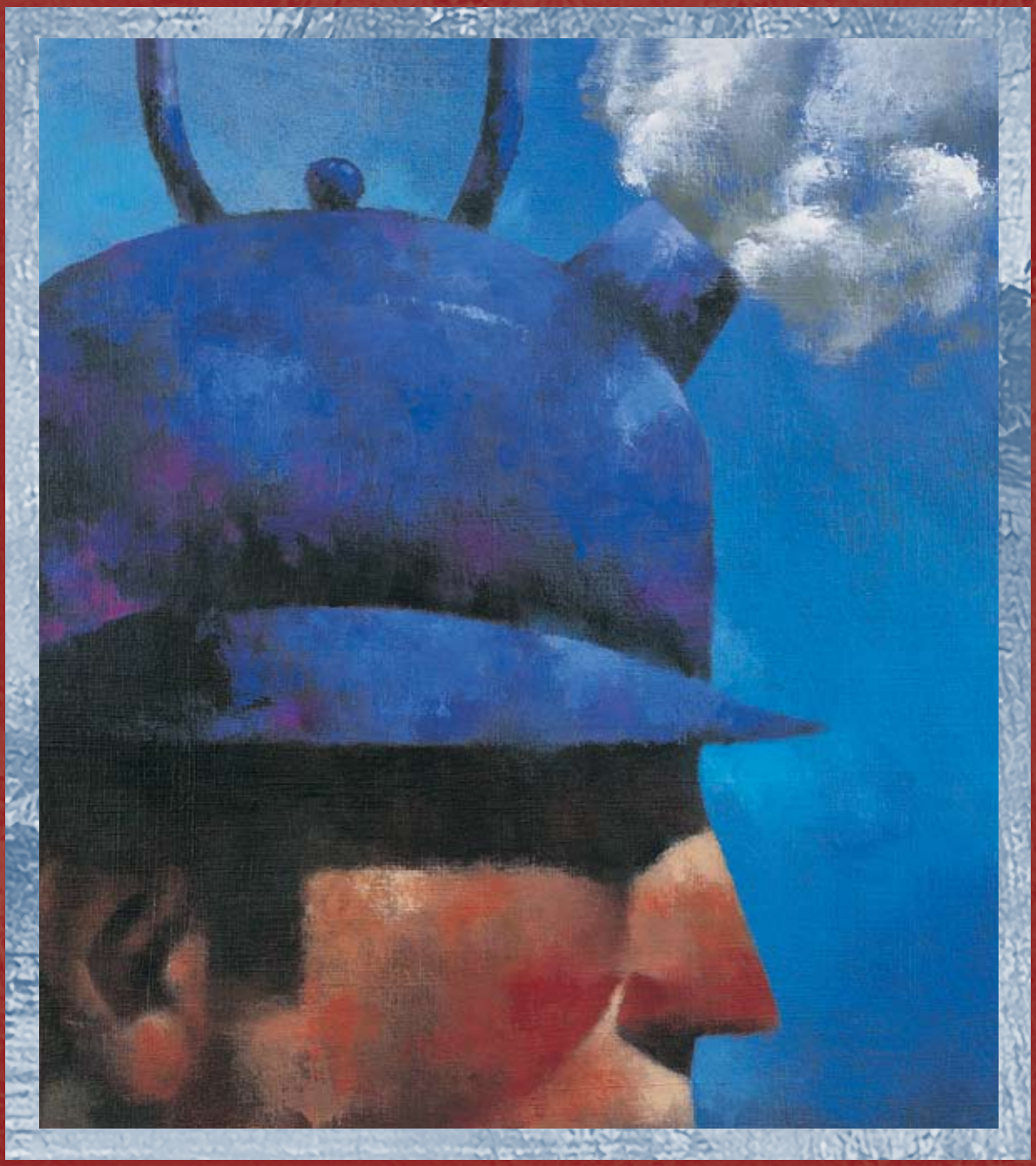


"HEADLINES FROM RECENT ARTICLES

flash before your eyes,
each one announcing an even larger

WHISTLEBLOWER

award against a competing company."

Having Your Cake and Eating It, Too — *The (Un)Enforceability of Releases on Pre-Filing Qui Tam Claims*. After weeks of skillful negotiation with a disgruntled employee's attorney, you are putting the final touches on a release to avoid what would have been a messy age discrimination lawsuit. During those negotiations you have discovered that your disgruntled employee was a pro — he had won a substantial verdict against his prior employer for similar claims. In hindsight, it was clear that the employee had spent the past six months setting up his next severance package. Just as you are congratulating yourself for drafting an iron-clad release, your email icon begins to blink.

You click open the email from the disgruntled employee and read, "I want to remind you that I still have concerns about several compliance issues that I brought to the company's attention over the last several months. I hope my replacement will have better luck than I did getting the company to take these concerns seriously." You shrink back into your chair wondering: *What concerns? What was he talking about?* Headlines from recent articles flash before your eyes, each one announcing an even larger whistleblower award against a competing company. You then look back at the release. Only moments ago, the document was a symbol of a crisis averted. Now, it looks weak and flimsy. Will the release cover this claim? If not, are there any actions you can take to guard against future *qui tam* claims brought by a released employee?

I. The False Claims Act Dilemma

The *qui tam* provision of the False Claims Act (FCA) encourages private citizens to bring a civil action on behalf of the United States against persons who defraud the government.[1] The term *qui tam* is an abbreviation for a Latin phrase which means, "he who sues on behalf of the king as well as for himself." The whistleblowing employee, called a "relator" in a *qui tam* action, must first file his or her complaint under seal, allowing the government time to decide if it wishes to intercede in the action before the complaint is served on the defendant.[2] During this initial period of review by the government, the *qui tam* action may only be settled and dismissed with written consent by both the court and the Attorney General.[3] To encourage insiders to come forward, the successful whistleblower may recover attorneys' fees and costs as well as a share of the recovery, usually up to 30% of the award.[4] If the government decides not to intervene following this initial review period, the whistleblower has the right to settle the claim.[5]

The FCA is silent, however, regarding the whistleblower's right to settle a potential *qui tam* claim *prior* to filing the claim in court. Doing so arguably prevents the government from ever becoming aware of the fraud and results in all of the settlement proceeds going to the whistleblower, not to the government. After all, the government is the party harmed by the fraud. The whistleblower just happened to be in the "wrong spot, at the right time" to take advantage of the claim. On the other hand, employers have an interest in finality when negotiating potential liability with their current and former employees, and the payout to the employee

would certainly act as a deterrent to future misconduct. While relatively few jurisdictions have addressed this issue, most courts that have done so have found that releases for yet-to-be-filed *qui tam* claims are void as against public policy.

II. The Current State of the Law

The prevailing case, *U.S. ex rel. Green v. Northrop Corp.*, arises from the Ninth Circuit.[6] The whistleblower in this case, Michael Green, had previously been employed as an investigator by Northrop Corporation's Advanced Systems Division. After being terminated, Green filed a wrongful discharge claim in state court alleging he had been fired for raising issues about Northrop's billing practices. To settle the discharge claim, Northrop paid Green $190,000 in exchange for Green's release of "any and all claims […] under the law."[7] Nine months later, Green filed a *qui tam* action against Northrop in federal court under the FCA, *raising the same billing issues* he had asserted in the settled state law suit. After the United States declined to intervene, the district court granted summary judgement, finding Green's settlement agreement in the prior suit barred his right to recovery.

The Ninth Circuit reversed and found that releases of *qui tam* claims prior to filing suit would undermine the central purpose of the FCA's *qui tam* provisions — incentivizing insiders to blow the whistle on fraud against the government. The Ninth Circuit was concerned that employers would settle with whistleblowers for an amount less than they would have to pay as a result of a successful *qui tam* claim. Under the FCA, whistleblowers only keep up to 30% of the recovery. The court reasoned that if pre-filing releases were allowed, a rational employee would be willing to accept a settlement for less than the total liability because the whistleblower would not have to share the settlement with the government. Moreover, the government, who was the wronged party in the first place, would recover nothing.

After the Ninth Circuit's ruling in *Green*, most district courts faced with a similar fact pattern have agreed that releases of *qui tam* claims prior to filing suit are unenforceable because they violate the public policy underpinnings of the False Claim Act.[8] This result makes final settlement with an outgoing employee virtually impossible. Even if the employee agrees to release any and every possible claim, that employee could literally deposit the settlement proceeds at the bank on the way to the courthouse to file a *qui tam* claim.

> The Ninth Circuit *reversed* a district court *ruling* and *found* that *releases* of *qui tam* claims *prior to filing* suit would *undermine* the *central purpose* of the FCA's *qui tam* provisions — *incentivizing* insiders to *blow the whistle* on *fraud* against the government.

III. A Glimmer of Hope?

Subsequent to *Green*, the Eighth and Ninth Circuits have found that in very limited situations, a pre-filing release may be enforceable to bar a future *qui tam* claim. Two years after *Green*, in *U.S. ex rel. Hall v. Teledyne Wah Chang Albany*, the Ninth Circuit considered the enforceability of pre-filing releases of *qui tam* claims where the government had already investigated the alleged *qui tam* claims and declined to intervene.[9] In this case, Christopher Hall, an engineer involved in the manufacture of nuclear reactor components for defendant Teledyne, alleged that Teledyne's manufacturing process did not meet government specifications.[10] Prior to filing any suit, in April of 1990, Mr. Hall brought this concern to management at Teledyne.[11] In response, Teledyne investigated the matter and concluded his concerns were unfounded.[12] Nevertheless, in January 1991, Teledyne informed the Nuclear Regulatory Commission (NRC) of Hall's concerns and the company's investigation.[13] Later that same month, Hall filed his own complaint with the NRC alleging Teledyne's failure to meet specifications.[14] In November 1991, the NRC informed Teledyne that after conducting its own investigation, it determined that the nuclear reactor components met specifications.[15]

Also in 1991, Hall initiated a state court action alleging a variety of employment related offenses.[16] In December 1993, Hall settled these claims with Teledyne and executed a broadly worded general mutual release. In 1994, less than one year after entering into the release, Hall filed a *qui tam* action in federal district court with the same allegations that Teledyne's manufacturing process did not meet government specifications.[17] The United States investigated, concluded the products met specifications, and declined to intervene in the action.[18]

The employer in *Hall* successfully argued that the prior release barred the plaintiff from proceeding with the *qui tam* claim. The court distinguished the case from *Green* noting that the federal government was aware of Hall's allegations and had investigated the allegations prior to Hall's settlement with Teledyne. Thus, in Hall, there was no concern that the release would prevent the government from learning about the alleged fraud.[19] Accordingly, under the *Hall* rationale, a release may be upheld if the defendant can prove that (1) the federal government had full knowledge of the plaintiff's charges before the release was executed, and (2) the federal government had already investigated the allegations prior to their release.[20] Thus, the *Hall* court creates an exception to the general rule that pre-filing releases are void as to future *qui tam* claims.

In 2001, the Eighth Circuit found a pre-

UNFORTUNATELY, HEALTHCARE ENTITIES *must assume* THAT PRE-FILING RELEASES OF *QUI TAM* CLAIMS WILL BE *unenforceable*. WHILE COUNSEL *may not* BE ABLE TO PROVIDE AN "*iron-clad guarantee*" THAT A FINAL RELEASE IS *indeed* FINAL, THEY CAN *undercut the ability* OF FORMER EMPLOYEES TO PURSUE A *QUI TAM* CLAIM.

filing release of a *qui tam* claim in a bankruptcy estate to be enforceable.[21] The Eighth Circuit, however, cautioned that its decision was extremely limited. The husband and wife relators in *U.S. ex rel. Gebert v. Transport Admin. Servs*. were terminated after their employer discovered the Geberts may have misappropriated over $500,000 in company assets. The Geberts subsequently filed for bankruptcy. When their former employer filed claims against them for misappropriation, the Geberts countered with a claim for $1.2 million. The bankruptcy trustee, the Geberts, and the former employer then entered into a settlement in which the trustee and the Geberts released the former employer for all claims. At no point, however, did the Geberts list among their schedule of assets a potential FCA claim.

The Geberts subsequently filed a *qui tam* lawsuit against their former employer. The Eighth Circuit, however, ruled the Geberts were barred from bringing the *qui tam* claim because of the release entered into during the bankruptcy proceedings. Moreover, the court found the Geberts to be judicially estopped from bringing the claim because the Geberts had failed to list their FCA claim in the schedule of assets before the bankruptcy court. The Eighth Circuit distinguished the Ninth Circuit's decision in *Green*, finding that the interest in enforcing the parties' release outweighed other policy concerns because the release was entered in the context of a bankruptcy proceeding rather than a general, independent release of a claim for money. Essentially, the court found that the public policy concerns addressed by *Green* were not present because the claim belonged to the bankruptcy estate, not to the former employees, and the proceeds of the release would flow to the estate instead of to the employee. The court noted, "the unique context of this case will have an exceedingly narrow application and, accordingly, will void nearly all of the public-interest harms discussed in [*Green*]."[22]

IV. Strategies for Uncertain Times

Unfortunately, healthcare entities must assume that pre-filing releases of *qui tam* claims will be unenforceable. While counsel may not be able to provide an "iron-clad guarantee" that a final release is indeed final, they can undercut the ability of former employees to pursue a *qui tam* claim. For instance, the release agreement should contain a representation and warranty section requiring that the employee affirmatively disclose any and all compliance issues with specificity, describe how the employee has firsthand knowledge of the issue, identify to whom and when the issue was reported, and indicate why they feel these claims have not been cured. This provision should contain the affirmation that the disclosure is true and correct to the best of the declarant's knowledge.

Doing so forces the employee to disclose all known concerns and helps narrow the universe of possible claims. Although a release may not be effective, counsel will at least know what possible claims may exist, placing settlement negotiations on a more level field. Also, if the former employee later asserts a *qui tam* claim on an undisclosed issue, counsel has ammunition to attack the credibility of the relator. Finally, if your company has investigated the compliance issue and found the allegations to be meritless, the company may consider informing the proper government authorities itself to come within the *Hall* exception and protect against later *qui tam* lawsuits. Thus, while you may not be able to keep your disgruntled employee out of the courtroom, you may be able to make him think twice before filing suit.

[1] 31 U.S.C. §3729, 3730(b).

[2] *Id.* at §3730(b).

[3] *Id.*

[4] *Id.* at §3730(d).

[5] *Id.*

[6] *U.S. ex rel. Green v. Northrop Corp.*, 59 F.3d 953 (9th Cir. 1995)(*Green*).

[7] *Id.*

[8] *See, e.g., U.S. ex rel. El Amin v. George Washington University,* 2007 WL 1302597 *3-8 (D.D.C. 2007) (finding the public policy objectives of the False Claim Act outweigh the Defendant's undisputed interest in enforcing the release); *U.S. ex rel. Longhi v. Lithium Power Technologies*, 481 F.Supp.2d 815, 818 (S. D. Tex. 2007) (finding that enforcement of such a release would run counter to public policy and serve to potentially shield those who allegedly commit fraud against the United States); *U.S. ex rel. Bahrani v. ConAgra, Inc.*, 1983 F. Supp. 2d 1272 (D. Colo. 2002) (denying defendant's motion to dismiss and finding a pre-filing release invalid), *rev'd on other grounds* 465 F.3d 1189 (10th Cor. 2006); *U.S. ex rel. Pogue v. American Healthcorp, Inc.*, 1995 WL 626514 (M.D. Tenn. Sep. 14, 1995), *vacated on other grounds*, 914 F. Supp. 1507 (M.D. Tenn. 1996); *U.S. ex rel. DeCarlo v. Kiewit/AFC Enters., Inc.*, 937 F. Supp. 1039 (S.D.N.Y. 1996); *but see U.S. ex rel. Whitten v. Triad Hosps., Inc.*, 2005 WL 3741538 (S.D. Ga. Oct. 27, 2005) (holding that a pre-filing release of qui tam claims *was enforceable and did not violate public policy*) *rev'd on other grounds, U.S. ex rel. Whitten v. Triad Hosps., Inc.*, 2006 WL 3626992 (11th Cir. Dec. 13, 2006).

[9] 104 F.3d 230 (9th Cir. 1997).

[10] *Hall*, 104 F. 3d. at 231.

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.* at 231-32.

[16] *Id.* at 232.

[17] *Id.*

[18] *Id.*

[19] *Id.* at 233.

[20] *Id.*

[21] *U.S. ex rel. Gebert v. Transport Admin. Servs.*, 260 F.3d 909 (8th Cir. 2001).

[22] *Id.*

WRITTEN *by*
TODD P. PHOTOPULOS

How Did That Information End Up As Plaintiff's Exhibit 1?

Submitting Information to the Clinical Trials Registry and Results Database Under the FDAAA — and Suggestions to Avoid Pitfalls.

Introduction

Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), sponsors are required to submit specific information regarding clinical trials to the Director of the National Institutes of Health (NIH) for posting on a clinical trial registry and results databank.[1] The Amendments further require that this databank website be easily searchable by laypersons. It is a plaintiff's attorney's dream come true when he or she finds a manufacturer's communication that can be shown to a jury to imply liability on the part of the manufacturer. This website will allow plaintiffs' attorneys to scrutinize and dissect a new "set" of manufacturer-provided information. They will understandably seek to use this information against the manufacturer.

Not only can plaintiffs' attorneys mine your submissions for potential adverse evidence, but the FDA can also impose severe sanctions if your company does not comply with the FDAAA. The FDA has several sanctions it can apply against the sponsor for failure to submit the requisite information and for submitting false and misleading information for inclusion in the registry or databank.

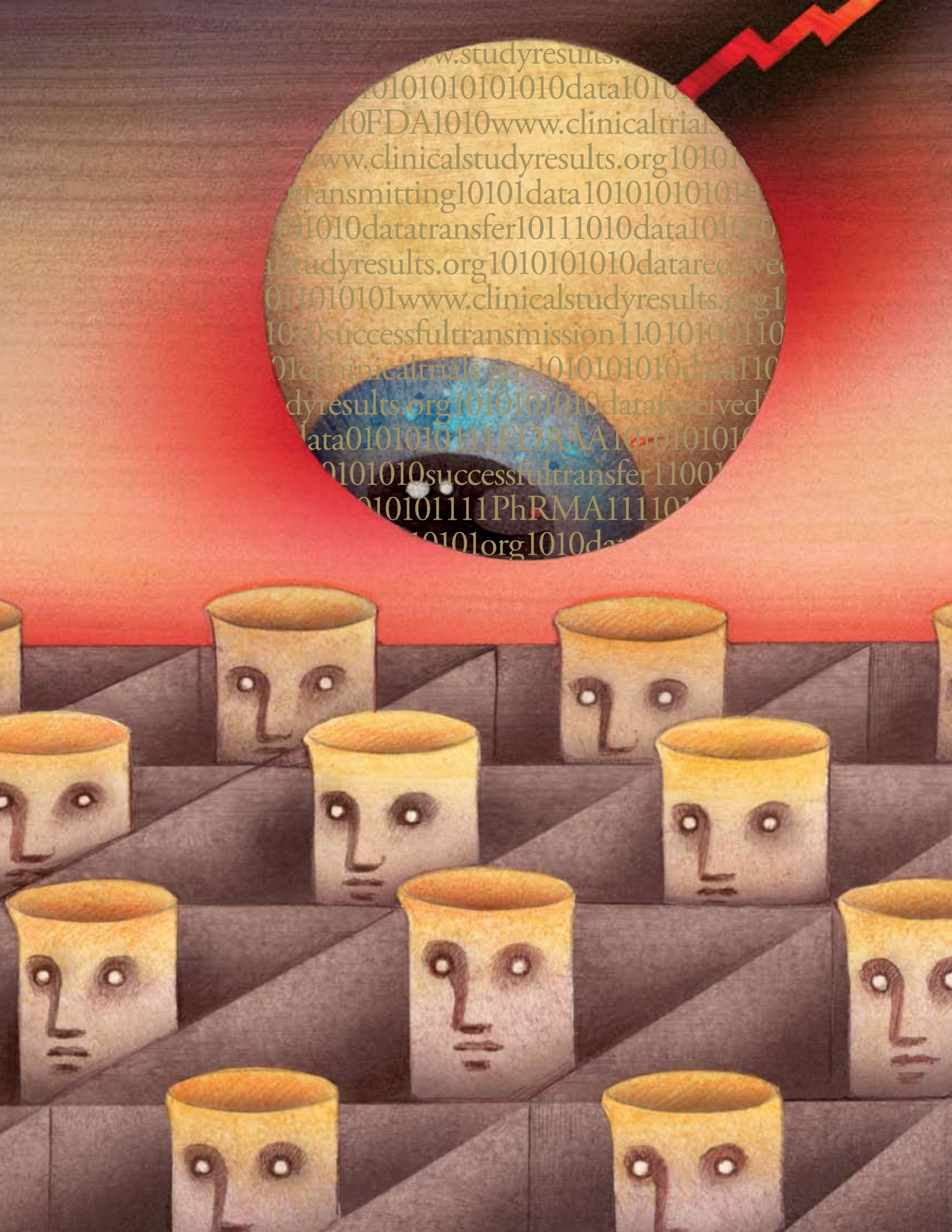
On the other hand, to counter the typical plaintiff's argument that clinical studies were "buried," or a manufacturer was less than forthcoming, a manufacturer will now be able to point to the accurate, straightforward information posted on the databank as proof it had nothing to hide. Additionally, the manufacturer can show that the public and the medical community had notice of the results of those studies which were properly described and posted in the databank.

Background

Prior to the passage of the FDAAA, federal statute required that the Director of the NIH maintain a website that contained information "on clinical trials for drugs for serious or life-threatening diseases and conditions."[2] Even though the database has been available at *www.clinicaltrials.gov* since February 29, 2000, as of 2006, it only contained information on slightly over 30,000 studies. This is a small number of studies compared to the number of clinical studies that take place each year.

For the last few years, there has been a groundswell of support for the idea that all Phase II and Phase III clinical studies should be listed on this or a similar website. For example, in 2004, the International Committee of Medical Journal Editors announced that clinical trials begun after July 1, 2005, must be listed in a public trials registry at initiation if they are to be considered for publication. In October 2004, The Pharmaceutical Research and Manufacturers of America (PhRMA) established a database which listed clinical trials at *www.clinicalstudyresults.org*. Some pharmaceutical companies also started their own clinical trial websites. In the legislative area, various bills requiring more disclosure of clinical trials have been introduced in the U.S. Senate and House over the last few years. The FDAAA codified this sentiment and included requirements for the Secretary of Health and Human Services, acting through the Director of the NIH, to expand the clinical trial registry and add a clinical data results database.[3]

Although it is beyond the scope of this article to set forth all the ways in which the FDAAA affects clinical trials, a summary of certain aspects of the law is helpful to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understand the issues facing a manufacturer who is the responsible party. The FDAAA requires a responsible party to submit information for any ongoing applicable device or drug clinical trial[4] to the NIH to be put in a registry available over the internet.[5] The information for any applicable clinical trial that is initiated after or is ongoing on December 26, 2007, is to be submitted no later than that date or twenty-one days after the first patient is enrolled in such a clinical trial. If the clinical trial is not for a serious or life-threatening disease, the responsible party may submit the information up to September 27, 2008.[6] Unless there are no changes to the information, the sponsor is to update the information at least annually.[7]

The FDA has several severe sanctions it can apply against the sponsor for failure to submit the requisite information and for submitting false and misleading information for inclusion in the registry or databank.

The statute sets forth a long list of information that must be submitted for the clinical study, some of which is quite fact-specific, such as the start and completion dates, target number of subjects, location of sites, and eligibility criteria. However, some of the requirements are more descriptive including the primary purpose, study design, a brief summary for the lay public, and outcomes, both primary and secondary.[8] It is in these more descriptive items that the danger lies if the submissions are not carefully worded, especially since the Director of the NIH is directed to make sure that the public will be able to search the clinical trials data registry by many criteria including disease, drugs being studied, and sponsors as well as by keyword.[9]

Additionally, the responsible party must submit to the Director within a certain timeframe after the clinical study is completed,[10] certain information for inclusion in a results database. Such results must be submitted for drugs that are approved or licensed under sections 262 or 355 of Title 21 or devices that are approved under Title 21 §§360(k), 360(e) or 360j(m).[11] Such information shall include, *inter alia*, demographic and baseline characteristics of patient samples, including patients excluded from the analysis, and primary and secondary outcomes.[12] Additionally, the Secretary is to promulgate regulations that provide that the registry and results databank include a summary of the clinical trial and its results in technical and "non-technical, understandable language for patients," if the Secretary determines that such summaries can be included without being misleading or promotional.[13]

The Secretary is also to promulgate regulations addressing how to include in the results databank information on serious adverse and frequent adverse events for these approved or licensed drugs. If the Secretary fails to issue those regulations by twenty-four months after September 27, 2007, the statute requires that there be tables: 1) with information as to anticipated and unanticipated serious adverse events grouped by organ system with frequency of the event in each arm of the clinical trial and 2) a table of anticipated and unanticipated adverse events not already listed that exceed a frequency of five percent within any arm of the study.[14] The responsible party would have to submit such information.

Potential Problems

The FDAAA has teeth, and the violation of some of its provisions can be disastrous. As evidenced by the listing below, failure to comply with its provisions as to clinical trials can have serious and far-reaching consequences, as well as hand plaintiffs' attorneys ammunition for any future litigation.

The statute requires that any information submitted by a responsible party "shall not be false or misleading in any particular."[15] If there is a violation of this section, the Director of the NIH "shall" include in the registry databank entry the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in

compliance with the law."[16] Such a statement would be something the plaintiff's attorney would latch onto to claim negligence *per se* and fraud in any future lawsuit. Additionally, any false or misleading statements could presumably be submitted to the Justice Department for review. The Justice Department has an increasing level of interest in healthcare fraud, as evidenced by the recent creation of a strike force to tackle healthcare fraud in Miami and planned strike forces in Los Angeles and Houston. Moreover, because any statements on the registry or databank will be fully accessible by the public and the medical community, there will no doubt be claims of injury due to the public's reliance on these "fraudulent" statements.

The FDAAA further states that if the responsible party has not submitted the required clinical trial information, the Director "shall" include in the registry and data results databank the following statement: "The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry."[17] Questions would be raised in any lawsuit regarding the drug or device as to why these results were not submitted and whether the manufacturer had something to hide. Similarly, if the responsible party for a clinical trial fails to submit the required primary and secondary outcomes, the Director of the NIH "shall" include a notice in the registry and results databank that the responsible party is not in compliance because the primary and secondary outcomes were not submitted for inclusion on the registry and results databank.[18]

> It is a plaintiff's attorney's dream come true when he or she finds a manufacturer's communication that can be shown to a jury to imply liability on the part of the manufacturer.

Certain applications for approval of a drug or device to the FDA must contain a certification that 42 USC 282(j) requirements have been met.[19] Therefore, a failure to follow this section may mean that the applicant will not be able to ask for FDA approval to market the drug or device. The failure to submit that certification, submission of false certification, submission of false and misleading information, or failure to submit required information under 282(j) are "prohibited acts" as set forth under 21 U.S.C. §331(jj). Anyone who violates this section is liable for a monetary penalty of not more than $10,000 for the violation. If the violation is not corrected within thirty days of the notification of violation, the person shall be liable for an additional fine of not more than $10,000 a day until the violation is corrected, with no limitation as to the amount of days the fine can continue.[20]

It is axiomatic that manufactures cannot promote off-label use of their drug or device; however, post-marketing studies are sometimes done to support a new use of a drug or device. The study may show that the drug or device is safe and efficacious for the off-label use. The manufacturer will need to submit information on such a study under §282(j), and such information will be posted on the clinical results database. The FDA may not have acted to approve such off-label use as yet. The allegation may be made that by submitting such information, the manufacturer is promoting off-label use on a website accessible to the public. States attorneys general are interested in and have investigated allegations of off-label promotion of drugs.

As can be seen from the above examples, the potential for problems for the manufacturer who is a responsible party are many.

How To Avoid Some Of These Problems

Some of this information was to be submitted for inclusion in the databank under the FDAAA by December 26, 2007, but steps can be taken to minimize risk in future submissions. Set up standard operating procedures that set forth all the steps that will be taken to ensure compliance with §282(j).

> The FDAAA has teeth, and the violation of some of its provisions can be disastrous. If there is a violation, the Director of the NIH "shall" include in the registry databank entry the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law."

These SOPs should include specific persons who will be responsible for drafting language, reviewing language, and making sure all information is submitted timely. Provisions should be made for some kind of internal or external audit after the process is in effect to make sure that the SOPs are followed. The SOPs should also include who should not be involved in this process. (See section on marketing below).

The language in any summary for completed clinical studies, or for the more subjective descriptions in the ongoing clinical studies, obviously needs to be drafted to accurately show the science involved. However, the manufacturer needs to be mindful that such submissions might be used in litigation. Therefore, the specific language of the submission also needs a review specifically with litigation in mind. The following checklist may be helpful:

- Are all necessary facts included without editorializing, advocacy, or promotion?
- How would each sentence or phrase hold up on its own, especially if taken out of the context of the other language in the submission?

• How would that phrase look blown up in an exhibit at trial?
• Is there scientific data to back up each statement?
• Does the summary of completed clinical studies disclose any risks or downsides of the study? Should it for this submission?

It is also important not to promote off-label use. Information regarding any post-marketing studies that are done to support a new use will be submitted to the FDA and will be posted on the clinical results database. Such summaries have to be even more carefully scrutinized before submittal to make sure they do not contain any promotional off-label use language. They also need to avoid any endorsement of early/erroneous conclusions and indicate the study limitations. The FDAAA did include a "Rule of Construction" that states that submission of clinical trial information "submitted in compliance with" §282(j) that relates to the use of a drug or device that has not been approved "will not be construed by the Secretary of Health and Human Services or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different for the intended use of the drug."[21] This rule of construction should be helpful to the manufacturer in defending any allegation of promotion of off-label use. However, it also begs the question, if such language could be construed as promotional, would it be language that is "in compliance with" §282(j)?

Do not let marketing or sales be involved in any way in reviewing what is submitted to the registry or databank. Neither marketing nor sales personnel should get any copies of this material either officially or unofficially prior to submisson to the Director of the NIH. In a large organization, a copy of proposed language finding its way to someone in sales and marketing can happen in an unofficial manner. A sales or marketing person then shoots off an e-mail with some thoughts. The e-mails become available to a plaintiff's attorney in discovery. Even if the e-mail or other communication does not affect what is posted, the plaintiff's attorney will tout it as evidence of one of their favorite themes: that the manufacturer "is putting profits over health and safety."

Review information submitted to the FDA for consistency. For example, adverse drug event reports must be submitted to the FDA within a certain short time frame of their occurrence as required by law. Adverse event reports are also part of annual reports to the FDA. Now, under the FDAAA, there will be another level of reporting of adverse reports from clinical studies on approved drugs. Unless the Secretary issues regulations to the contrary, these reports will be in the form of tables.

DO NOT LET MARKETING OR SALES BE INVOLVED IN ANY WAY IN REVIEWING WHAT IS SUBMITTED TO THE REGISTRY OR DATABANK.

Questions may be raised if the numbers on the tables do not match earlier adverse drug event report numbers. There may be a valid explanation; however, looking for consistency in the numbers up front, with documentation regarding any differences, will be more helpful than trying to figure out what happened later on. By the time this issue comes up at trial, the person who prepared the tables may have left the company or, most likely, will not be able to duplicate his or her thought processes.

Have a system in place to make sure all information required is submitted on time. This recommendation seems obvious, but failure to submit information on clinical studies before the FDAAA was not a big issue. This fact may have led to a feeling that the submission of such information was not a priority. Failure to do so now can have serious consequences as stated above.

Finally, have someone responsible either to check the FDA website or to be on the e-mail list for the FDA, specifically to watch for proposed regulations and guidances on the issue of the clinical trial registry and results database.

Conclusion

Knowing the regulations regarding the clinical trials and results database and submitting the information required will be a learning process and time consuming at first. Failure to properly think about and plan for these submissions can be risky and have serious consequences. Having good procedures in place will make the submission process go more smoothly and, if done correctly, can be of benefit to your company.

[1] The law actually defines "responsible party" to mean the "sponsor" as defined in 21 CFR §50.3 or the principal investigator of the clinical trial if he or she is so designated by certain parties. 42 U.S.C. §282(j)(1)(A)(3). For purposes of this article, however, we will assume that the manufacturer is the responsible party.

[2] 42 U.S.C. §282(i).

[3] 42 U.S.C. §282(j)(2)(A)(i), 42 U.S.C. §282(j)(3)(E).

[4] "The term 'applicable drug clinical trial' means a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug subject to section 355 of Title 21 or to section 262 of this title. 42 U.S.C. §282(j)(1)(A)(iii). The term 'applicable device clinical trial' means — (I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 360(k), 360e, or 360j(m) of Title 21 against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and (II) a pediatric postmarket surveillance as required under section 360l of Title 21." 42 U.S.C. §282(j)(1)(A)(ii).

[5] 42 U.S.C. §282(j)(2)(C).

[6] *Id.*

[7] 42 U.S.C. §282(j)(4)(C).

[8] 42 U.S.C. §282(j)(2)(A)(ii)(I).

[9] 42 U.S.C. §282(j)(2)(B).

[10] *See* 42 U.S.C. §282(j)(3)(E)(i).

[11] *See* 42 U.S.C. §282(j)(3)(C).

[12] 42 U.S.C. §282(j)(3)(C)(i-iv).

[13] 42 U.S.C. §282(j)(3)(D)(iii).

[14] 42 U.S.C. §282(j)(3)(I).

[15] 42 U.S.C. §282(j)(5)(D)(i) (emphasis added).

[16] 42 U.S.C. §282(5)(E)(iv).

[17] 42 U.S.C. §282(j)(5)(E)(iii).

[18] 42 U.S.C. §282(j)(5)(E)(ii).

[19] 42 U.S.C. §282(j)(5)(B).

[20] *See* 21 U.S.C. §333(f)(3).

[21] *See* Pub. L. 110-85, Title VIII §801(d), Sept. 27, 2007.

Written *by* Melissa Baltz

EX PARTE CONTACT BETWEEN A PLAINTIFF'S NON-PARTY TREATING PHYSICIANS AND DEFENSE COUNSEL IN PERSONAL INJURY CASES

The cases below are limited to the requirements under state law. As a practical matter, to comply with federal HIPAA requirements, an attorney who wishes to contact an adverse party's treating physician should first obtain a valid HIPAA authorization or a court or administrative order broad enough to cover verbal communications with treating physicians. Additionally, none of the cases below place any obligation upon an individual physician to speak with defense counsel. As one court noted, physicians are "free to react in any way dictated by their professional consciences, from fully discussing [a plaintiff's] medical history and condition to abruptly slamming their office doors in the attorneys' faces."[1]

THE FOLLOWING CASES hold that *ex parte* contact between a plaintiff's non-party treating physicians and defense counsel is permitted provided the discussion is limited to medical information relevant to the case:

Alaska: Trans-world Investments v. Drobny, 554 P.2d 1148, 1152 (Alaska 1976).

Delaware: Green v. Bloodsworth, 501 A.2d 1257, 1258-60 (Del. Super. 1985).

District of Columbia: Street v. Hedgepath, 607 A.2d 1238, 1247 (D.C. 1992).

Idaho: Morris v. Thomson, 937 P.2d 1212, 1217-18 (Idaho 1997).

Kentucky: Roberts v. Estep, 845 S.W.2d 544, 547 (1993).

Maryland: Butler-Tulio v. Scroggins, 774 a.2d 1209, 1216-17 (Md. App. 2001).

Michigan: Domako v. Rowe, 475 N.W.2d 30, 36 (Mich. 1991).

Missouri: Brandt v. Med. Def. Assocs., 856 S.W.2d 667, 671 (Mo. 1993).

New Jersey: Stempler v. Speidel, 495 A.2d 857, 864 (N.J. 1985).

New York: Arons v. Jutkowitz, -- N.E.2d --, 2007 WL 4163865 *10-11 (N.Y. 2007).

Rhode Island: Lewis v. Roderick, 617 A. 2d 119, 122 (R.I. 1992).

Texas: In re Collins, 224 S.W.3d 798, 805 (Tex. App. 2007).

Wisconsin: Steinberg v. Jensen, 534 N.W.2d 361, 371-72 (Wisc. 1995) (holding that limited conversations are appropriate, provided certain disclosures are made; but that "a private question and answer session wherein the lawyer asks questions designed to elicit previously unknown information from the physician" is not permitted).

THE FOLLOWING CASES find that *ex parte* contact between a plaintiff's non-party treating physicians and defense counsel is not permitted holding, in general, that such *ex parte* communications violate the implied covenant of confidentiality that exists between physicians and patients. Moroever, many of the courts rationalize that discussion of the patient's confidences under circumstances other than through formal discovery is potentially harmful to the interests of the patient in that the physician might disclose intimate facts regarding the patient which are unrelated and irrelevant to the mental or physical condition placed at issue in the lawsuit.

Arizona: Duquette v. Superior Court, 778 P.2d 634, 639 (Ariz. App. 1989).

Florida: Acosta v. Richter, 671 So.2d 149, 156-57 (Fla. 1996).

Illinois: Mondelli v. Checker Taxi Co., 554 N.E.2d 266, 270-274 (Ill. App. Ct. 1990).

Indiana: Cua v. Morrison, 626 N.E.2d 581, 586 (Ind. App. 1993).

Minnesota: Wenninger v. Muesing, 240 N.W.2d 333 (Minn. 1976) but see Minnesota Statute §595.02, Subd. 5 (allowing informal discussions between defense counsel and treating physicians provided notice is given to plaintiff's counsel 15 days in advance and plaintiff's counsel has an opportunity to be present).

Mississippi: Scott v. Flynt, 701 So.2d 998, 1007 (Miss. 1996).

North Carolina: Crist v. Moffat, 389 S.E.2d 41, 45-47 (N.C. 1990).

Ohio: Hammonds v. Aetna Casualty & Surety Co., 243 F. Supp. 793 (N.D. Ohio 1965).

Pennsylvania: Alexander v. Knight, 177 A.2d 142, 146 (Pa. Super 1962).

Tennessee: Alsip v. Johnson City Medical Center, 197 S.W.3d 722, 723-4 (Tenn. 2006).

Utah: Sorensen v. Barbuto, -- P.3d ---, 2008 WL 268978, *5-6 (Utah 2008).

Washington: Loudon v. Mhyre, 756 P.2d 138, 140-42 (Wash. 1988).

West Virginia: State ex. rel Kitzmiller v. Henning, 437 S.E.2d 452, 455-56 (W. Va. 1993).

[1] *Davenport v. Ephraim McDowell Memorial Hosp., Inc.*, 769 S.W.2d 56, 62 (Ky. App. 1998).

Navigating Through the Serious Implications of an FDA Warning Letter

Your company has received a Warning Letter addressing certain manufacturing activities that were cited in a 483 form and are now highlighted in the Warning Letter. The FDA routinely issues guidances and other instructions, formal and informal, to assist companies in maintaining good practices with respect to maintenance of their facilities. Still, the majority of companies have received and are all too familiar with what is known in the industry as a Warning Letter. This article addresses examples of underlying conduct while focusing on the following: 1) specific examples in the manufacturing area that could potentially be the subject of the Warning Letter; 2) the guidances and regulations applicable to the cited conduct; 3) steps a company should take to address and respond once it has received a letter; and 4) the potential litigation implications.

Introduction

After an inspection, FDA investigators issue a form FDA-483 which lists the adverse observations made during an inspection. Following the review of the 483 and the establishment inspection report (EIR), the FDA District Office may elect to send the inspected company a Warning Letter.

A Warning Letter differs from an FDA-483 in that the Warning Letter indicates that higher level FDA officials, as opposed to an individual investigator or District Office, have reviewed the inspection findings and concluded that the findings warrant formal notification of serious violations.

The Warning Letter is not a final action. The FDA Reference Guide provides: "A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued."[1] Warning Letters, unlike FDA-483s, are posted publicly to the agency's website (*www.fda.gov/foi/warning.htm*). Additionally, responses submitted on behalf of the company as to corrective actions are also posted on the same site.

The Federal Food, Drug, and Cosmetic Act, Code of Federal Regulations; guidances from the FDA; and a limited body of case law govern the FDA's authority to issue Warning Letters and other communications

related to manufacturing processes, the effect of such letters on a company's continued research and development, as well as any potential legal implications.

The Compliance Program Guidance Manual Program provides an outline to the FDA staff on how to handle various aspects of the governing activities, including drug manufacturing inspections.[2]

> A Warning Letter *differs* from an FDA-483 in that the Warning Letter indicates that *higher level* FDA officials, as *opposed* to an individual *investigator* or District Office, have *reviewed* the inspection *findings and concluded* that the findings warrant *formal* notification of *serious violations*.

Suggested Action for Company

Once a company has received the Warning Letter, certain steps should be followed to assess the background and circumstances of the conduct underlying the Warning Letter. These steps include:

A. Evaluate Violations and the Basis for Violations Cited in Letter.

The company should start by analyzing what the basis was for the Warning Letter and determine whether the inspection giving rise to the Warning Letter was a routine inspection, the result of MedWatch reports, or the result of other specific complaints. The company should assess the status of the inspection and look back at the FDA-483 to analyze observations noted in the FDA-483. The company will most likely have already prepared a response to the 483, initially in an exit interview, followed by a formal written response. Additionally, the company should look back to the EIR and analyze inspection observations and links to evidence supporting observations.

B. Preparing the Response and Other Actions to Consider.

A formal response to the Warning Letter will need to be submitted to the FDA.[3] Below is a sample outline for what should be included in the response.

1. Statement of commitment to comply with applicable laws and regulations.

2. Statement recognizing the seriousness of the Warning Letter and the company's commitment to addressing all issues raised.

3. An address of each item in the Warning Letter individually.

4. Scope of corrective action plan, including detailed reports on what has been done and what will be done in the future to correct the issues identified in the letter.

Corrective actions and follow up correspondence updating the agency on each step taken to address the cited conduct should be taken until the company receives a final letter from the FDA stating that "the matter is satisfactorily closed." In addition to the specific corrective actions put in place to address the conduct cited in the Warning Letter, consider implementing one or more of the following: (1) Policy letter or other formal change to policies to prevent similar conduct in the future; (2) meeting or teleconference with FDA to discuss conduct; (3) depending on the impact that the cited conduct has on a product, consider issuing a recall notice and/or sending a Dear Healthcare Provider Letter informing the field of the cited conduct.

> Corrective *actions* and follow up *correspondence* updating the agency on *each step taken* to address the *cited* conduct should be taken *until* the company receives a *final letter* from the FDA stating that "the matter is *satisfactorily closed*."

Potential Liability Implications

The Warning Letter could potentially impact litigation involving the manufacturing facility and its products directly. As mentioned above, the Warning Letter and the relevant responses will be publicly available and easily obtained from the agency's website. While the Warning Letter is not an individual basis for liability, the company should expect to see it in any product liability suit, particularly in the depositions of company representatives. Arguments can be made to exclude the Warning Letter at trial, and in many instances, the company may be successful in excluding the Warning Letter depending on the jurisdiction and extent of connection between the cited conduct and the event giving rise to litigation. However, even if the cited conduct is not directly relevant to the basis for lawsuits, plaintiffs may attempt to use the Warning Letter in any claim against the company to show an alleged pattern or history of bad manufacturing practices.

In assessing liability and the potential impact of the Warning Letter, the company may want to consider taking the following precautionary measures:

1. Collect and maintain all documents pertaining to the cited conduct and the Warning Letter.

The Warning Letter *could potentially* impact *litigation* involving the manufacturing *facility* and its *products directly* — as the *warning letter* and the *relevant* responses will be publicly available and *easily* obtained from the agency's website.

2. Collect and maintain Adverse Event Reports that stem from products connected to the facility at issue.

3. Compose a list of individuals with knowledge of the cited conduct and consider conferences between these individuals and the legal department.

Plaintiffs will attempt to use the Warning Letter, as well as any previous Warning Letters or untitled letters, as a basis to show that the company has a pattern or practice of unlawful manufacturing.

The company will have several defenses to the Warning Letter should it be used in depositions and/or admitted at trial. The defenses will be based on the corrective actions taken to address the cited conduct as well as any follow-up actions or correspondence from the FDA. Below are themes that may or may not be applicable depending on the company's course of action for responding to the Warning Letter and FDA's decisions.

1. The Warning Letter was not a blanket condemnation of the manufacturing operations at the company. The Warning Letter was a complaint directed at certain discrete events.

2. The company took the FDA's allegations very seriously and undertook a thorough investigation.

3. To support the argument that the company took the Warning Letter seriously and addressed the cited conduct, the company will rely upon the details of response, including date, content, and any additional follow-up conversations or correspondence.

4. The company took actions to ensure that any product potentially affected by the cited conduct was evaluated, and proper recourse was taken to address any adverse effect.

5. The company corrected the cited conduct by undertaking specific actions to address the processes cited in the Warning Letter.

6. The FDA required no further action and found that the company's responses were appropriate.

If the company is faced with liability and the Warning Letter is exploited, the company will have arguments to exclude the Warning Letter from being used in litigation. The following analysis is based on the Federal Rules of Evidence and will need to be modified depending on the applicable law.

The company will have *several* defenses to the Warning Letter should it be *used* in *depositions* and/or admitted *at trial*. The defenses will be based on the *corrective actions* taken to address the *cited conduct* as well as any follow-up *actions* or correspondence *from* the FDA.

As part of its regulatory procedures, FDA employees issue untitled letters and Warning Letters to companies to afford those companies an opportunity to correct perceived violations before the FDA decides whether to file an official enforcement action against the company.[4] The FDA itself makes clear that a "Warning Letter is informal and advisory" and does not constitute final agency action.[5] Warning Letters and other informal FDA letters, therefore, do not meet any of the requirements for a hearsay document to be admissible under the public records or business records exception to the hearsay rule. Such communications provide a preliminary evaluation by FDA staff of a company's manufacturing practices. They do not report on the activities of the FDA itself.[6] The FDA specifically states that it has no duty to issue Warning Letters or other such communications, and therefore the letters are not written "pursuant to duty imposed by law as to which matters there was a duty to report."[7] The Warning Letters and other such communications are communications from FDA staff that precede any official enforcement action and contain allegations not based upon any formal or adjudicated finding of regulatory violations, which constitute opinions rather than factual statistics.[8]

Finally, the FDA untitled and Warning Letters and other such communications are not the kind of trustworthy report described in Rule 803. Communications such as these lack the trustworthiness required to fall within the hearsay exception because they do not represent the official or final position of the agency.[9] Because of this inherent lack of trustworthiness, such communications are also not "business records" under Rule 803(c)(6). Rule 803(6) excepts written records made in the regular course of business "unless the sources of information or the method, purpose or circumstances of preparation indicate that it is not trustworthy."[10]

Additionally, the company can argue that FDA Warning Letters or other unofficial statements by FDA employees or participants in FDA advisory committee meetings should be excluded under Rules of Evidence 401 and 403. In the first instance, unless a

EXHIBIT "A"

A POORLY PERFORMED DEPOSITION of a company representative on videotape can haunt litigation for years to come in the mass tort context. It may be something as inconsequential as a sweaty brow or nervous tick or a series of "I dunnos" which unintentionally communicate an appearance of evasiveness that undermines the witness's substantive testimony.

Numerous studies have been conducted on the effects and impact of the videotape medium on jurors. "When jurors take their seats in the jury box, they bring an affinity for television and packaged information developed over countless hours of television viewing," says Karen Martin Campbell.[1]

Using videotape to present evidence "may impact the way the information is processed and judgments are formed" by the jury.[2] Research shows that although individuals are typically critical and analytical of live communication, that "we routinely accept [television's] communication without question."[3]

Within the past decade or so, the videotape deposition has proven to be a very powerful and effective tool in the courtroom. All too frequently, the opposing party uses the company witness deposition adversely, and if the witness has not been adequately prepared for the medium, he or she may not come off as credible and trustworthy.

Rule 32 of the FEDERAL RULES OF CIVIL PROCEDURE governs the use of depositions in court proceedings. It makes no distinction between a paper or videotape format. Rule 32(a)(2) provides that "[t]he deposition of a party or of anyone who at the time of taking the deposition was an officer, director, or managing agent, or a person designated under Rule 30(b)(6) or 31(a) to testify on behalf of a public or private corporation, partnership or association or governmental agency" may be used "by an adverse party for any purpose."[4]

The deposition may also be used by any party for purposes of contradicting or impeaching the testimony of a deponent as a witness[5] or when the witness is unavailable because of events such as death, age, illness, infirmity, imprisonment, or lives more than 100 miles from the place of trial or hearing.[6] Moreover, effective December 1, 2007, "[u]nless otherwise stipulated or ordered by the court, a deposition is limited to 1 day of 7 hours."[7]

Given the punch of video on the perspective of jurors, part of the lawyer's job is to prepare the company witness to be a master of the video medium so as to convey credibility. Here are a few practical tips:

- When you are giving a videotaped deposition, think of it as your reality television show where the camera is always on you, even when you are not speaking.

- Be aware of your non-verbal communication. I saw a deponent once get so flustered that he put the wrong the hand on the Bible, shifted his eyes under his brows, and mugged to the camera. The entire exchange took less than fifteen seconds, but it would be quite damaging to the deponent's credibility if played to a jury. Being calm and avoiding distracting facial gestures, hand movements, and paper shuffling are crucial to building credibility. Be prepared to get into the substance and to get out the company's side of the story when the appropriate questions are asked.

- Be aware of time when answering questions. Long pauses are not recorded in the written transcript but on video may look evasive, uncertain, or nervous.

- Make sure that the camera is in front of you and not cocked at an angle. Watching a person speak in profile diminishes the impact of the words.

- Wear conservative clothing. Solids work well.

- Practice. Practice. Practice.

Videotaped depositions present a wonderful opportunity to relate to a jury and communicate your side of the story.

[1] Campbell, Karen Martin. "Roll Tape — The Admissibility of Videotaped Evidence in the Courtroom," *26 U. Mem. L. Rev.* 1445, 1447 (Summer 1996).

[2] Miller, Gerald R. & Norman E. Fontes, "Videotape on Trial: A View from the Jury Box," 58 (1974).

[3] Baran, Stanley J. *The Viewer's Television Book: A Personal Guide to Understanding Television and Its Influence.* 26-27 (1980).

[4] Fed. R. Civ. P. 32(a)(2) (Emphasis added).

[5] *Id.* at 32(a)(1).

[6] *Id.* at 32(a)(3) (A)-(E).

[7] *Id.* at 30(d)(1).

WRITTEN *by*
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product at issue was manufactured at the site that formed the basis of the Warning Letter, that letter is simply irrelevant to any of the disputed facts in the case. Moreover, any minimal probative value of this evidence is substantially outweighed by the undue prejudice to the company, confusion of the issues, and undue delay that would result from its admission.

Introduction of informal FDA letters may inaccurately suggest to the jury that the FDA found the company acted improperly, when in fact the letters are not the final and official position of the FDA. The jury may not understand the important difference between the position of an employee of the FDA and a final and official determination of the FDA, attaching undue significance to the contents of any such letter simply because it comes from a government agency.

Admission of these letters and other unofficial statements that appear to be associated with the FDA would also inevitably result in undue delay and needless presentation of cumulative evidence. The company would have to present the jury with evidence that establishes the proper context for any unofficial statements by FDA employees or advisory committee participants and explain why they are not the official FDA position and not binding upon the FDA or the company. This would require evidence of the structure, policies, and procedures of the FDA and its regulatory process and/or evidence regarding the advisory committee structure and process. The company would also be entitled to present evidence and argument to impeach the FDA employee-witnesses or committee participant — something difficult to do if these hearsay statements are admitted and there is no witness to cross examine as to their motives and reasoning in making the statement.

Conclusion

In order to address a Warning Letter received or anticipated, a company should take immediate steps to ascertain the entire basis for the letter and any effects the cited conduct may have on products in the market. In formulating a response, the company should obtain all relevant information and brainstorm a plan of action to address each of the cited items forming the basis for the Warning Letter. The company should consider implementing broader policy changes depending on the likelihood for future problems relating to its manufacturing facilities. In preparation for any potential litigation, the company should be aware that the Warning Letter and its responses will be available in the public domain.

Introduction of *informal* FDA letters may *inaccurately suggest* to the *jury* that the FDA found the company *acted improperly*, when in fact the *letters* are not the *final* and official *position* of the FDA. The jury may not understand the *important difference* between the position of *an employee* of the FDA and a *final and official* determination of the FDA.

[1] *See* "Chapter 4: Advisory Actions," *Regulatory Procedures Manual*, Section 4-1-1 (March 2004), available at <http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf>.

[2] FDA Compliance Program Guidance Manual Program, Drug Manufacturing Inspections, 7356.002, available at <http://www.fda.gov/ora/cpgm/defaulthtm#drugs>. The CPGMP introduction provides: "FDA compliance programs provide guidance and instructions to FDA staff for obtaining information to help fulfill agency plans in the specified program area. These compliance programs neither create or confer any rights for, or on, any person and do not operate to bind FDA or the public. Alternative approaches may be used as long as said approaches satisfy the requirements of applicable statutes and regulations. These programs are intended for FDA personnel but are made available electronically to the public as they become available."

[3] *See* Chesney, David L. and Anne E. Kelly, "Responding to 483s and Warning Letters," International Society for Pharmaceutical Engineering, December 1998, available at the ISPE website, <http://www.ispe.org/cs/chapter_web_sites/boston_area_chapter/technical_articles/responding_to_483s_and_warning_letters>. This article summarizes the FDA's main concerns in reviewing responses to Warning Letters as the following:
- What is the impact on the product?
- What are you doing about the specific citation?
- What was the root cause failure in the implicated quality system and how is that being addressed?
- How will you prevent reoccurrence? […]
- How and why did this happen?
- What could have prevented it?
- Who was responsible?

[4] *See* "Chapter 10: Prior Notice," *Regulatory Procedures Manual*, Section 10-1-3 (March 2007), available at <http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch10.pdf>.

[5] *See Chapter 4, supra*, Section 4-1-1.; *see Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 934 n.9 (C.D. Cal. 1996) ("FDA regulatory warning letters do not constitute final agency action" and therefore do not reflect a final conclusion of wrongdoing); *Professionals and Patients for Customized Care v. Shalala*, 847 F. Supp. 1359 (S.D. Tex. 1994) ("warning letters issued by the FDA are deemed to be informal communications that do not constitute final action").

[6] *See* Lilly, Graham C., *An Introduction to the Law of Evidence*, §7.19, at 312 (3d ed. 1996) (exception applicable to records of "the internal function of a particular agency" and not "observations of […] conditions external to the office").

[7] *See Chapter 4, supra*, Section 4-1-1 ("FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action").

[8] *Accord Smith v. Isuzu Motors Ltd.*, 137 F.3d 859, 862 ("Our conclusion [to exclude staff memos relating to automobile safety standards because they were not the "factual findings" of NHTSA] is in accord with other circuits that have held that interim agency reports or preliminary memoranda do not satisfy Rule 803(8)(C)'s requirements."); *see also City of New York v. Pullman, Inc.*, 662 F.2d 910, 915 (2d Cir. 1981) (holding that an interim recommendation by a transit authority staff member to the transit authority administrator was not a factual finding of an agency within the meaning of Rule 803(8)(C) because "the broad language did not embody the findings of an agency, but the tentative results of an incomplete staff investigation"); *United States v. Gray*, 852 F.2d 136, 139 (4th Cir. 1988) (holding inadmissible "a tentative internal report not purporting to contain agency factual findings").

[9] *See Toole v. McClintock*, 999 F.2d 1430, 1434-35 (11th Cir. 1993) (holding trial court abused its discretion in admitting FDA report regarding safety of breast implants because "Rule 803 makes no exception for tentative or interim reports subject to revision and review").

[10] Fed. R. Evid. 803(6).

Written by Alyson Jones

Letters Of Intent: friend Or foe?

The use of letters of intent continues to be widespread in all types of business transactions. Also referred to as memorandums of understanding, agreements in principle, or commitment letters, letters of intent aim to memorialize the general terms of a deal, facilitate future negotiations, and smooth the path toward a definitive agreement. If not carefully thought out and meticulously drafted, however, a letter of intent can prove disastrous.

There are numerous advantages to entering into a letter of intent prior to finalizing a business transaction. Letters of intent provide some assurance that the parties possess a legitimate interest in seeing a deal through to closing. Letters of intent also set the ground rules for negotiations and provide a framework for the final agreement. Another major benefit of entering into a letter of intent is the potential to save a great deal of time and money. Letters of intent flush out preliminary issues and allow them to be resolved prior to negotiating the finer points of the final agreement. Because preliminary matters are out of the way, negotiations can be more focused and straightforward, and a final agreement can be reached more quickly. Letters of intent also expose situations in which the parties' desires are too divergent,

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allowing them to walk away without wasting time and incurring substantial expense in protracted negotiations.

Other positive aspects of letters of intent include creating a feeling of moral obligation to see the deal through to conclusion, providing order and structure to negotiations, avoiding ambiguity and other perils of verbal communications, and making it easier for the purchasing party to obtain financing.

Notwithstanding the foregoing benefits, there are many potential pitfalls associated with letters of intent. Delays are a problem frequently encountered when using a letter of intent. While originally designed to save time, negotiating a letter of intent can actually end up wasting valuable hours. Time spent drafting the letter of intent may be more effectively spent drafting the final agreement. Also, if the parties become wrapped up in the minute details before working out more universal issues, they may harden their respective positions and prematurely shut down negotiations. Excessive expense can also make letters of intent an unattractive option. Unless the underlying transaction is a fairly complex deal, a party may end up spending more money to draft a comprehensive letter of intent and transform its contents into a definitive agreement than they would have spent if they had simply proceeded to negotiate the final agreement. Other pitfalls include the triggering of burdensome notification obligations to customers, creditors, unions, suppliers, and government entities; promoting confusion and fostering ambiguities which can be exploited by the other party; and disclosing sensitive information.

While these risks are certainly troublesome, the most common and most dangerous hazard inherent in utilizing a letter of intent is the possibility that a dispute will arise as to whether the letter's provisions are binding or nonbinding. These types of disagreements trigger the bulk of litigation involving letters of intent and force the court or a jury to interpret the parties' intentions. In construing the letter of intent, a court will likely examine the wording of the letter, consider the context of negotiations, review the performance of any obligations, and weigh any open issues. The court may also apply what it deems to be commercially reasonable terms to the letter. The end result of this process could leave the parties stuck with a deal that was not completely negotiated and that has missing or unexpected material terms.

For example, in *Logan v. D.W. Sivers Co.*, 169 P.3d 1255 (Or. 2007), the parties entered into a letter of intent to establish the framework for the sale of a piece property. Twenty-one days after the letter of intent was signed, the Seller sold the property to a third party. The Purchaser filed suit for breach of the non-solicitation provision of the letter of intent. In response to the Purchaser's allegations, the Seller argued that 1) the terms of the letter were too indefinite to be enforced and were intended to be non-binding; 2) the non-solicitation provision was intended to be binding only as long as the parties chose to continue negotiations; and 3) the Purchaser's failure to deliver a draft Purchase and Sale Agreement within 15 days of the execution of the letter of intent excused its obligation to comply with the non-solicitation provision.

Despite the multiple, lengthy statements purportedly establishing the non-binding nature of the letter, the Supreme Court of Oregon held that the Seller was bound by the terms of the non-solicitation provision. First, the court found that the following provision clearly created a binding promise with respect to non-solicitation of third parties:

> [H]owever, that in consideration of Purchaser's good faith efforts to review the due diligence material provided by Seller, Seller agrees to be bound to provide the required due diligence documents to Purchaser within the time required and to comply with the Non-Solicitation provision set forth above.[1]

The court then rejected the Seller's argument that the lack of commitment by the parties to the negotiations released it from the non-solicitation clause. In reaching its decision, the Court declined to apply *Feldman v. Allegheny Inter., Inc.*, 850 F.2d 1217 (7th Cir.1988), a case cited by the Seller for the proposition that the non-solicitation

provision was operative only as long as both parties elected to pursue the transaction. The court noted that unlike the non-solicitation clause in *Feldman*, the non-solicitation provision at issue was not couched in terms of the parties' continued commitment to negotiations but, instead, spoke in terms of a specific period of time of 60 days. Thus, the Seller's sale of the property to a third party within the 60 day period constituted a breach of the non-solicitation provision. Lastly, the court refused to excuse the Seller from the non-solicitation provision due to the Purchaser's failure to provide a draft Purchase and Sales Agreement within 15 days after the execution of the letter of intent. The court ruled that the language used in the letter of intent, "approximately 15 days," was ambiguous and that it was not unreasonable for the jury to conclude that delivery of the draft on day 21 was timely.

Notwithstanding its finding that the Seller breached the non-solicitation provision of the letter of intent, the court held that because the non-binding terms of the letter of intent did not require the Seller to sell the property to the Purchaser, the Purchaser's proper measure of damages was the expense incurred in negotiating the final deal and not losses which resulted from the lack of sale. Unfortunately, both parties ended up with the fuzzy end of the lollypop due to a poorly drafted letter of intent. Undoubtedly, both sides incurred substantial expense and expended valuable time to see this matter through trial and appeal. Had the provision regarding the delivery of the draft Purchase and Sales agreement been specific instead of speaking in terms of approximate days, the Purchaser would have almost certainly delivered the draft in a timely fashion, and the Seller would not have sought a buyer elsewhere. Had the Seller understood that the 60 day provision would bind him to deal solely with the Purchaser through periods of inactivity, he would have likely requested a change in terms or even walked away from the deal. Had the Purchaser realized that his damages would be limited due to the nonbinding nature of the letter, he would have surely requested a liquidated damages provision or would have had the opportunity to make a cost benefit analysis of filing a lawsuit. In summary, if more thought and care had been put into drafting the letter of intent, the parties would have reached a final agreement or would have realized that they were too far apart to continue negotiations. Either way, they would have avoided a costly trip to the courthouse.

Because most parties feel more comfortable having the basic terms of an agreement memorialized early in the negotiations process and because a letter of intent does offer numerous benefits, it is improbable that the use of letters of intent will fall by the wayside. However, the existence of risks such as those discussed above should serve as a reminder that the drafting of a letter of intent should not be taken lightly. While not an exhaustive list, the following guidelines will help you capitalize on the benefits and reduce the pitfalls presented by letters of intent:

- Be brief.
- Be definite and precise, but refrain from including specific details of essential terms unless there is an intent to be bound.
- Include an express statement that the letter is not binding or that it contains both binding and non-binding provisions; clearly label any provision intended to be binding and set it apart from other provisions. Be specific when setting forth obligations in binding provisions (i.e., avoid ambiguous language like "approximately 15 days").
  - Examples of binding provisions: confidentiality regarding negotiations, confidentiality of information contained in due diligence materials, no-shop or break-up provisions, anti-clubbing provisions, non-solicitation of employees and/or customers, notification of competing bids, payment of certain fees, termination triggers, and limitations of public disclosure. For some of the above, you may want to consider entering into a separate agreement that will survive the letter of intent.
  - Examples of nonbinding provisions: structure of the deal, purchase price, representations and warranties, conditions to closing.
- Include other key provisions such as:
  - Details regarding the transaction including a recitation of the parties involved, a description of the transaction itself (purchase of business, settlement, assets being acquired), particulars of the transaction's structure.
  - Obligation to adhere to the agreement in good faith.
  - Terms of payment.
  - Time limits for completion of obligations under terms of the letter.
  - Time limits for entering into a final agreement and/or closing.
  - Important covenants and key provisions (see examples of binding and non-binding provisions listed above).
  - Details on how the parties will carry out obligations or will otherwise operate between the signing of the letter of intent and the execution of the final agreement.
  - Indemnification provisions.
  - Provisions regarding governing law and jurisdiction and/or arbitration in lieu of legal action.
  - Representations and warranties.
  - Terms and conditions of any side agreements.
- Use a signature line for all parties intended to be bound by the letter of intent.
- Take steps to meet your obligations under the letter of intent.

[1] *Logan v. D.W. Sivers Co.*, 169 P.3d 1255 (Or. 2007).

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