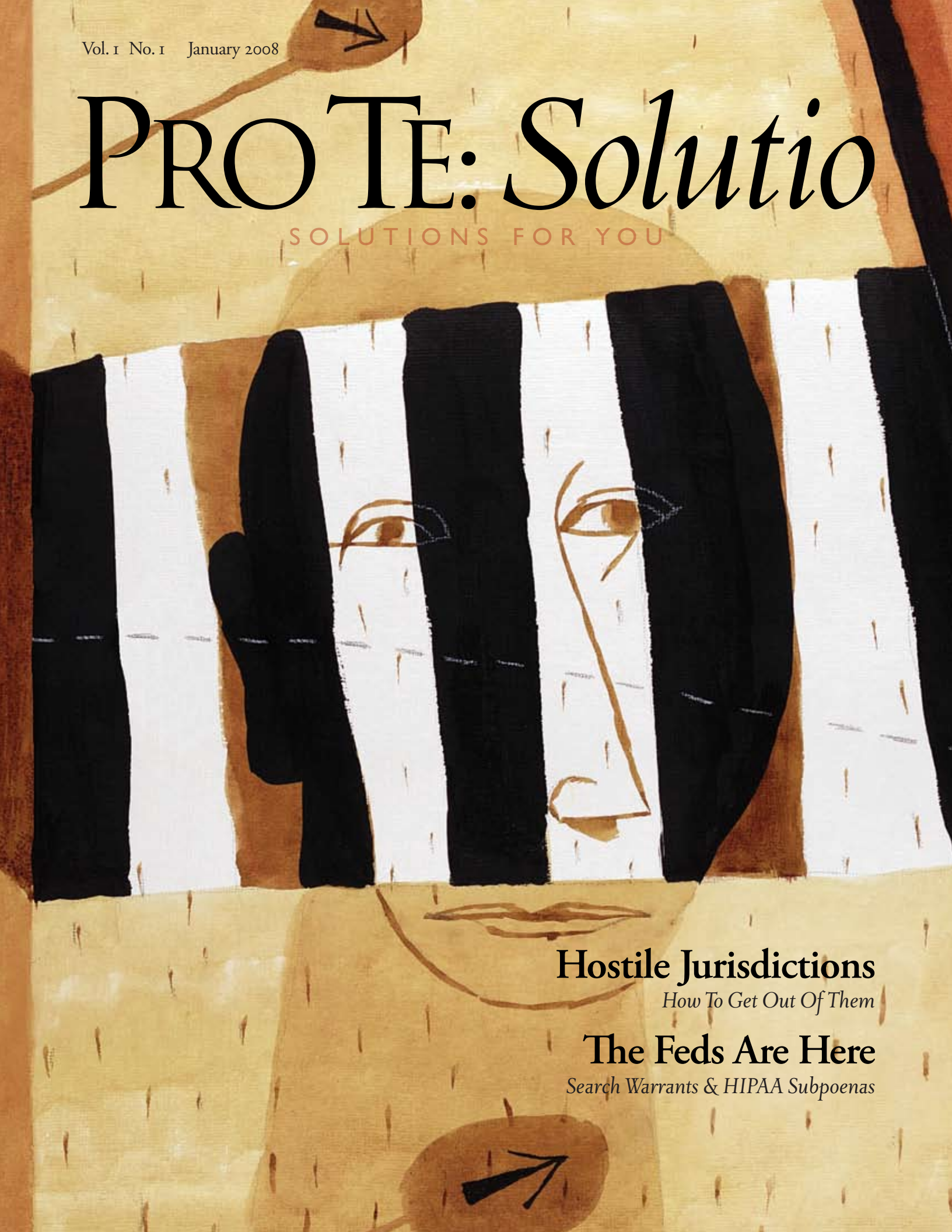
Vol. 1 No. 1 January 2008

Pro Te: *Solutio*

SOLUTIONS FOR YOU



Hostile Jurisdictions

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Dear Clients:

You are important to Butler Snow.

We recognize that those of you in the Pharmaceutical, Medical Device, and Healthcare arena spend every day making a difference in the lives of others. You develop, manufacture and supply new medicines and devices that improve, lengthen, and save lives; you provide medical care to the sick and disabled; and you provide facilities for those in need of life-saving services such as dialysis. Yet the pharmaceutical and healthcare industries are under siege.

The perfect storm: In this fiercely competitive industry, you are not only confronted with product liability and medical negligence litigation, but now wholesale pricing, consumer, and third-party payor actions, often spawned by state attorneys general, as well as patent or intellectual property controversies. Government investigations and Congressional hearings have become common, ignited adverse media publicity, and precipitated qui tam actions. Verdicts of hundreds of millions of dollars threaten your existence. And, while confronting these challenges, you must conduct business, close transactions, and provide for your own employees.

In order to better serve our clients in these difficult times, Butler Snow has reorganized its Pharmaceutical, Medical Device, and Healthcare Industry Department. The different avenues of attack upon the healthcare industry necessitate a multi-disciplinary approach and team work. Our group includes those with significant experience ranging from corporate transactions to product liability litigation, from labor and employment counseling to commercial litigation, from white-collar investigations and defense to medical negligence and Medicaid and Medicare compliance consultations. Although we have many talented trial lawyers, our aim is first to prevent litigation through risk management and appropriate corporate counseling.

As part of our initiative, and in an effort to better serve you, we have designed this quarterly publication, *Pro Te: Solutio* (For You: Solutions). It is being made available only to our clients, in the hopes of providing ideas for problem solving. Butler Snow recognizes that you are bombarded with materials describing new developments in the law. Although we will periodically address such issues, our focus is a little different: We hope to provide you with practical insights based on experience. We welcome your feedback and suggestions for improvement.

Our goal is 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. 1 January 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 or Charles Johnson, as well as any of the attorneys listed on the inside back cover of this publication.

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DEPARTMENTS

Hostile Jurisdictions

And how to get out of them…especially when you cannot get to federal court.

> [W]hat I call the 'magic jurisdiction,' […is] where the judiciary is elected with verdict money. The trial lawyers have established relationships with the judges that are elected; they're State Court judges; they're popul[ists]. They've got large populations of voters who are in on the deal, they're getting their [piece] in many cases. And so, it's a political force in their jurisdiction, and it's almost impossible to get a fair trial if you're a defendant in some of these places. The plaintiff lawyer walks in there and writes the number on the blackboard, and the first juror meets the last one coming out the door with that amount of money. […] The cases are not won in the courtroom. They're won on the back roads long before the case goes to trial. Any lawyer fresh out of law school can walk in there and win the case, so it doesn't matter what the evidence or the law is.
>
> Richard "Dickie" Scruggs, "Asbestos for Lunch" Panel Discussion at the Prudential Securities Financial Research and Regulatory Conference (May 9, 2002), in *Industry Commentary* (Prudential Securities Inc., N.Y., New York) June 11, 2002, at 5.

I. The Problem

There are jurisdictions in virtually every state where it is very difficult, nigh impossible, for a corporate defendant to obtain a fair trial. This difficulty, caused by an apparent and prevalent disdain for corporate America in these locales, can be explained by — but not justified by — sundry factors. For instance, it is an undisputed sad fact that, in many of these cities and counties, the population is poor, uneducated, and underemployed. Jobs and opportunities for improvement are scarce. In atmospheres such as these, an "us against them" mentality makes sense, and protecting your neighbor may be a more attractive avenue than preserving justice.

Another factor impacting the hostile atmosphere toward large defendants can be the immeasurable influence of the few wealthy and successful residents, politicians, and ministers. Local individuals who wield such influence in communities many times have held meetings in churches, union halls, and local fire stations to teach people "how to be good jurors." Their propagandizing mantra generally is that, as jurors, these Regular Joes finally are empowered to make a difference —

either for their peers or to slap the powerful. Or both.

Yet a third factor may be simply a family bond. Because many of these locales attract few outsiders as residents, it is not uncommon for counties to have small populations where everyone not only knows everyone else, but is also related to most everyone else. What happens to one affects all because the community consists of only a handful of extended families.

For all of these reasons, corporate defendants are often victims of extremely large verdicts. In the more infamous jurisdictions, the filing of an action there may amount to no more than a legal form of extortion or blackmail — regularly encouraging settlements of significant amounts. In a vicious cycle, these verdicts and settlements attract even more litigation, attorney advertising, and solicitation of lawsuits. Trying cases in these places requires an understanding that, sans a nearly miraculous outcome, any relief must be had through appeal — unless a change of venue can be accomplished.

II. The Solution

In a hostile jurisdiction, you have two options for winning: (1) Obtain a venue transfer and do not try the case there in the first instance, or (2) try the case in the bad jurisdiction and place all of your eggs in the appellate basket, hope that you have a reversible error, and hope that you preserved it. Fortunately, these solutions are not mutually exclusive. In fact, the failure of a court to transfer the litigation may be your golden reversible error. But, a change of venue is not an easy decision to obtain. Transfer of the litigation to another jurisdiction requires thoughtful planning from the onset. Not only must the issue of improper venue be asserted in the initial pleadings, it must be the subject of intense (i.e., time-consuming and sometimes expensive) investigation and discovery. Although every case is different, the following investigation should be considered:

1. Search newspapers with subscription bases in the jurisdiction (and television and radio stations) for information concerning the plaintiff and his/her family (such as marriage announcements, obituaries, marriage licenses) and contacts within the community. Search these same media for attorney advertisements regarding the litigation, publicity regarding the product, and any litigation in other areas. Search also for comments by prominent members of the community that might bear on the litigation and notices of meetings regarding the product in the community.

2. Search birth records of plaintiffs and known relatives at the State Office of Vital Statistics, which also has death, marriage, and divorce records, to determine relationships with others in the community.

In a hostile jurisdiction, you have two options for winning: (1) Obtain a venue transfer and do not try the case there in the first instance, or (2) try the case in the bad jurisdiction and place all of your eggs in the appellate basket, hope that you have a reversible error, and hope that you preserved it.

3. Search probate, estate, and land records to determine ownership and histories of the plaintiffs' residences, the identity of others in plaintiffs' families (even though they may be cousins once removed), and the location of plaintiffs' residences in relationship to others in the community.

4. Search the local or district clerk's office to identify prior litigation involving plaintiffs or their relatives; significant verdicts in similar cases and the identity of jurors, parties, and attorneys; and the number of plaintiffs involved in litigation in the county (compared to the number of registered voters). If litigiousness in the particular jurisdiction creates an apparent bias that you wish to assert in support of a motion for change of venue, the number of lawsuits and number of plaintiffs involved, compared to the total population of the county, is important to support your claim.

5. Compare a list of known relatives of the plaintiffs with plaintiffs in other litigation, particularly other pharmaceutical and mass tort cases.

6. Identify any relatives of plaintiffs who are court employees serving in a relevant function — especially those with roles in jury registration, lists, summons, or selection; important city/county officials; city employees with power and influence; and politicians, business owners, or possible employers of other residents in the jurisdiction.

7. Research plaintiffs' connections to other residents in the community through organizations such as unions, churches, social clubs, or even health clubs. Determine, for example, the size of the church that each plaintiff attends, when services are held, and the identity of other congregation members who have filed similar litigation.

8. Arrive early on the day of jury selection to see which potential jurors arrive together or arrive with plaintiffs. Bring or hire help for this task if necessary.

III. Application

This investigation must be supplemented by discovery such as interrogatories and depositions of the plaintiffs and family members or employers to identify relatives of the plaintiffs. Such inquiries must delve into areas such as where the relatives live, were educated, by whom they are employed, and their involvement in other litigation.

The purpose of this extensive investigation and discovery into issues other than the substance of the lawsuit is to establish a web of interconnections within the

jurisdiction so apparent that the court must find that the entire city or county is tainted by potential bias. Faced with rural jurisdictions in Mississippi, we embarked upon such a plan to establish that a fair trial could not be held for a corporate pharmaceutical company. The counties involved, Jefferson and Claiborne, were notorious as cottage industries for mass tort litigation, for an excess number of plaintiff verdicts (some outrageously large), and the involvement of hundreds of residents as plaintiffs.

IV. The Result

Just prior to jury selection in Jefferson County, the court transferred the case to neighboring Claiborne County. After collecting much of the same information again, we filed another motion for change of venue, which we supplemented during and following jury selection. Losing that motion, we followed with a motion to strike the venue. On appeal, after an adverse verdict, the Mississippi Supreme Court held that the trial court abused its discretion by improperly changing venue to Claiborne County: "The record is replete with evidence that Janssen sufficiently proved bias in the community of Claiborne County. Therefore, although the trial court correctly found that it was proper to change venue from Jefferson County, we find that Claiborne County is not a proper venue in which a fair trial may be conducted. This issue alone merits reversal."[1]

The facts supporting this conclusion were that 38 of the original 155 plaintiffs were from Claiborne County; 114 residents of the jurisdiction had similar suits; of the 105 qualified prospective jurors not excused for illness or hardship, over one-half had personal relationships with plaintiffs or their counsel. Six prospective jurors actually had claims against the defendant for use of the product at issue. Many of those remaining as prospective jurors knew one or more of the plaintiffs or had seen negative attorney advertising or news reports about the drug in question.

Other prominent facts included in the motion established that (1) prominent residents such as the mayor, police officers, and relatives of politicians were plaintiffs; (2) there existed an unusually high volume of litigation in the county when one considered the number of lawsuits compared to the general population; (3) the named plaintiffs had close relationships with the district clerk, justice court judge, and constable; (4) the plaintiffs were related to innumerable county residents (although we did attempt to number them); and (5) one plaintiff had been an assistant high school principal in the small county for 29 years.

The purpose of this extensive investigation and discovery... is to establish a web of interconnections within the jurisdiction so apparent that the court must find that the entire city or county is tainted by potential bias.

As for pretrial publicity, Janssen supported its venue motion with excerpts from depositions from plaintiffs who testified that they had heard about the lawsuit "on the television like everybody else." Many testified that advertising, not medical injury diagnosed by a doctor, had prompted their lawsuit. The evidence established that the county had been absolutely bombarded with attorney advertisements and attorney-organized meetings and had been inundated with plaintiff-propelled gossip. Other evidence used in support of the motion included awards in the counties in the immediately preceding three years of $150 million and $48 million. Thus, it became apparent that the adverse message had been pervasively accepted in the community and that a fair trial could not be had.

V. Finale

The ascertainment of impartial justice is, or should be, the supreme goal — indeed the very purpose of existence — of all courts. A fair trial necessarily contemplates the right to be tried in an atmosphere in which public opinion is not saturated with bias, hatred, or prejudice against the defendant. A fair trial must take place where jurors do not have to overcome that atmosphere or the later silent condemnation of their fellow citizens if they render a defense verdict. But, as with all things of value, a fair trial does exact a price. Ensuring an unbiased atmosphere requires substantial efforts to evaluate and demonstrate the prevailing attitudes in the jurisdiction. In the words of Sir Winston Churchill, it takes "blood, toil, tears, and sweat."[2] But, if you prevail on your change of venue motion, it will be one of your "finest hour[s]."[3]

[1] *Janssen Pharmaceutica, Inc., and Johnson & Johnson v. Bailey et al.*, 878 So.2d 31 (Miss. 2004).

[2] Churchill, Winston. "Blood, Toil, Tears, and Sweat." Address to the House of Commons. 13 May 1940. Retrieved 7 December 2007, from *The Churchill Centre* web site: http://www.winstonchurchill.org/i4a/pages/index.cfm?pageid=391.

[3] Churchill, Winston. "Their Finest Hour." Address to the House of Commons. 18 June 1940. Retrieved 7 December 2007, from *The Churchill Centre* web site: http://www.winstonchurchill.org/i4a/pages/index.cfm?pageid=418.

Written *by* Christy Jones

The Feds Are Here – What Do We Do Now?

The Problem: You just arrived at your office expecting to begin work for the day. Instead, in walk a dozen or more FBI and HHS Office of Inspector General (OIG) agents who show you a search warrant for the premises. Alternatively, they could hand you a subpoena which references 18 U.S.C. § 3486 and is labeled *Subpoena Duces Tecum* but does not have the words "grand jury" on it. What do you do now? Based on our experience handling healthcare fraud investigations, both as private attorneys in the White Collar Crime and Government Investigations Practice Group and as former Assistant United States Attorneys, we lay out below the suggested steps to take when met with this situation.

A. What to Do When Faced With a Search Warrant for the Premises.

1. Call Your Outside Counsel.

You have no right whatsoever to resist a search warrant. A search warrant is issued on probable cause by a Magistrate Judge. This means that a Magistrate Judge has already reviewed an affidavit from an agent and possibly even taken testimony from an agent. In issuing a search warrant, the Magistrate Judge has indicated that he/she is convinced there is probable cause to believe that some criminal conduct may have occurred and that there may be evidence of that criminal conduct on the premises which the agents have requested to search. This means that you, your business, and/or your employees may already be the subject of an ongoing criminal investigation. It is equally possible, however, that the government may have reason to believe that there is evidence in your possession that may have no criminal significance with respect to your operations but which would constitute evidence of criminal conduct for a related party. For instance, if your business is a clinic connected to a hospital, the investigation may concern the hospital but not your individual clinic. In any event, it would be wise under all circumstances for you to speak to the government only through your counsel.

Therefore, the first thing you should do is notify your outside counsel as soon as agents appear with a search warrant. Not within the first hour, not after the search has begun, not after the search is completed. You should notify your outside counsel *as soon as agents arrive* with a search warrant. After you have called outside counsel, the search warrant is the first piece of paper you need to look at very carefully.

2. Review the Warrant.

Agents serving a search warrant must provide you with a copy of the entire warrant which will describe the premises that are to be searched and set the parameters for the search. You can determine by reading the warrant whether your entire office is to be searched or whether only one suite is to be searched. While it may seem strange to suggest it, be sure to check the description of the property to be searched as stated in the search warrant against your address. While not a common event, on occasion, the search warrant may have an incorrect address. In such an event, it is not a valid warrant for searching your building. Be certain that the agents have authority to search your premises before they begin the search.

As the search is proceeding, you also want to make sure that the search does not go beyond what is authorized in the search warrant. For example, if the search authorizes a search of 101 Brown Street, Suite A, but your business occupies Suites A, B and C, then agents are not authorized to enter or to search any of Suite B or C,

even if these are adjoining suites. Do not under any circumstances consent to additional searches. If you consent to these searches, you will have waived your constitutional objections to the validity of the search warrant.

3. Identify Potentially Privileged Materials.

Generally speaking, a search warrant does not authorize the seizure of privileged materials, in particular attorney-client privileged materials. Privileged materials may, however, be taken away from your premises in the course of a search. It is common practice with both the FBI and the OIG for there to be, in effect, two teams who appear to participate in the search. One team is the actual search team who investigates the alleged criminal conduct and reviews all of the documents or other materials, including computers and electronic data. If the FBI or OIG anticipates that privileged materials may be obtained in the search, often a "dirty team" will be brought along with the search team. The "dirty team" will segregate all privileged materials from the rest of the search results and the rest of the search team. Privileged materials include attorney-client privileged materials, attorney work-product materials, psychological or psychiatric records (depending on the nature of the premises being searched) or materials which contain evidence of drug or alcohol treatment. Those privileged materials may initially be taken by the agents, but they will then be isolated and segregated from the remainder of the search results and returned to you or your attorney. The use of a "dirty team" allows the search team not to become tainted by having access to these privileged materials. If possible, identify early on for the agents what you believe to be privileged materials. This will facilitate the work of the "dirty team" and will, to the extent possible, limit the inadvertent seizure of privileged materials.

> ...THE FIRST THING *you* SHOULD *do* IS *notify* YOUR OUTSIDE *counsel* AS SOON AS *agents* APPEAR *with a* SEARCH WARRANT.

If there is not a "dirty team" present at the time of the search, a motion for the return of privileged documents may be necessary following the search. Obviously, this is a matter which will need to be handled by your attorney. It is your attorney's responsibility to protect your attorney-client privilege, your patients' privileges, and any other work-product or similar privileges which may attach to documents seized from your premises.

4. Maintain an Inventory.

As the search is taking place, you should maintain an inventory of all that is being seized. In fact, after the search is concluded, this is precisely what FBI and OIG agents will be required to do themselves The lead agent will be responsible for preparing a complete inventory of each and every item seized from your premises, the location from which those items were seized, and a general description of the items seized. Within five to seven days after the search is conducted (if not sooner), you will be provided with a copy of this inventory. If your offices are a large amount of space, this inventory could become quite voluminous. Regardless of the length of the inventory or the amount of time required to prepare the inventory, you are entitled to a complete and accurate inventory.

5. Do Not Consent to Voluntary Interviews Without Counsel.

A search warrant is not an authorization to interview anyone, but rest assured that the agents will likely ask plenty of questions while they are conducting the search. Once the search team appears at your office, you are free to release any of your employees and send them home. Indeed, once the search has commenced, theoretically, you are even free to go yourself. A search is not a custodial situation. When the agents are in your offices conducting a search, they have no legal right to require you to answer questions, but they are at liberty to ask all the questions they choose to ask and to make notes on your answers.

Since a search warrant does not generate a custodial setting and you are free to leave, agents have no obligation to advise you of your rights before asking you questions. Thus, any statements you or your employees make and any questions answered can be used in developing further leads for the investigation and may ultimately be used against you in the event that the investigation results in criminal charges.

Thus, once the search has begun, you should call all of your employees together and advise all of them that they have a right to decide whether to talk to the agents or not to talk to them, that they have a right to have the company's attorney present if they do talk to agents, and that they have a right to tell you precisely what they were questioned about in the event that they are questioned outside your presence or outside the presence of your attorney. Take care also to instruct employees that they should in no way interfere with the agents regardless of whether they decide to be interviewed by the agents.

> A SEARCH WARRANT *is not* AN AUTHORIZATION TO *interview anyone,* BUT REST ASSURED *that the* AGENTS WILL LIKELY ASK *plenty* OF *questions* WHILE THEY *are* CONDUCTING *the* SEARCH.

If you allow your employees to be interviewed, make every effort to attend those interviews or have your attorney attend as they happen. If this is not possible because of simultaneous interviews, remember to take the time to debrief your employees who are interviewed outside of your presence to determine what types of questions

the government agents asked and what subjects they explored. This will give you valuable information about the scope, the purpose, or the nature of the government's investigation.

6. Understand the Process.

Knowing what to expect can help minimize the business interruption caused by the execution of a search warrant. Generally, there will be a large team of agents, and they will want to secure the premises and, at least initially, probably will not want to let anyone else into the building. It is safe to say that if you are the target of a search, the process will probably take most of an entire day. To make the process go more smoothly, you may want to instruct all non-essential employees that they can go home.

One of the first things that the agents will do after they arrive on the scene is sketch out a map of your offices or your building. This map will be used to help them prepare the inventory which you will be provided after the search is completed. It is not uncommon for agents to go through the building with a pad of sticky notes labeling offices with numbers or letters, labeling file cabinets, desks, desk drawers, filing cabinet drawers, even bookcases and shelves on bookcases with numbers or letters in order to identify precisely where items seized in the search were when they were seized. When they arrive to conduct a search, agents often will bring with them a large number of boxes. Sometimes they will bring large envelopes. Sometimes they will bring plastic evidence bags. All of these will be used to box, package, and seal items which are seized during the search.

Most searches will also authorize the seizure of computers or computer hard drives and computer storage media such as CD-ROMs, backup tapes or disks, USB storage devices — essentially any type of electronic storage device you can imagine. The FBI has specialized computer evidence personnel, referred to as "CART" personnel (Computer Analysis and Response Team), who will attempt to image the hard drives on your computers onsite if this can be done in a reasonable amount of time. If it does not appear that the hard drives can be imaged in a reasonable amount of time onsite at your premises, then it will be necessary for the computers to be seized, taken back to the FBI offices and imaged by the CART personnel at the FBI offices. After these images are created, generally the computers will be returned to the owner.

7. Be Active After the Search.

In reality, there is not much you can do while a search is underway other than take a deep breath, talk things over in detail with your outside counsel, and wait patiently for the agents to complete their task. After the agents have completed the search, however, there are some important steps that you, through your outside counsel, should pursue in a short period of time. First, contact the prosecutor who is handling the case. Sometimes your attorney will learn that you are not, in fact, the subject of the investigation. Second, discuss the search with your employees, explaining that you intend to cooperate, as you have already cooperated, with the government and that any documents related to those which have been seized should be at all costs maintained. A third step is to consider the necessity of an internal investigation. If you have learned from the prosecutor or from the search itself the nature of the government's investigation, then it may be possible to allow your outside counsel to conduct an internal investigation in order to determine whether there is, in fact, any reason to believe that you or your employees have been engaged in any conduct which may have generated the investigation by the government.

8. Develop a Media Response.

Quite often, the execution of a search warrant generates media attention. You, along with your attorney, need to discuss a media strategy. This strategy may be simply a posture of "no comment." In most instances this is the best strategy. The media are inclined to draw conclusions about the nature of an investigation, sometimes based on very limited information about the nature of the investigation. Anything you say to the media may not necessarily be reported accurately. Accordingly, a posture of media silence may be in your best interest. Whatever path you choose, you and outside counsel need to decide whether you are going to have contact with the media or have no contact with the media.

B. What to Do When Faced With a HIPAA Subpoena Duces Tecum.

When Congress passed the Health Insurance Portability and Accountability Act (HIPAA), Congress authorized the Department of Justice to issue administrative subpoenas under 18 U.S.C. § 3486, which is the statute cited on the face of your *Subpoena Duces Tecum*. These subpoenas are authorized to be issued when a criminal investigation into alleged healthcare fraud has been initiated. Indeed, this type subpoena is referred to by DOJ personnel as "AIDs" or "HIPAA subpoenas," and they are authorized only when the government agents are involved in "healthcare oversight" investigations. Generally speaking, "healthcare oversight" means the government is investigating allegations that false claims or false documents have been submitted in the context of providing and/or seeking payment for healthcare services. When FBI and HHS-OIG agents are wearing their "healthcare oversight" hats, so to speak, they are not required to obtain the usual HIPAA-related waivers or consent to review patient medical records.

> One *of the* clear risks associated *with treating* a subpoena *as a* civil discovery request *is that* the govern-ment *may decide* that the company *is not cooperating.*

Grand jury subpoenas and HIPAA subpoenas are very different animals, even though both can be used in connection with on-going criminal investigations. One of those differences is the matter of grand jury secrecy. The Federal Rules of Criminal Procedure, in particular Rule 6(e), mandates that criminal prosecutors may not share the results of a grand jury subpoena with their civil counterparts in the United States Attorney's Offices or in the Department of Justice Civil Division. This grand jury secrecy prohibition does not apply at all to a HIPAA subpoena. Consequently, the results of a HIPAA subpoena served upon you for your records could be used not only in connection with a criminal investigation but also in connection with the government's evaluation of a whistleblower *qui tam* lawsuit.

1. Limit the Scope of the Subpoena.

When a subpoena is served, often your attorney will have an opportunity to negotiate with the government in order to determine exactly what it is the government wants in response to the subpoena. In discussing a subpoena with the prosecutor, your counsel can attempt to limit the amount of information which you are required to produce or the manner in which you are required to respond to the subpoena. Some subpoenas are drafted so broadly that they may call for a substantial amount of information when, in reality, the government wants a much smaller universe of information. Even if a large universe of documents is sought, outside counsel may be able to negotiate an on-going "rolling production" schedule which permits you to begin producing some documents while you continue reviewing and preparing additional documents for later production.

2. Identify and Protect Privileged Materials.

A clear advantage of responding to a subpoena as opposed to a search warrant is that, through your outside counsel, you have an opportunity both to review and to protect privileged and confidential material which you cannot do in the context of a search warrant. Your attorney will be able to review each and every document which is responsive to the subpoena for attorney-client privilege or work-product privilege or any other non-disclosure privilege prior to making a production of documents to the government.

3. Respond Fully to the Subpoena.

What you should do in order to comply with a grand jury or HIPAA subpoena, first and foremost, is not treat a subpoena as a routine civil discovery request. Do not attempt to adopt the kind of hunker-down, non-cooperative posture that often is the course of action in the context of civil litigation. One of the clear risks associated with treating a subpoena as a civil discovery request is that the government may decide that the company is not cooperating. If the subpoena has not met with a favorable production of documents, then the government may proceed to the next step by seeking a search warrant.

> In discussing *a* subpoena *with the prosecutor,* your counsel *can* attempt to limit *the* amount *of* information *which you are* required *to produce or* the manner in which *you are* required *to* respond *to the* subpoena.

Additionally, if the government is able to prove that a company or an individual employee or officer of the company has deliberately failed to produce documents that are responsive to a subpoena, then the individual or the company may actually be charged with obstruction of justice. No company wants to be accused of failing to cooperate, nor does a company want to be charged with obstruction of justice (and HIPAA includes a specific healthcare fraud obstruction statute, 18 U.S.C. § 1518).

4. Instruct Employees to Retain Responsive Information in Paper and Electronic Formats.

Finally, upon receipt of a subpoena, whether it be a grand jury subpoena or a HIPAA subpoena, it is essential to issue a directive to your employees who are likely to have responsive documents or electronic data. This directive should have the effect of suspending your normal document retention or document destruction policy and instructing your employees that they should retain all information in paper and electronic formats notwithstanding any provisions in your document retention policy. Outside counsel can assist you in drafting a document hold notice to your employees.

The Result: Healthcare fraud investigations remain a priority for the Department of Justice. In Fiscal Year 2005 (the most recent year for which statistics are available), United States Attorney's Offices opened 935 new criminal healthcare fraud investigations involving 1,597 potential defendants. There were already 1,689 pending investigations involving another 2,670 potential defendants, and there were 382 filed cases pending which involved 652 defendants. Through the efforts of the DOJ, FBI, and HHS-OIG, approximately $1.47 billion in judgments and settlements were obtained in healthcare fraud cases and proceedings. All of these cases started with an allegation of some wrongdoing which then produced a search warrant or a HIPAA subpoena designed to test the allegation. If you understand what your rights are, what authority the agents executing the search have, the process involved, and how outside counsel can help you, you will be in a better position to protect those rights and minimize any damage to your company.

Written *by* Bob Anderson

WHAT STATES HAVE ADOPTED THE LEARNED INTERMEDIARY DOCTRINE?

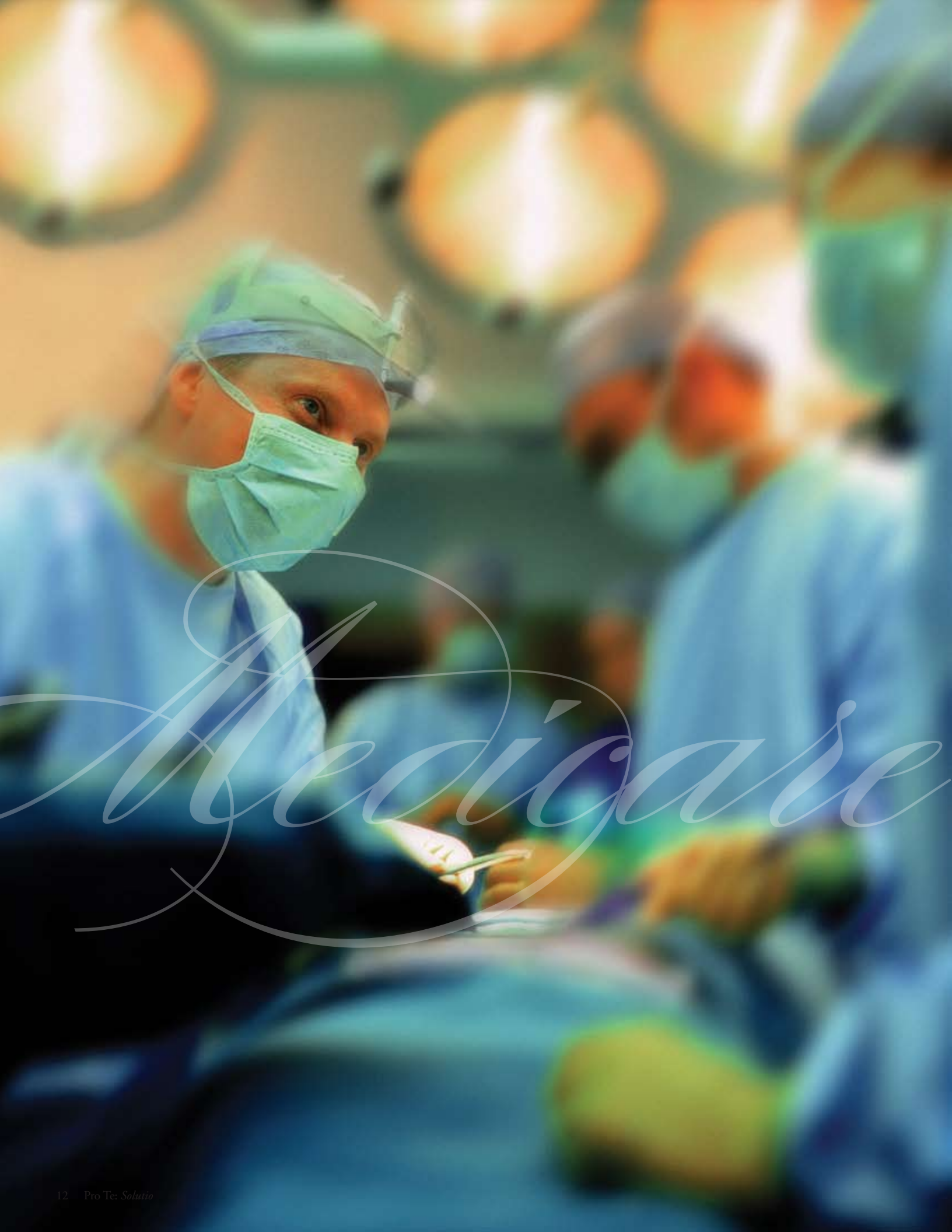
The majority of jurisdictions, including the following states, have accepted that a drug manufacturer is relieved from warning each patient who receives a product when the manufacturer properly warns the prescribing physician of the product's dangers:

Alabama: Walls v. Alpharma USPD, 887 So.2d 881, 883 (Ala. 2004).
Alaska: Shanks v. Upjohn Co., 835 P.2d 1189, 1200 & n.17 (Alaska 1992).
Arizona: Piper v. Bear Medical Systems, Inc., 883 P.2d 407, 415 (Ariz. App. 1993).
Arkansas: West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991).
California: Carlin v. Superior Court, 920 P.2d 1347, 1354 (Cal. 1996).
Colorado: Hamilton v. Hardy, 549 P.2d 1099, 1110 (Colo. App. 1976).
Connecticut: Hurley v. Heart Physicians, P.C., 898 A.2d 777, 783-84 (Conn. 2006).
Delaware: Lacy v. G.D. Searle & Co., 567 A.2d 398, 400-01 (Del. 1989).
District of Columbia: Mampe v. Ayerst Laboratories, 548 A.2d 798, 801 & n.6 (D.C. 1988).
Florida: E.R. Squibb & Sons, Inc. v. Farnes, 697 So.2d 825, 827 (Fla. 1997).
Georgia: McCombs v. Synthes, 587 S.E.2d 594, 595 (Ga. 2003).
Hawaii: Craft v. Peebles, 893 P.2d 138, 155 (Hawaii 1995).
Idaho: Sliman v. Aluminum Co. of America, 731 P.2d 1267, 1270 (Idaho 1986).
Illinois: Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1127 (Ill. 2002).
Indiana: Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 548-59 (Ind. App. 1979).
Kansas: Savina v. Sterling Drug, Inc., 795 P.2d 915, 928 (Kan. 1990).
Kentucky: Larkin v. Pfizer, Inc., 153 S.W.3d 758, 761 (Ky. 2004).
Louisiana: Kampmann v. Mason, 921 So.2d 1093, 1094 (La. App. 2006).
Maryland: Rite Aid Corp. v. Levy-Gray, 894 A.2d 563, 577 (Md. 2006).
Massachusetts: Cottam v. CVS Pharmacy, 764 N.E.2d 814, 820 (Mass. 2002) (but questions applicability of doctrine to contraceptives, see MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 69-70 (Mass. 1985)).
Michigan: Smith v. E.R. Squibb & Sons, Inc., 273 N.W.2d 476, 479 (Mich. 1979).
Minnesota: Mulder v. Parke Davis & Co., 181 N.W.2d 882, 885 n.1 (Minn. 1970).
Mississippi: Miss. Code Ann. §11-1-63(c)(ii); Janssen Pharmaceutica, Inc. v. Bailey, 878 So.2d 31, 57 (Miss. 2004).
Missouri: Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146-47 (Mo. 1967).
Montana: Hill v. Squibb & Sons, 592 P.2d 1383, 1387-88 (Mont. 1979).
Nebraska: Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 841-42 (Neb. 2000).
Nevada: Allison v. Merck & Co., 878 P.2d 948, 958 n.16 (Nev. 1994) (plurality op.).
New Jersey: N.J. Stat. §2A:58C-4; Perez v. Wyeth Laboratories, Inc., 734 A.2d 1245, 1257 (N.J. 1999) (note exception for DTC advertised products in Perez v. Wyeth Laboratories, Inc., 734 A.2d 1245, 1256 (N.J.,1999).
New Mexico: Serna v. Roche Laboratories, Division of Hoffman-LaRoche, Inc., 684 P.2d 1187, 1189 (N.M. App. 1984).
New York: Spensieri v. Lasky, 723 N.E.2d 544, 549 (N.Y. 1999).
Ohio: Ohio Rev. Code §2307.76(c); Howland v. Purdue Pharma, L.P., 821 N.E.2d 141, 146 (Ohio 2004).
Oklahoma: Edwards v. Basel Pharmaceuticals, 933 P.2d 298, 300-01 (Okla. 1997).
Oregon: Oksenholt v. Lederle Laboratories, 656 P.2d 293, 296-97 (Or. 1982).
Pennsylvania: Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1385 (Pa. 1991).
South Carolina: Madison v. American Home Products Corp., 595 S.E.2d 493, 496 (S.C. 2004).
Tennessee: Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994).
Texas: Humble Sand & Gravel, Inc. v. Gomez, 146 S.W.3d 170, 190-91 (Tex. 2004).
Utah: Schaerrer v. Stewart's Plaza Pharmacy, Inc., 79 P.3d 922, 928-29 (Utah 2003).
Virginia: Pfizer, Inc. v. Jones, 272 S.E.2d 43, 44 (Va. 1980).
Washington: Washington State Physicians Insurance Exchange & Ass'n v. Fisons Corp., 122 Wn.2d 299, 338, 858 P.2d 1054(1993).

The following jurisdictions are silent on acceptance of the learned intermediary theory. Federal courts, however, have made an Erie prediction that the jurisdictions would adopt the learned intermediary doctrine:

Iowa: Petty v. United States, 740 F.2d 1428, 1440 (8th Cir. 1984).
Maine: Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 13 (1st Cir. 1995).
New Hampshire: Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 656 (1st Cir. 1981).
North Dakota: Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1017 (8th Cir. 2004).
Puerto Rico: Guevara v. Dorsey Laboratories, Division of Sandoz, Inc., 845 F.2d 364, 366 (1st Cir. 1988).
South Carolina: Odom v. G.D. Searle &. Co., 979 F.2d 1001, 1004 (4th Cir. 1992).
South Dakota: McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 231 (D.S.D. 1983), aff'd, 739 F.2d 340 (8th Cir. 1984).
Wisconsin: Monson v. AcroMed Corp., 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999).
Wyoming: Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 851-53 (10th Cir. 2003).

West Virginia has specifically rejected the doctrine with respect to prescription medical product cases. State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 913-14 (W.Va. 2007). Rhode island and Vermont have no precedent, state or federal, addressing the learned intermediary rule.


Medicare

Medicare Secondary Payer Act

The opportunity to resolve a lawsuit can present itself at almost any time during the course of personal injury litigation. A case may settle shortly after the first demand letter is written, moments before the jury returns from deliberations, or somewhere in between. Regardless of when the settlement negotiations move from a possibility to a reality, it is in the best interests of the attorneys — and their respective clients — to keep Medicare's interests in mind due to the implications and issues presented by the Medicare Secondary Payer Act.

Failure to do so could not only derail a potential settlement, but could also result in monetary penalties for recovery of funds paid by Medicare (including *double damages*) assessed *after* settlement against numerous "entities," including the parties, lawyers, and healthcare providers. In other words, a litigant tortfeasor could be subject to the damages trifecta by compensating a plaintiff for his medical damages as part of a settlement agreement, then later finding itself on the hook to Medicare for twice the amount of those damages because no one considered Medicare's interests prior to settlement.

Consider a scenario where a plaintiff suffers severe injuries, incurs significant damages, and vigorously pursues (and obtains) a trial date. Although the company that the plaintiff has sued vehemently disputes its liability, a jury could possibly return a seven-figure judgment if the case proceeds to trial. In addition to the potential judgment, the company also will incur substantial attorneys' fees and other costs associated with serious trial preparation. As such, settlement negotiations ensue, and the parties agree that the company will pay an amount sufficient to cover the plaintiff's $750,000 medical lien, pay attorneys' fees and costs, and leave the seriously-disabled plaintiff approximately $250,000. Literally on the courthouse steps, the parties learn that the plaintiff's employer intends to terminate the plaintiff's benefits in exchange for the employer waiving part of a claim for reimbursement — thus making the plaintiff eligible for Medicare coverage. It also comes to light that the plaintiff may have already filed under Medicare or Medicaid without the knowledge of counsel or any of the parties. With these developments, is it advisable to consummate the settlement? If so, how should the settlement proceed and who should be involved? Or is the deal dead in the water?

This article discusses the ramifications when Medicare's interests come into play and certain steps that may be taken to avoid the above situation.

I. What Is The Medicare Secondary Payer Act?

In 1980, Congress initiated a series of amendments to the Medicare Act, 42 U.S.C. §§ 1395-1395hhh in an effort to "reduce Medicare costs by making the

government a secondary provider of medical insurance coverage when a Medicare recipient has other sources of primary insurance coverage."[1] The amendments are commonly known as the Medicare Secondary Payer provisions (MSP).[2] The MSP provides that Medicare is precluded from paying for any item or service of medical care, for which it otherwise would have been obligated to pay, when payment has been made or can reasonably be expected to be made under a workers' compensation plan, an automobile or liability insurance policy, a self-insured policy, or under no-fault insurance.[3]

Medicare is authorized, however, to make conditional payments for medical care when a primary plan has not made or cannot reasonably be expected to make payment promptly.[4] A primary plan (or any entity that receives payment from a primary plan) is required to reimburse Medicare for any conditional payment "if it is demonstrated that such primary plan has or had a responsibility to make [the] payment."[5] Further, "[a] primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."[6]

A litigant tortfeasor could be subject to damages trifecta by compensating a plaintiff for his medical damages as part of a settlement agreement, then later finding itself on the hook to Medicare for twice the amount of those damages because no one considered Medicare's interests prior to settlement.

If a settlement is involved, Medicare's claims must be paid up front out of the settlement proceeds before any distribution occurs, as Medicare has a priority right of recovery for conditional payments. If reimbursement is not made before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received (i.e., the settlement date), Medicare may charge interest on the amount of the reimbursement until reimbursement is made.[7]

The terms of the MSP were more concisely described in Fanning v. U.S., et al., 346 F.3d 386 (3rd Cir. 2003):

"[T]he MSP bars Medicare payments where 'payment has already been made or can reasonably be expected to be made promptly' by a primary plan. [...] The MSP defines a 'primary plan' as 'a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance.' This provision 'is intended to keep the government from paying a medical bill where it is clear an insurance company will pay instead.' Second, the MSP provides that when Medicare makes a payment that a primary plan was responsible for, the payment is merely conditional and Medicare is entitled to reimbursement for it."[8]

II. Does It Apply In My Case?

The short answer: Medicare's interests must be considered in all appropriate tort and workers' compensation settlements if the settlement involved payment of past and future medical bills. Passage of time is not an issue as there is no statute of limitations that affects this program.[9]

A. Workers' Compensation Cases

For purposes of the MSP, workers' compensation programs are primary payers of medical expenses for persons receiving workers' compensation benefits for healthcare.[10] There are two circumstances that trigger the requirement for Medicare approval in workers' compensation cases: 1) when the injured party has been both Medicare-eligible since the time of his or her injury and when the injured person is 65 years of age or older or has been on Social Security disability for 24 months or longer and 2) when the gross settlement exceeds $250,000 and the injured party has a reasonable expectation of being Medicare-eligible within 30 months.

Medicare's interests must be considered in all appropriate tort and workers' compensation settlements if the settlement involved payment of past and future medical bills. Passage of time is not an issue as there is no statute of limitations that affects this program.

B. Liability Cases (Other than Workers' Compensation Cases)

Prior to the enactment of the Medicare Prescription Drug, Improvement and Modernization Act in 2003 (MMA), courts across the country were split on the question of whether the MSP applied to liability settlements. In *U.S. v. Baxter Int'l*, 345 F.3d 866 (11th Cir. 2003), the U.S. government claimed that it had a right to recover Medicare's conditional payments from the class action settlement proceeds in the nationwide breast implant litigation. The parties had reached a settlement without considering or protecting Medicare's right of recovery for payments it had made to treat the plaintiffs' implant-related injuries.[11] The Eleventh Circuit Court of

Appeals held that Medicare did have a right to recover from the liability settlement proceeds.[12]

Other circuits disagreed. Courts in cases such as *Thompson v. Goetzmann*, 337 F.3d 489 (5th Cir. 2003) and *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 202 F.R.D. 154 (E.D. Pa. 2001) held that the MSP did not apply to third-party liability settlements because a litigant tortfeasor could not be expected to pay "promptly" as required by the MSP; therefore, the settlement fund could not be considered a "primary plan" and Medicare could not recover its payments from the liability settlement proceeds. Moreover, the *Bone Screw* Court held that an entity that funds its own liability insurance settlement is not a "self-insured" plan under the MSP.[13]

The enactment of the MMA and its amendments to the MSP, however, resolved these conflicting decisions. See *Brown v. Thompson*, 374 F.3d 253, 258 (4th Cir. 2004). In *Brown*, a Medicare beneficiary entered into a settlement agreement in a medical malpractice action and then sought to prevent Medicare from recovering its conditional payments by arguing that 1) a litigant tortfeasor could not be expected to pay "promptly" and 2) the defendant was not "self-insured" as defined by the MSP.[14] The court held that the new language of the MMA "plainly entitles Medicare to reimbursement of any payment it makes for medical services if a primary plan later pays for those services as part of a settlement agreement — regardless of whether that primary plan could have been expected to pay promptly when medical services were provided."[15] The court further held that the MMA clarified the definition of "self-insured" to include "[a]n entity [...that] carries its own risk [...] in whole or part."[16] The court also pointed out that the very purpose of the new definition of "self-insured" in the MMA was "to remedy the effects of 'recent court decisions' that would allow 'firms that self-insure for product liability' to be 'able to avoid paying Medicare for past medical payments related to the claim.'"[17] The *Brown* case casts aside any doubt that the MSP is applicable to third-party liability settlements funded by a self-insured tortfeasor.

While the Center for Medicare and Medicaid Services (CMS) does not presently require review and approval of liability settlements, review of a settlement in such cases is the only way to avoid future problems and to ensure that Medicare deems its interests adequately protected. While CMS suggests this process takes between 45 and 60 days, the reality could be much longer.

III. What Duties Do I Have?

If you learn that Medicare has made a payment for one or more of the settling plaintiffs' medical expenses, then you have an affirmative duty to notify Medicare of the mistaken Medicare payment and the liability settlement:

(a) If a third party payer learns that CMS has made a Medicare primary payment for services for which the primary payer has made or should have made primary payment, it *must* give notice to that effect to the Medicare intermediary or carrier that paid the claim [...]

(c) If a plan is self-insured and self-administered, the employer must give notice to CMS. Otherwise, the insurer, underwriter, or third party administrator must give the notice.[18]

The reporting requirements of involved parties appear to have grown recently. On December 29, 2007, President Bush signed Senate Bill 2499 into law. Section 111 of the bill is of particular interest as it amended, among other things, submission requirements related to the Medicare Secondary Payer Act. Notably, the amendment states the following:

(A) Requirement – On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph, an applicable plan shall —

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this title on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Required Information – The information described in this subparagraph is —

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.[19]

On December 29, 2007, President Bush signed Senate Bill 2499 into law. Section 111 of the bill is of particular interest as it amended, among other things, submission requirements related to the Medicare Secondary Payer Act.

Although not yet tested, the above language has been interpreted to mean that parties must determine whether a plaintiff is entitled to Medicare benefits and, if so, advise the government when a liability dispute involving said claimant(s) is resolved through a settlement, judgment, or otherwise, regardless of whether or not there is a determination of liability. Failure to timely report could involve severe penalties.

The duty to ascertain the existence of a Medicare claim cannot be placed on someone else. If the primary payer fails to

Case Scenario: A global healthcare manufacturer, which I will refer to as "GHM," acquired a foreign "boutique" company that made an innovative medical device. The deal went down without a hitch, and both parties to the transaction were very happy. The product fit perfectly within GHM's long-term objectives, and the success of the product seemed assured. It was a device with the potential to save millions of lives.

By all accounts, GHM's acquired product saved a significant number of lives. But the first report of a death signaled a possible problem. Reports of additional fatalities soon followed from other parts of the world.

GHM immediately sprung to action when it received the first hint of a potential safety issue. It assembled a top team of scientists to investigate each fatality, and it subsequently launched a voluntary worldwide recall of the product. It notified the U.S. Food and Drug Administration and other health authorities of the findings of its internal investigations and pulled the product off the market. GHM, however, didn't stop there. It publicly acknowledged that a change in manufacturing practices may have contributed to the reported deaths.

In the interest of patient safety, GHM embarked on the most conservative course of action conceivable: permanent cessation of manufacturing the medical device. All GHM plants that manufactured the device and components for the device terminated operations. Employees were laid off. In the shadows of this very painful and public experience were trundles of lawyers signing up plaintiffs. A deluge of lawsuits and public investigations followed.

GHM, a valued and long-standing firm client, hired us to work with the company and an international team of lawyers to defend its interests at home and abroad. I was involved in the unique capacity as lawyer-filmmaker to find a solution to preserving evidence necessary for the defense of the global litigation.

The Solution: With the impending shut down of all GHM facilities associated with manufacturing the device and components of the product, it would not be long before the manufacturing story – the crux of the defense – would be lost in the dust building up in the non-operational plants. Time was of the essence.

Working with in-house counsel, key GHM scientists and engineers, and key personnel at the manufacturing facilities, we delved into learning all aspects of the manufacturing process. It was a collaborative endeavor to sustain key evidence, and everyone worked long hours without complaint to get the best results. From interviews and group strategy sessions, we developed a script for filming each facility. Because we were part of the litigation team, the script fell into the important protections of the attorney-client privilege and the attorney work-product doctrine.

With a completed script and an experienced crew, we headed abroad to film the manufacturing process for the device at issue. The production phase of the filming project had challenges, such as lost equipment and luggage along the way and working with former employees who felt hurt, but the results were well worth the challenges. The final film, a labor of focused energy by a committed team from multiple disciplines, contributed to the overall success of the litigation.

Written *by*
Anita Modak-Truran

continued

reimburse Medicare for such claim, "the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party."[20]

IV. But Does It Have Teeth?

Again, the short answer is the best answer: Yes, it does have teeth and cannot be ignored. The MSP authorizes the U.S. government to recover Medicare conditional payments as followed:

(iii) Action by United States. In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A), collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity [...].[21]

Indeed, "CMS has a direct right of action to recover" from any primary payer.[22] Moreover, pursuant to the recent amendment regarding reporting requirements, individuals who fail to follow said requirements "shall be subject to a civil money penalty of $1,000 for each day of noncompliance with respect to each claimant."[23] To put it bluntly, ignoring Medicare's statutory right to recovery could result in monetary penalties to plaintiffs, lawyers, and healthcare providers.

V. What Steps Can I Take?

One should err on the side of caution and consider all scenarios to determine if Medicare has provided or will provide the claimant with any coverage for injuries or medical expenses which may be related to

the litigation. At the outset, with each individual case, one should always refer to the statutes and regulations to determine the law and guidelines applicable to a particular situation, as the steps necessary to protect the company's interests and Medicare's interests will ultimately depend on the facts of each case. Some suggestions and starting points follow:

1. Early on in the discovery process, you should include specific interrogatories and requests for admissions directed to the plaintiff on this matter. Inquire whether the plaintiff currently is a Medicare beneficiary, whether the plaintiff ever has been a Medicare beneficiary, whether the plaintiff reasonably expects to become a Medicare beneficiary, whether the plaintiff ever has sought such benefits/filed a claim/etc., and whether Medicare has any kind of lien. You may find it advisable to include a note reminding the respondents of their continuing obligation to advise you if the plaintiff's circumstances change or if the plaintiff becomes aware of additional material information relative to the discovery requests.

To put it bluntly, ignoring Medicare's statutory right to recovery could result in monetary penalties to plaintiffs, lawyers, and healthcare providers.

2. If the settling plaintiff is not on Medicare, has never been on Medicare, and has no reasonable expectation of being on Medicare, then the MSP provisions do not come into play and Medicare consideration is not necessary.

3. If the settling plaintiff is on Medicare at the time of the settlement and the possibility exists that Medicare paid some of the plaintiff's medical treatment, then the safest alternative is to notify Medicare of the settlement. Note that if a party learns that CMS made a Medicare payment that the primary payer has made or should have made, then the decision to notify Medicare is no longer optional and timely notice must be given to the Medicare intermediary or carrier that paid the claim; if the plan is self-insured and self-administered, notice must be given to CMS prior to the distribution of any settlement proceeds.

4. If a medical set-aside is necessary due the possibility of payment of future medical expenses, then Medicare should be notified of the settlement so that an agreeable set-aside amount can be determined.

What about settlement situations that arise when it is unknown whether Medicare has made a payment that another payer should have made — despite your excellent discovery requests? One alternative would be to draft the release in a manner that places the liability of paying any conditional payments on one or more parties and/or their attorney(s). Of course, this approach — agreements notwithstanding — does not totally insulate the parties because the United States still could initiate an action against the entities that are or were required or responsible to make payment under a primary plan — *and* seek double damages.

Parties also may be faced with the possibility of Medicare determining that a large amount of money be set aside to cover future expenses — so large in some cases that the amount may kill the settlement deal, as referenced in the scenario cited at the beginning of this article. In that case, again, the parties may include language in the release that allows either party to withdraw from the settlement if they disagree with the set-aside amount. Of course, this approach recognizes that some time will pass before determination of a set-aside is made; nevertheless, it moves resolution of the case forward and provides a viable means to, at a minimum, stay the prospect of additional, and quite possibly unnecessary, discovery and trial expenses while a set-aside determination is made.

VI. Conclusion

Prior to the inevitable time when the issue of settlement is broached, you already should have considered — and conducted discovery concerning — any potential Medicare implications. Clients should be well-briefed on the issues so as to fully understand the obligations, time restrictions, and potential penalties. Likewise, candor at the outset with opposing counsel may assist in both parties' understanding the many facets of the statute and will likely assist in resolution of the case to the satisfaction of all parties. Because the United States could proceed against any entity — including the plaintiff's attorney — this may be the one issue on which both sides may agree.

[1] *Thompson v. Goetzmann*, 337 F.3d 489, 495 (5th Cir. 2003).

[2] *Brown v. Thompson*, 374 F.3d 253, 257 (4th Cir. 2004).

[3] 42 U.S.C. § 1395y(b)(2)(A); 42 C.F.R. §411.50.

[4] 42 U.S.C § 1395y(b)(2)(B)(i).

[5] 42 U.S.C. § 1395y(b)(2)(B)(ii).

[6] *Id.; see also* 42 C.F.R. § 411.22(b)(3): "A primary payer's responsibility for payment may be demonstrated by [...] a settlement [...]."

[7] *Id.; see also* 42 C.F.R. § 411.24.

[8] Citations omitted.

[9] 42 C.F.R. § 411.24(f) (2006).

[10] 42 U.S.C. § 1395y(b)(2)(A); 42 C.F.R. § 411.40-45.

[11] *U.S. v. Baxter Int'l*, 345 F.3d 866 (11th Cir. 2003).

[12] *Id.*

[13] *Bone Screw*, 202 F.R.D. at 165-66.

[14] *Brown v. Thompson*, 374 F.3d 253, 258 (4th Cir. 2004).

[15] *Id.* at 258.

[16] *Id.* at 261-62.

[17] *Id.* at 262 (citing H.R. Rep. No. 108-178(II), at 189-90.).

[18] 42 C.F.R. § 411.25.

[19] 42 U.S.C. § 1395y(b)(8)(A-B).

[20] 42 C.F.R. § 411.24(i)(1).

[21] 42 U.S.C. § 1395y (emphasis added).

[22] 42 C.F.R. § 411.24(e).

[23] 42 U.S.C. § 1395y(b)(8)(E)(i).

Written *by* Michael Hewes

Protecting Intellectual Property When Using Independent Contractors

YOU NEED TO SCHEDULE your rooms, track assets, direct people, meet increasingly onerous record-keeping protocols, and exchange data across legacy systems. You need the hardware; you need the platforms, but building and integrating these systems is not what your clinic, outpatient center, pharmaceutical, or other healthcare business does. As a general rule, no matter how good you are at vein access, dialysis, or anything else, you should not even try to write your own code, design your own network, or move into another technical sphere. You can and should hire outside software developers, IT configuration specialists, and other independent contractors to help.

You have to, but there is extreme danger in this reliance. If you do not have the right agreement with your outside developers, you do not own what they have created.

This is a critically important point, in part because it runs counter to common assumptions. If you pay an independent contractor (a non-employee) to create something for your business, you do not own it. Repeat: You do not own it. You paid for it. It may be derivative of your own work. It may be essential to your business plan. It may have been created by your wife's cousin or you may have paid a good deal for it, but you do not own it. When this lack of ownership is discovered,

the market will punish your business severely, if not kill it, depending on the importance of the lapse.

How is this possible?

Understanding ownership in independent contractor relationships requires knowledge of trade secret, copyright and patent law, and how different agreements are adapted to deal with those legal concerns.

The Essential but Insufficient NDA

Many high-level managers in the healthcare industry have internalized the importance of Non-Disclosure Agreements. NDAs are tossed across the table or emailed over and typically executed with little scrutiny. The parties can silently congratulate themselves for their sophistication and move ahead with their work, knowing that they are "covered." Not quite.

NDAs deal primarily with matters of trade secret protection. A trade secret can be just about any information that derives independent economic value because it is not generally known. It could be the shape of the implosion chamber of a thermonuclear device or your mom's spaghetti recipe, any information that has potential value because it is not widely known. So, how can you possibly talk with investors, vendors, technical contractors, and other essential players in your healthcare enterprise without spilling the beans — an NDA. No NDA, no obligation to keep information secret, no trade secret protection in the disclosed information. Simple. Trade secret law respects and protects secrets. Something is only a secret if the people who know it are bound to maintain its secrecy.

Executing a good NDA is generally a very good thing. (There are of course innumerable complexities and risks attendant to both disclosing and receiving another party's secrets, including neutering your business in the field, but that is a topic for another article.) The problem is the error in logic that leaps from the internalized (even if not understood) truth that NDAs are very important, particularly to healthcare enterprises that often must place critical data and process management on third-party platforms, to the conclusion that an NDA is the right document for all seasons. A good NDA does precisely what it was drafted to do: protect the confidentiality of proprietary information. It does not deal with ownership of new information and intellectual property.

If you are *just* disclosing information with no discussion or development of new information, an NDA may be enough. If you are engaging the other party to develop something new for your business, whether it is code, a prototype, new graphics, marketing text, or anything else, an NDA is inadequate.

> So, how *can it be* that you can pay someone *to* create something for you *and not own* the work product? In a nutshell, *the law favors* inventors and authors, vesting patent rights *and* copyrights, respectively, *in those* whose creativity gave rise *to the* subject matter.

Beyond Secrecy: Content, Code and Inventions

So, how can it be that you can pay someone to create something for you and not own the work product? In a nutshell, the law favors inventors and authors, vesting patent rights and copyrights, respectively, in those whose creativity gave rise to the subject matter.

Copyright

Simply put, copyright protects original works of authorship of any sort — text, images, video, code — any original expression that can be fixed in a tangible medium.[1] If someone is creating your Web site or the architecture of your database, your promotional video or your application, you are in the realm of copyright protection. If a work is not created by an employee within the scope of his or her employment, the copyright vests in the author — the videographer or that grad student intern helping out two days a week. What you get by default is a non-exclusive license to the code or other work. Congratulations, you have just financed your first potential competitor. Your contractor is free to resell or use the work for himself.

Patent

Patent law is much the same. A patent is the strongest form of intellectual property protection, and your patent position will certainly be among the most important factors in maintaining a competitive advantage in almost any healthcare vertical. It may be the strongest private monopoly the state grants, and it can cover any invention — process, device, chemical compound, drug, plant, organism, just about anything — so long as it is novel, useful, and non-obvious.[2] Unless the inventor, employee or not, has expressly assigned his rights in an invention, the inventor owns any patent interest in the invention at issue. The law is particularly jealous of the individual's right to invent, and some states, most notably California, have right-to-invent statutes that go beyond federal law in giving employees broad rights to invent and own their work.[3] If your independent contractor comes up with something, even if it is merely an improvement to your own work, they own it. It is theirs to protect. If they apply for and receive a patent for their invention, it is theirs. (If they liked working for you, perhaps their licensing terms will be reasonable.) As with copyright, you, at best, end up with a non-exclusive license, a "shop right" to use the invention due to the role of your funds and equipment in the process.[4]

The Fix

The fix is relatively simple: Use the right agreement for the job. Copyright law permits two bites at the apple. Thanks to a provision in the Copyright Act, inserted to permit the continued use of independent contractors in the creation of studio movies, if the content at issue is a "work made for hire," copyright ownership vests initially in the hiring party.[5] There is no such thing as an implied or de facto work made for hire. The statute requires a signed writing that designates the product as a "work made for hire." In addition, the work must fall within one of seven enumerated categories which may or may not apply to you. In short, you must have an executed agreement with a work made for hire provision, most likely using the statutory magic words ("work made for hire"), if you want to claim copyright ownership from the time pen hits paper or key stroke generates character.

If you are not in one of the seven categories or you fail to get such an agreement signed, copyrights may be assigned, though here, too, the statute requires a signed writing — an executed agreement.[6] (Assignments are also subject to termination after 35 years if that matters for your purposes.[7]) Likewise, patent rights may be assigned via a signed writing, and both the Patent Office and the Copyright Office permit the recordation of assignments to provide notice of your ownership to the world.

What is the Big Deal?

So, why the diatribe when everything can be fixed with a simple assignment? Why worry if the person doing the work is a long-standing vendor who would never try to leverage your mistake for their own gain? If you never have a serious transaction, you may be fine. Perhaps nobody will ever know. However, if it is ever in someone's interest to scrutinize the assets of your business, you will pay a price. Obviously, the time to get someone to sign a document is at the outset. If they want the job, they will sign. The later it is in the game, the closer to a financing event or sale, the more expensive getting an assignment of the rights in the intellectual property you are using may become. That one person who did not sign a solid developer agreement will have power similar to a hold-out homeowner stalling a big construction project. If the invention or work at issue is material to your business, it could be a deal killer. At a minimum, expect a severe haircut on valuation. The interns from ten years ago, your cousin who made your logo when you started — all of it — will be examined in due diligence, and the holes you inadvertently left will be filled by money out of your pocket.

Use a Good Agreement

If you are engaging a developer of any sort, or even just someone who is adding marketing or other brain power to the business, use an agreement that has:

- confidentiality provisions — You still have trade secrets to protect, and you need to keep your inventions and critical business data under wraps to preclude the devastation of an unplanned use or disclosure (yet another topic);
- a work made for hire provision for copyright-protected matter;
- a back-up assignment of copyright-protected matter;
- an assignment of inventions;
- an identification of any existing intellectual property the developer claims as his, to ensure there are no fights over what he brought to the table and what he created for you; and
- a further assurances clause requiring the contractor to sign any additional short-form assignments or other documents as may be useful for effecting and recording the assignments.

Protection ownership is not rocket science. You simply need a good agreement, and you need to use it. If the market tells you that your business does not work, so be it. To prevail in the market but lose on a technicality is an avoidable tragedy.

[1] 17 U.S.C. § 102.

[2] 35 U.S.C. § 101.

[3] Cal. Labor Code § 2870.

[4] See e.g. *Allegheny Steel & Brass Corp. v. Elting*, 141 F. 2d148, 149 (7th Cir. 1944).

[5] 17 U.S.C. §§ 101 and 201(b).

[6] 17 U.S.C. § 204.

[7] 17 U.S.C. § 203.

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