

# Topics in PAIN MANAGEMENT

Vol. 28, No. 5

Current Concepts and Treatment Strategies

December 2012

## CME ARTICLE

### Can You Spot a Fake? Waddell Signs and Other Red Flags

Clifford Gevirtz, MD, MPH

*Learning Objectives: After participating in this activity, the physician should be better able to:*

1. Perform and evaluate the Waddell signs to detect fakery by a patient.
2. Perform the Hoover test.
3. Delineate 4 red flags that indicate drug-seeking behavior.

As pain physicians, we live in an era of doctor-shopping and questionable disability claims. Several physicians have been prosecuted based not on their actions but rather on the subsequent actions of their patients. Similarly, the *New York Times*<sup>1</sup> reported about a group of retired Long Island Railroad workers who routinely applied for disability, with 90% securing a disability rating.

To bring this to the fore, as physicians whose clinical practice should involve excellent powers of observation and analysis, we should ask ourselves, “Can I spot a fake?” and “How can I do so with more accuracy?” By reading this article, the practitioner will learn some specific tools and practices that can augment other diagnostic skills to make sure we provide appropriate care for patients who are in pain and deserve our trust and best efforts, while preventing abuse and misuse of pain care and medications by individuals who are possibly coming to us under false pretenses.

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#### Waddell Signs

With few objective measures of pain other than what a patient reports to the care team, detecting fakery by a patient who reports pain can be a challenge. Even the concept of a set of characteristics indicating faked pain does not sit well with all providers.

Waddell signs are controversial, and the original intent by the author, Scottish orthopedic surgeon Gordon Waddell, MD, FRCS(Ed), was to provide a test that would help to

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determine whether back pain in a given patient might have a nonorganic cause. The test was not devised specifically to catch a fake but to provide another clinical screen to help in identifying patients who require more detailed psychological assessment.


## **Tenderness is a deep or diffuse nondermatomal report of pain to a superficial stimulus.**

Waddell signs, however, have been peer-reviewed and constitute the best objective evidence that the patient could be faking symptoms in some way. There are 5 potential Waddell signs. When 3 or more of these signs are present, there is a significant probability that the pain is nonorganic, and other signs presented in this article will provide other clues to uncover fakery. It is important to document the findings objectively and to treat the patient respectfully; but having done that, it is also important to note that the physician cannot prescribe medications or assign disability on the basis of these findings.

The 5 Waddell signs or tests are as follows:

1. Tenderness;
2. Simulation testing;
3. Distraction testing;
4. Regional disturbances; and
5. Overreaction.

The continuing education activity in *Topics in Pain Management* is intended for clinical and academic physicians from the specialties of anesthesiology, neurology, psychiatry, physical and rehabilitative medicine, and neurosurgery as well as residents in those fields and other practitioners interested in pain management.

 Wolters Kluwer Health | Lippincott Williams & Wilkins  
*Topics in Pain Management* (ISSN 0882-5646) is published monthly by Lippincott Williams & Wilkins, 16522 Hunters Green Parkway, Hagerstown, MD 21740-2116. **Customer Service: Phone (800) 638-3030, Fax (301) 223-2400, or Email customerservice@lww.com.** Visit our website at [lww.com](http://lww.com).

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**Publisher: Randi Davis**

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*Topics in Pain Management* is indexed by SIIC (Sociedad Iberoamericana de Información Científica).

### **Tenderness**

Tenderness is a deep or diffuse nondermatomal report of pain to a superficial stimulus such as a light rolling of the skin or light pinch. It is important to differentiate this type of stimulus from one applied in evaluating fibromyalgia, in which the pressure is applied to specific points in the 4 quadrants of the body.

The degree of pressure in evaluating for fibromyalgia is enough to cause the examiner's fingernail bed to blanch. In the Waddell test of tenderness, however, a pinch of skin is gently pulled or rolled. Similarly, in a patient with complex regional pain syndrome (CRPS) I or II, although there may be allodynia and dysesthesia, it is usually not referable to deeper portions of the limb.

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## **Regional disturbances are primarily motor and include sensory deficits that do not follow an anatomic distribution.**

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### **Simulation Testing**

Simulation testing is an attempt to see whether the patient reports pain under a simulation circumstance that would not be painful. During the test, the examiner looks for a report of pain in the lumbar region to axial loading of the head or to body rotation with the shoulders and pelvis in line. For example, placing a text-book on the head of a patient should not cause back pain, even in a patient with an acutely herniated disc. Similarly, log rolling a patient in the supine position should not cause back pain.

### **Distraction Testing**

Distraction testing is repetition and comparison of the results of a provocative test in an obvious and then a less obvious nonstandard fashion. The most common example of this is performing the straight-leg raising test in the supine and then in the sitting position. If the patient cannot get past 30 degrees in the supine position but can fully extend the leg in the sitting position, there is something amiss, and the difference is considered a positive Waddell sign.

Another example is performing reflex testing repeatedly and observing different responses. A Babinski test should be consistently negative or positive regardless of whether the leg is elevated.

### **Regional Disturbances**

Regional disturbances are primarily motor and include sensory deficits that do not follow an anatomic distribution. An example would be a patient reporting both shoulder and intrinsic hand muscle weakness while the wrist flexors and extensors are intact. This would require 2 separate lesions that spare the intervening nerve roots.

Another example of a regional disturbance would be pain that encircles the thigh and does not have a radicular pattern. In contrast, glove and stocking loss can occur in patients with peripheral neuropathies, but there is usually a clear cause such as diabetes mellitus or human immunodeficiency virus infection.

Similarly, muscle weakness testing can be quantified. There are computerized devices<sup>2-4</sup> that provide a force-time curve instead of merely a reading of the maximum force, which constitutes a better method for evaluation of strength because they are difficult to fool. Similarly, range of motion and strength can be measured objectively with repetition, after which it should be very clear if results are inconsistent.

### **Overreaction**

Overreaction, within the context of cultural variation, includes disproportionate verbal and facial expressions, unconventional anatomic movements and postures, and inappropriate responses to the examination. Again, it is important to differentiate CRPS I and II in this context, because there should be overt signs of edema, skin color changes, nail and hair changes, and temperature differences, which can be discerned objectively. In CRPS, the patient may adopt an abnormal posture in an extremity, but he or she consistently holds that posture throughout the examination.

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## **Practitioners can use the Hoover test to confirm the presence of malingering with regard to paralysis or weakness in the legs.**

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### **Looking at Low Back Pain With Discordant Findings**

Table 1 compares appropriate and inappropriate signs and symptoms of back pain. It takes a clever would-be patient to master the physical findings and give a creditable pain history, but being sensitive to inconsistent findings can reveal fakery.

#### **Hoover Test**

Practitioners can use the Hoover test to confirm the presence of malingering with regard to paralysis or weakness in the legs. In this test, the patient is supine, and the examiner raises one leg of the patient while the keeping a hand underneath the patient's other supine leg. The tendency is for the patient to press down on the supine leg, and the downward movement of the heel of the foot is felt by the examiner's hand. The absence of any movement of the supine leg indicates true leg paralysis or weakness.

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## **Between 85% and 95% of poisoning deaths result from prescription drug misuse.**

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### **Poisoning Deaths—Unintended Consequence Of Irresponsible Pain Prescribing**

Each day throughout the United States, about 75 people die and 2000 people are treated in an emergency department due to unintentional poisoning. When these episodes are further evaluated, between 85% and 95% of poisoning deaths result from prescription drug misuse. The Centers for Disease Control and Prevention

**Table 1. Comparison of Symptoms and Signs of Physical Disease and Inappropriate Illness Behavior in Chronic Back Pain**

	<b>Appropriate Behavior</b>	<b>Inappropriate Behavior</b>
Pain localization	Corresponds to dermatomal, myotomal, or sclerodermal distribution	Poor correlation to anatomic distribution
Numbness	Corresponds to dermatomal distribution	Whole leg or arm
Motor weakness	Weakness in muscles from corresponding nerve roots	Whole leg weakness or giving way
Time pattern	Variable intensity	No intervals of variation
Simulated axial loading	No pain	Pain
Simulated rotation	No pain	Pain
Straight leg raising test	No change on distraction	Improves with distraction

(CDC)<sup>5</sup> reports that the increase in deaths from drug overdose is a direct result of increasing abuse and misuse of prescription opioids and other controlled substances.

In some states, this increase is directly related to the abundant supply of narcotic medications made available via malicious, illegal, and excessive prescribing by individual physicians operating out of what have been termed “pill mill” pain management clinics.

For example, recently a Florida physician was arrested and his medical license summarily suspended. From January through August 2011, this physician reportedly prescribed 250,000 oxycodone pills to his patients. By comparison, in all of California, just 300,000 pills were prescribed in the last 6 months of 2010. The federal government has stepped up law enforcement actions

against physicians and others who prescribe excessively and inappropriately.

The presence of some or all of the following circumstances should raise the prescriber’s index of suspicion and constitute red flags (Table 2).

***Even Before the Examination: Waiting Room and Reception Behavior Signs***

Often, drug seekers will exhibit unusual behavior in the waiting room, such as melodrama with moaning and wailing out loud in front of others. Beware of those patients who feel the need to lie down on the lobby floor while waiting to be shown to a room. These are also the patients who will declare loudly that they are

**Table 2. Red Flags: A Guide for Pain Medication Prescribers**

The patient is from out of state.
The patient requests a specific drug by name and states that alternative medications do not work.
The patient says his or her previous physician closed the practice.
Previous treatment records cannot be obtained.
The patient claims he or she cannot afford indicated or appropriate diagnostic testing.
The patient presents to the physician with an MRI scan or results ordered by another physician.
The patient presents to the appointment with his or her pharmacy profile showing specific drugs he or she wants prescribed.
Several patients arrive at the office together in a carpool.
The patient tests positive for illegal drugs (including marijuana).
Drug screening reveals no prescribed medication in the patient’s system.
The patient recites textbook symptoms.
The patient pays in cash only and has no insurance.
The patient calls for early refills and prescriptions or regularly reports that medications are lost or stolen.
The patient’s pain level remains the same over several subsequent visits even though aggressive opiate therapy has been instituted.
The patient is noncompliant with the physician’s treatment plan (ie, not going for physical therapy or additional diagnostic testing).



in the worst pain of their lives and need to be attended to immediately, before anyone else.

Drug seekers often will refuse to provide identification to registration clerks, will declare they have no primary care physician (to eliminate verification of medical history), will provide no insurance information, and, in some cases, present with the statement, "I'm on vacation" or "I'm visiting friends/relatives."

Upon evaluation, the pain symptoms are usually either textbook specific or extremely vague. Typically, drug seekers present reporting back pain, kidney stones, or migraines. On weekends or off-hours, suspect patients will state that they need their prescriptions refilled or that the prescription has been lost or stolen and needs to be replaced.

Drug seekers often demand a particular drug and, regardless of diagnosis, are hesitant or refuse a different drug. When offered a substitute medication, drug seekers often will claim to be allergic to that medication, stating that they "forgot" to list it as an allergy during intake. The physician should be particularly suspicious of the patient who claims to be allergic to the generic form of a narcotic but not the branded form. (Brand-name medications have a higher street value.) At times, drug seekers will claim that there are only 1 or 2 medications that control their pain and "nothing else ever works."

## Drug seekers and addicts have been known to use children and elderly people to obtain pain medication prescriptions.

Drug seekers are typically resistant to other forms of pain control or therapy. For instance, transcutaneous electrical nerve stimulation and acupuncture will almost always be refused by a drug seeker. These patients also tend to be noncompliant in following up with primary care physicians and present for multiple visits in a short time for the same complaint.

Providers must also be suspicious of family members of the very young and of the elderly when prescribing or administering controlled substances to those patients. Drug seekers and addicts have been known to use children and elderly people to obtain pain medication prescriptions for themselves. Drug seekers can also be "professional patients," or "middlemen," so to speak, for drug dealers. For example, paraplegics and amputees may be hired by drug dealers as professional patients with phantom limb pain and paid per prescription.

## What to Do When a Drug Seeker Presents to Your Facility

As for what to do when a suspected drug seeker presents to your office, you should start out doing what you should do for any new pain patient. Make sure you perform a thorough history, physical examination, and assessment, and document all findings.<sup>6</sup> Take the time to question the patient and elicit as

much detail as possible. Many times, just by thorough assessment, drug seekers will admit to being at other clinics, 24-hour urgent-care facilities, and other medical settings and will express dissatisfaction regarding the service, medications, or treatment they received.

Make sure you or your staff collect enough identifying information and document and include it with the medical record. This information will help you to track patients and will make it as easy as possible for the next provider to retrieve information regarding previous visits. A photocopy of the patient's driver's license is an excellent means of identification.

Ensure that prescriptions have the quantity written in both numeric form and spelled out as words, which will prevent the patient from changing #10 to #40.<sup>7</sup>

If the patient claims that his or her prescription was lost or stolen, require that the patient call the police and obtain a police report. Patients with criminal backgrounds are extremely hesitant to involve the police. Refuse prescriptions until proper investigation and documentation have been completed.

Keep copies of original prescriptions in the patient's medical record. If a pharmacy calls to question the quantity of a prescription, for example, the on-hand copy can be obtained for verification purposes.

Always keep blank prescription pads out of easily accessible areas and do not carry them in your pockets and into patient rooms.

## Best Excuses

In the course of 25 years of practice, I have heard some wonderful excuses as to how patients lost their medication. In some of the 6 cases mentioned below, I have included my verbal or internal response, but practitioners should feel free to craft their own.

1. Patient: "I dropped my pills in the lake when I went canoeing."  
Me: "If you are taking pills for pain management, why are you canoeing?"
2. Patient: "I left my pills in the car, and they were stolen, could you replace them?" (Doesn't everyone keep their medications on the front seat of their car in plain sight?)  
Me: "Do you have a copy of the police report? I will need it."
3. Patient: "My medication fell in the toilet, and when I went to grab it, I accidentally hit the flusher."  
Me: I have never been able to replicate this trick in years of trying.
4. Patient: "I think someone broke into my house and stole my pills, can you call in a new prescription for me?"  
Me: "I'm sorry to hear that. I will need a copy of the police report before I can prescribe more pills."

5. Patient: "I know the bottle said take 1 to 2 every 4 to 6 hours, but I figured that if I took 4 to 6 every 1 to 2 hours it would work better. Now I need a refill."

Me: Being a moron and unable to follow directions is a clear reason not to continue opiates, but I will word this more diplomatically with a patient.

6. My all-time favorite. Patient: "My dog ate them."

Me: "In that case, I'd like to see the vet bill for the poor animal."

### You Cannot Judge a Book by Its Cover

Jung and Reidenberg<sup>8</sup> reviewed several cases of high-profile prosecutions of physicians for prescribing opioids, in which the prosecutors claimed that the doctors should have known the individuals were feigning pain solely to obtain prescriptions. They conducted a study to determine how readily physicians can tell that patients lie.

### The authors concluded that deception is difficult to detect.

First, they performed a literature search for studies of standardized patients used to evaluate physicians' practices. Standardized patients are actors taught to mimic a patient with a specific illness. The articles were then reviewed for the frequency with which the physician correctly identified which office visits were made by the standardized (lying) patients.

The investigators found 6 studies of practicing physicians using standardized patients, in which there was a reported frequency with which these actors were identified as the standardized patients. Physicians identified the fake patients about 10% of the time. Some real patients were erroneously identified as actors.

The authors concluded that deception is difficult to detect. In the current legal climate surrounding prescribing opioids, accepting patient reports of pain at face value can have significant legal consequences for the physician. Although doctors must make every reasonable effort to confirm the diagnosis and need for

opioid therapy, allowance must be made for the fact that conscientious doctors can be deceived.

### Conclusions

Dealing with fakes and drug seekers has, unfortunately, become common in pain practice. Vigilance is our only weapon against those who would deceive us and exploit our profession. Careful examination and objective documentation remain the key to safe practice. Physicians can call upon a toolkit that includes Waddell signs, the Hoover test and other objective tests, common sense, healthy skepticism, and the collective experience of seasoned physicians who have noticed specific patterns among drug-seeking patients. By learning to use these tools, physicians practicing in pain management can ensure that they use every means available to prescribe narcotic medications only to patients who need them. They may still be fooled now and then, but an occasional miss is far less likely to lead to criminal prosecution than is a pattern of reckless prescribing to every patient who asks for narcotics. ■

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## New Complications of Epidural Abscess and Arachnoiditis Emerge in Meningitis Outbreak Victims

Anne Haddad

It's a case of iatrogenesis upon iatrogenesis: More than a month after federal agencies reported the outbreak of fungal meningitis caused by tainted vials of methylprednisolone in patients who were injected with the drug to treat back pain, the Centers for Disease Control and Prevention (CDC) reported a new complication: preliminary reports of spinal epidural abscesses and arachnoiditis in some of the patients undergoing treatment for fungal meningitis.

The cases of meningitis have been traced to vials produced between July and September by New England Compounding Center (NECC), in Framingham, Massachusetts. Both NECC and Ameridose, also in Massachusetts and sharing some of the same owners as NECC, have closed and had their products recalled.

In addition to the fungus-tainted methylprednisolone, the FDA announced in late October that ongoing investigation of NECC

revealed bacteria in certain lots of preservative-free betamethasone and in one batch of a cardioplegia solution the compounder center prepared.<sup>1</sup>

Despite a growing list of suspicious findings from the pharmacies, the actual outbreak of illness was, as of November 12, limited to the patients developing fungal infections from the tainted methylprednisolone. The epidural abscesses and arachnoiditis emerged within a subset of the patients who were being treated for these fungal infections.

According to its website, the CDC “has received preliminary reports of spinal epidural abscesses and arachnoiditis occurring among a portion of patients undergoing treatment for fungal meningitis due to this outbreak. CDC does not know at this time how many patients developed these disorders or why they occurred. Both conditions are rare but serious disorders in the general population that require prompt medical attention.”<sup>2</sup>

The *New York Times* reported November 2 that about a third of the 53 patients treated for meningitis at St. Joseph Mercy Hospital in Ann Arbor, Michigan, have returned with abscesses.<sup>3</sup>

“This is a significant shift in the presentation of this fungal infection,” Lakshmi K. Halasyamani, MD, chief medical officer of St. Joseph Mercy Hospital, told the *Times*. “An epidural abscess is very serious. It’s not something we expected.”

Halasyamani said the concern is that these patients were taking drugs that had appeared to be working against *Exserohilum*, the fungus causing their original infection.

Michigan has more meningitis cases than any other state in the country—at least 128 out of 438, as of November 12, according to the CDC website. Numbers of cases of meningitis seem to be growing on a daily basis in the outbreak. The CDC site keeps a current count.

A spinal epidural abscess involves inflammation and a collection of pus around the spine, in the area where a medication has been injected. Symptoms can include fever, headache,

back pain, and neurological problems such as weakness and unusual changes in sensation. An MRI scan needed to diagnose it.

Arachnoiditis is inflammation of the arachnoid, one of the membranes that surrounds and protects the nerves of the spinal cord. The condition can be caused by irritation from chemicals, infection, or direct injury to the spine. Symptoms can include numbness, tingling, and a characteristic stinging and burning pain in the lower back or legs. Other possible symptoms include debilitating muscle cramps, twitches, or spasms; bladder, bowel, or sexual dysfunction; or paralysis of the lower limbs.

The CDC recommends that patients presenting with arachnoiditis be treated even if this condition is not specifically mentioned in the CDC case definitions for this outbreak.

“The case definition for this outbreak is a surveillance tool developed to assist with the identification and reporting of cases,” the CDC website said. “The case definition is not intended to guide clinical decision-making and patient management. Patients who present with signs and symptoms of arachnoiditis should be clinically assessed on the basis of clinical judgment and managed accordingly. CDC will continue working with clinicians and public health officials to obtain more information about the occurrence of arachnoiditis in these patients and refine its clinical guidance as needed.” ■

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## Methylprednisolone: Risky Even When Sterile

Anne Haddad

A little-reported aspect of the outbreak of meningitis related to methylprednisolone is that many physicians have stopped using that formulation as the preparation of choice for epidural corticosteroid injection. And they have discontinued use of this particular corticosteroid because of risks completely unrelated to the fungus determined to be in the vials produced and shipped by New England Compounding Center in Framingham, Massachusetts.

Evidence presented a few years ago indicated methylprednisolone itself might carry a greater risk of neurologic injury.<sup>1</sup> This finding, and a subsequent one that noted methylprednisolone has a larger particle size and therefore could be more likely to cause neurologic infarction,<sup>2</sup> led many pain experts to switch to other corticosteroid preparations, such as dexamethasone, for epidural injections.

Scanlon et al<sup>1</sup> documented a significant risk of serious neurologic injury after cervical transforaminal epidural corticosteroid injection with methylprednisolone. They reported that a growing body of evidence supports an embolic mechanism, although other possible mechanisms could be needle-induced vasospasm or vertebral artery perforation leading to thrombosis.

Derby et al<sup>2</sup> theorized that particulate size could be a factor, and set out to document the sizes of various corticosteroids used in transforaminal epidural corticosteroid injections. They theorized that particles that are smaller than red blood cells could be safer.

The Derby et al study did not involve patients and was not a clinical trial, but the investigators did evaluate 4 types of corticosteroid preparations in various solutions, using light microscopy.

Derby et al<sup>2</sup> documented that dexamethasone sodium phosphate particle size was 10 times smaller than red blood cells and

that they did not appear to aggregate. When mixed with 1% lidocaine HCl solution and with contrast dye, the size of the particles remained unchanged. They documented that triamcinolone acetate and betamethasone sodium phosphate showed variable sizes: some were larger than red blood cells, and aggregation of particles was evident.

The Derby et al team documented that methylprednisolone acetate showed the majority of particles smaller than red blood cells that were not aggregated, but the methylprednisolone particles were densely packed.

Derby et al<sup>2</sup> concluded that dexamethasone, whose particles were significantly smaller than red blood cells and which also had the least tendency to aggregate and the lowest density, could be less likely to lead to embolic infarcts.

“Until shown otherwise in clinical studies, interventionalists might consider using dexamethasone or another corticosteroid preparation with similar high solubility and negligible particle size when performing epidural injections,” they wrote.

The fact that another drug has been recommended as safer than methylprednisolone may or may not affect the suits against the

physicians (see article, *below*), because there may not be a link between the meningitis cases and the neurologic infarction risks the Scanlon et al<sup>1</sup> study found to be high with methylprednisolone.

However, it is worth noting that cost could be a factor in why a pain clinic might continue to choose methylprednisolone over other corticosteroid preparations, said Clifford Gevartz, MD, MPH, editor of *Topics in Pain Management* and a pain specialist in New York.

A list of the clinics that had received the tainted vials from New England Compounding Center seems to comprise mostly independent clinics rather than large medical centers. The large medical centers have greater purchasing power with the most reputable medication suppliers and therefore can buy the best preparations at a discounted price, Gevartz said. ■

### References

1. Scanlon GC, Moeller-Bertram T, Romanowsky SM, et al. Cervical transforaminal epidural steroid injections: more dangerous than we think? *Spine*. 2007;32(11):1249-1256.
2. Derby R, Lee S-H, Date ES, et al. Size and aggregation of corticosteroids used for epidural injection. *Pain Med*. 2008;9(2):227-234.

## Pain Physicians Who Unknowingly Injected Tainted Methylprednisolone Likely to Be Named in Lawsuits

### However, Physicians Not Likely to Be Found Liable

Anne Haddad

The news continues to develop in the tragic outbreak of fungal meningitis in patients who received epidural corticosteroid injections of methylprednisolone prepared by a compounding pharmacy in Massachusetts. By the beginning of November this year, the outbreak accounted for 438 cases as of November 12, 2012—32 of which resulted in death—with more cases expected.

An estimated 14,000 patients in 19 states may have received injections from the lots implicated in the outbreak, although it remains to be seen how many develop meningitis. As of early November, the Centers for Disease Control and Prevention (CDC) reported that 97% of these patients had been contacted for follow-up.

New cases were identified nearly a month into the crisis, and 2 additional states were added to the list of those where vials had been shipped, indicating that the impact of the outbreak could grow much larger and reach states that were not named in the original news reports.

Physicians who have injected any of the drugs from New England Compounding Center in Framingham, Massachusetts, should check the CDC website daily.

The most important thing for physicians to do is to be vigilant about contacting patients if they have received any of the preparations that the CDC and the FDA have determined to be tainted or possibly tainted. The CDC also advises what to do for patients who may have received injections of tainted corticosteroids and when to consider antifungal therapy.

The FDA and CDC provide sample communications physicians can use to contact patients.

In addition, there are a few important points that legal and medical experts interviewed by *Topics in Pain Management (TPM)* have emphasized.

### Expect Physicians to Be Named

Any physician who injected the tainted medications can expect to be named in the resulting lawsuits that are already developing, mainly because it is standard practice for plaintiffs to start out naming all potentially liable parties. *The Washington Post*<sup>1</sup> reported on October 21 that at least 1 plaintiff had filed suit in Virginia naming the clinic that gave her the shot in addition to New England Compounding Center.

However, physicians and clinics are less likely to be found liable if there was no way they could have known of the practices or lapses in security that led to the tainted medication. But the question of whether they could have known is likely to play out in the legal arena. More on this is given later from Dallas malpractice defense attorney William Chamblee, JD, who spoke with *TPM*.

As for the standard of care in epidural corticosteroid injections, one issue may be that methylprednisolone has already been found to have potentially higher risk of complication than other corticosteroids, based on studies of neurologic infarcts in patients who have received methylprednisolone.<sup>2,3</sup> (See article, “Methylprednisolone: Risky Even When Sterile,” page 7.)



## What to Do If You Are Named in a Meningitis Suit

Should any *Topics in Pain Management* readers be among the physicians who injected the tainted methylprednisolone from New England Compounding Center, and subsequently find themselves named in a lawsuit, William Chamblee, JD, a Dallas attorney specializing in malpractice defense and product liability, recommends the same procedure for any situation in which a physician is sued for malpractice:

1. First of all, call your insurance carrier—immediately. The carrier will assign an attorney who will advise you.
2. Do not talk to the patient or the patient's attorney—let your attorney do that.
3. With your attorney's help, send a letter to the patient that the physician/patient relationship is being terminated as a result of the lawsuit. Chamblee says this is a universally recognized practice, and you can do this without abandoning the patient. "It's hard, if not impossible, to continue to care for a patient who has sued you. The trust has been violated."

The letter should also responsibly offer to provide the patient with the name of another provider to continue care, and the offer to forward the patient's records to the new provider. You should also offer to provide care on an emergency basis, if needed, until the patient can find another provider.

"For physicians, this comes down to no more than and no less than what the physician knew or should have known when he or she treated the patient," Chamblee said.

"If there was no rule against it, no law forbidding it, and the physician has no reason to believe that the pharmacy is in violation of any accepted standards, then you have to allow that it was acceptable practice on the part of the physician," Chamblee said.

"It would be hard to find or believe the physician had any responsibility whatsoever," Chamblee said. "If, however, there were to be found that there were recalls of the medication in question beforehand, or even publicity about a problem, one would expect the physician to have some knowledge."

### Much Precedent Exists

"There are sufficient examples of this in history," Chamblee said of the issue of product liability cases in which physicians are the intermediaries who are injecting, implanting, prescribing, or administering a product found later to be harmful.

"This is not unique. In my 28 to 29 years of practice, I've seen about 20 lawsuits [with comparable circumstances]. In breast implant litigation, plaintiffs sued the doctors and the manufacturers," he said, but the physicians were not held liable.

"In the 1980s, when 85% of hemophiliacs became infected with HIV because the blood supply was not yet tested for the virus, patients sued the blood banks and physicians. And when pedicle screws used in orthopaedic surgery began to cause problems, patients sued the manufacturer and the surgeons."

"So if our legal history is any guide, we can expect that physicians will be named in the lawsuits," Chamblee said. "But you would also be hard-pressed to find one of them in which the doctors were found to have any responsibility. They were almost as innocent as the patient. They just didn't know."

Chamblee said that just from reading the reports in this case, based on his experience in similar lawsuits, he would expect physicians not to be found liable for their patients contracting meningitis from medications provided by New England Compounding Center.

"They're likely going to go after the pharmacy first," Chamblee said of patients who have been harmed.

"They're likely *not* going to go after the doctor" in the end, he said, but the chances that many of the plaintiffs will name the physician and clinic in the suit initially are "better than 50/50."

Of course, Chamblee said, physicians should have, by now, made every opportunity to notify their patients if they might have gotten any of the infected medication, and advised them on whether to pursue antifungal therapy.

"I'd notify them by phone and letter, with a letter describing the conversation on the phone, and include the date and time of the call," Chamblee said, "because 1 out of 100 will say, 'they never called me.'"

### Suits Filed in Federal and State Courts

Before the end of October, at least a dozen lawsuits already had been filed against the compounding center in federal and state courts.<sup>1</sup>

One plaintiff's attorney noted that if physicians bought the preparations from the compounding pharmacies in large batches, that could represent a breach of the standard of care, according to the article in *The Washington Post*,<sup>1</sup> which quoted Christopher Chestnut, an attorney who is representing a Florida man and has filed a meningitis-related suit against New England Compounding Center.

Chestnut told *The Washington Post* that physicians generally are not sued for product liability, which requires that the plaintiff prove only that a product was defective and it caused them harm. Suits against the physicians and clinics would need to claim malpractice and, therefore, would need to prove that the physician deviated from the standard of care, and that this breach harmed the patient. He noted that the point about batches ordered, versus individual prescriptions for each patient, would be one that plaintiff's attorneys will investigate.

Other attorneys in *The Washington Post* article noted that legal proceedings could be complicated by whether the cases will become a class action, whether New England Compounding Center will declare bankruptcy, and whether its insurance coverage

will provide enough for all the plaintiffs. There may not be a deep-enough pocket for the potentially thousands of claims—another reason that clinics and physicians may find themselves named in the suits as well. According to *The New York Times*,<sup>4</sup> New England Compounding has suspended operations and laid off most of its employees.

### Scrutiny of Compounding Pharmacies

Compounding pharmacies such as New England Compounding Center, which prepared and sold the methylprednisolone now found to be tainted, have less regulation and compliance monitoring than do pharmaceutical manufacturers, says William Chamblee, JD, an attorney in Dallas who specializes in medical malpractice defense and product liability cases.

Physicians should ensure that any compounding pharmacy they purchase from is meeting all the requirements in its home state, which can usually be determined by contacting the health department for the state in which the pharmacy is located.

But just how far must a physician go to investigate a compounding pharmacy before doing business with it? Now that the outbreak of meningitis has drawn attention to New England Compounding Center, some worrisome details are coming to light. But short of doing an in-person onsite inspection and going through records at multiple public regulating agencies, it is unlikely that a physician can know of the problems.

In case anything can be learned from this example, it is worth noting some of the details that have emerged about the company.

### Pharmacy Failed to Sterilize Some Products

Regulators in Massachusetts are investigating the compounding center after the outbreak, and found safety and sterility procedures lacking, according to an article in *The New York Times*<sup>4</sup> on October 23.

*The New York Times* reported that Madeleine Biondolillo, MD, director of the Bureau of Health Care Safety and Quality in the Massachusetts Public Health Department, said records from New England Compounding Center raise questions about whether the pharmacy adequately tested its products before sending them to clinics.

Biondolillo told *The New York Times* that the company's records suggest that staff failed to sterilize products for the adequate amount of time to guarantee sterility. The records indicate that the company sent out products before test results confirmed their safety, raising suspicion about the accuracy of the results stating the products passed the tests. Clearly, there is reason to doubt the accuracy of such test results, considering the outbreak of fungal meningitis.

### Dirt and Debris Found

*The New York Times* reported that mats used to trap dust and dirt just outside the clean rooms inside the pharmacy were “visibly soiled with dirt and assorted debris,” according to a report by the Massachusetts Board of Registration in Pharmacy that Biondolillo quoted at a news conference. The board report also indicated that hoods in the sterile compounding area were not properly cleaned, and that a leaking boiler next to a clean room created conditions that could foster contaminant growth.

## Resources

Stay informed about the meningitis outbreak related to epidural corticosteroid injections:

- **Centers for Disease Control and Prevention (CDC)**  
<http://www.cdc.gov/HAI/outbreaks/meningitis.html>  
 This site has CDC's latest news on the outbreak.
- **U.S. Food and Drug Administration**  
<http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm>  
 The FDA and CDC list some of the same material—use whichever site is most easily navigable for you.
- **International Academy of Compounding Pharmacies (IACP)**  
<http://www.iacprx.org/displaycommon.cfm?an=1&subarticlenbr=284>  
 The IACP also provides updates and information about compounding pharmacy standards.

Outside the compounding center, investigators noted that the property includes a recycling center owned by the same family.

The FDA and Massachusetts state regulators are also investigating 2 other drug companies connected to New England Compounding Center. Ameridose, of Westborough, Massachusetts, and Alaunus Pharmaceutical of Framingham, like New England Compounding, all list Barry Cadden, the chief pharmacist, and his brother-in-law, Gregory Conigliaro, as managers in documents filed with the state. Conigliaro's brother and sister-in-law, Douglas and Carla Conigliaro, seem to be major shareholders in the companies, according to *The New York Times* article.

### History of Complaints

*The New York Times* reported on a previous complaint about New England Compounding, going back to its first year in 1998. Some complaints involved selling medicine in bulk without a prescription for an individual patient.

Another complaint in 2004 involved methylprednisolone. State health officials threatened action after the company “failed to comply with accepted standards” when mixing the corticosteroid. In March 2012, the state investigated a complaint about the potency of a solution used in eye surgery. But no action was taken in either case. ■

### References

1. Aizenman NC. Lawsuits piling up against New England Compounding over meningitis deaths. *The Washington Post*; October 21, 2012. Accessed October 23, 2012.
2. Scanlon GC, Moeller-Bertram T, Romanowsky SM, et al. Cervical transforaminal epidural steroid injections: more dangerous than we think? *Spine*. 2007;32(11):1249-1256.
3. Derby R., Lee S-H, Date ES, et al. Size and aggregation of corticosteroids used for epidural injection. *Pain Med*. 2008;9(2):227-234.
4. Goodnough A. Sterility found lacking at drug site in outbreak. *The New York Times*; October 23, 2012.

## Topics in Pain Management CME Quiz

To earn CME credit, you must read the CME article and complete the quiz and evaluation assessment survey on the enclosed form, answering at least 70% of the quiz questions correctly. **Select the best answer and use a blue or black pen to completely fill in the corresponding box on the enclosed answer form.** Please indicate any name and address changes directly on the answer form. If your name and address do not appear on the answer form, please print that information in the blank space at the top left of the page. Make a photocopy of the completed answer form for your own files and mail the original answer form in the enclosed postage-paid business reply envelope. Your answer form must be received by Lippincott CME Institute by **November 30, 2013**. Only two entries will be considered for credit.

**Online quiz instructions:** To take the quiz online, **log on to your account at <http://www.topicsinpainmanagement.com>**, and click on the “CME” tab at the top of the page. Then click on “Access the CME activity for this newsletter,” which will take you to the log-in page for [CME.lwwnewsletters.com](http://CME.lwwnewsletters.com). Enter your **username and password for this screen as follows:** Your **CME username** will be the letters LWW (case sensitive) followed by the 12-digit account number above your name on the paper answer form mailed with your issue. Your **CME password** will be **1234**; this password **may not** be changed. Follow the instructions on the site. You may print your official certificate **immediately**. Please note: Lippincott CME Institute, Inc., **will not** mail certificates to online participants. **Online quizzes expire at 11:59 pm Pacific Standard Time on the due date.**

1. **When 3 or more Waddell signs are present, there is a significant probability of fakery.**
  - A. True
  - B. False
2. **If a superficial stimulus such as a pinch results in a diffuse nondermatomal report of pain in a patient without signs of CRPS, this is a positive Waddell sign.**
  - A. True
  - B. False
3. **If simulation testing such as axial loading of the head or body rotation with the shoulders and pelvis in line leads to a report of pain in the lumbar region, this is a positive Waddell sign.**
  - A. True
  - B. False
4. **All of the following statements regarding the Hoover test are true except**
  - A. To conduct the Hoover test, the patient is supine, and the examiner raises one leg of the patient while keeping a hand underneath the patient’s other supine leg.
  - B. The tendency is for a normal patient to press down on the supine leg, and the downward movement of the heel of the foot is felt by the examiner’s hand.
  - C. The absence of any movement of the supine leg indicates true leg paralysis or weakness.
  - D. The absence of any movement of the pelvis indicates true leg paralysis or weakness.
5. **All of the following statements are red flags with regard to prescribing opiates except**
  - A. The patient pays in cash only and has no insurance.
  - B. The patient calls for early refills and prescriptions or regularly reports that medications are lost or stolen.
  - C. The patient reports the loss of his or her medication and has a police report confirming the loss.
  - D. The patient’s pain level remains the same during several subsequent visits, although aggressive opiate therapy has been instituted.
6. **When offered a substitute medication, drug seekers often will claim to be allergic to that medication, stating that they forgot to add it to their list of allergies during intake.**
  - A. True
  - B. False
7. **It is appropriate to be suspicious of the patient who claims to be allergic to the generic form of a narcotic but not the branded form.**
  - A. True
  - B. False
8. **All of the following statements are red flags with regard to prescribing opiates except**
  - A. Several patients arrive to the office in a carpool.
  - B. The patient tests positive for illegal drugs (including marijuana).
  - C. Drug screening reveals no prescribed medication in the patient’s system.
  - D. The patient uses Medicaid as his or her form of payment.
9. **Drug seekers are typically resistant to other forms of pain control or therapies such as transcutaneous electrical nerve stimulation or acupuncture.**
  - A. True
  - B. False
10. **In research analyzed by Jung and Reidenberg, practicing physicians were able to distinguish standardized patients about 10% of the time, and some real patients were erroneously identified as actors.**
  - A. True
  - B. False

## NEWS IN BRIEF

### FDA Issues Alert on Over-the-Counter Topical Pain Relievers

The FDA recently issued an alert that certain over-the-counter (OTC) products that are applied to the skin for the relief of mild muscle and joint pain have been reported to cause rare cases of serious skin injuries, ranging from first- to third-degree chemical burns.

When these products are applied to the skin, they cause a local sensation of warmth or coolness; they should not cause pain or skin damage. However, there have been rare cases of serious burns following their use. A search identified 43 cases of burns on the application site associated with the use of OTC topical muscle- and joint-pain relievers containing the active ingredients menthol, methyl salicylate, or capsaicin. The products associated with these cases include patches, balms, and creams.

The search included medical literature, as well as:

- The FDA's Adverse Event Reporting System (AERS) database (from 1969 through April 21, 2011); and
- The National Electronic Injury Surveillance System—Cooperative Adverse Drug Event Surveillance (NEISS-CADES) database (from 2004 to 2010).

The FDA notes that all cases in this series include burns that were confirmed by a health care professional. In the case series, there were reports of burns ranging from first-degree to third-degree, but many cases did not specify the degree of the burn. Many cases occurred following a single application of the OTC topical muscle- and joint-pain reliever, with severe burning or blistering occurring within 24 hours of the first application of the product.

A majority of the second- and third-degree burns were reported with the use of products containing menthol as the single active ingredient or products containing both menthol and methyl salicylate, where the concentration of the ingredients was greater than 3% menthol and 10% methyl salicylate. A few cases reported using a capsaicin-containing product. Some of the burns led to serious complications requiring hospitalization.

#### Advice for Providers and Patients

The FDA advises health care providers who recommend these products to counsel patients about how to use the products appropriately and inform them about the risk of serious burns. If a patient experiences pain, swelling, or blistering of the skin where an OTC topical muscle- and joint-pain reliever was applied, providers should advise the patient to discontinue using the product. Consumers should seek medical attention if they develop any of these effects and avoid tightly bandaging or applying heat to the application sites.

At this time, the FDA does not require that labels of OTC topical muscle and joint topical pain relievers carry a warning about the risk of serious burns. However, health-care providers are encouraged to report adverse events involving these products to the FDA's MedWatch Safety Information and Adverse Events Reporting program online at [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm). Providers can call 1-800-332-1088 to request a reporting form. (See U.S. Food and Drug Administration. Rare cases of serious burns with the use of over-the-counter topical muscle and joint pain relievers. FDA Drug Safety Communication, September 13, 2012; <http://www.fda.gov/Drugs/DrugSafety/ucm318858.htm>). —Adapted from an article in *Lippincott's Bone and Joint Newsletter*.

#### Coming Soon:

- Sex and Gender Issues in Pain
- Reports from the New York State Society of Anesthesiologists Post-Graduate Assembly
- Continuing Coverage of News in the Meningitis Outbreak Related to Epidural Corticosteroid Injections of Tainted Methylprednisolone