



# Section on Toxic, Environmental & Pharmaceutical Torts (STEP)

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## The Dangers of Bisphosphonate Drugs A Litigation Introduction

*By Michael Monheit and Tracy A. Finken, Philadelphia, Penn.*

In a December 13, 2004 press release, doctors at Long Island Jewish Medical Center (LIJ) announced that they had discovered a link between bisphosphonate drugs and osteonecrosis of the jaw (ONJ), or literally, death of the jaw bone tissue.<sup>1</sup>

Bisphosphonates are a class of drugs used to treat osteoporosis as well as prevent the metastasis of certain cancers into the bones. They lessen the body's ability to resorb

bone, a process that naturally takes place in order to allow new bone cells (called osteoblasts) – to occupy the skeletal structure.

The names and manufacturers of the most popular bisphosphonate drugs are: Zometa (generic name: Zoledronate) and Aredia (Pamidronate) manufactured by Novartis AG; Fosamax (Alendronate) is from Merck & Co.; Actonel (Risedronate) and Didronel (etidronate), products of Procter & Gamble Pharmaceuticals. Zometa and Aredia are administered intravenously.

Fosamax and Actonel are oral bisphosphonates and are often used in cancer patients.

### THE STUDY CONFIRMING THE LINK

The discovery of the link between ONJ and bisphosphonates was published in the Journal of Oral and Maxillofacial Surgeon.<sup>2</sup> The report prompted both the U.S. Food and Drug Administration (FDA) and bisphosphonate drug maker Novartis AG

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-ENDOWED BY: DAVID S. SHRAGER-

## Investigating and Developing Vioxx Cases - A Nurse's Perspective

*By Nursine Shuman Jackson, M.S.N., R.N., Pittsburgh, Penn.*

The evolving story of Merck's drug, Vioxx continues to command keen attention from lawyers. New analyses of old data that Merck released to the FDA in May 2006 show that short term Vioxx users are at greater risk of heart problems than was previously portrayed, and that the cardiotoxic effects of the drug continue long after the use of Vioxx ends.<sup>1</sup> Because additional Vioxx users will now qualify as additional claimants, it seems timely to review the process of case investigation and intake for clients facing injury from taking the drug.

### DATA COLLECTION

Law firms involved in Vioxx litigation should be highly motivated to perform methodical and well-planned data collection in a format that can be efficiently reviewed and merged into legal documents. Our evolving understanding of injuries causally connected to Vioxx use, and the time frame, dosages, and other confounders that result in injuries has already changed which Vioxx users actually qualify as

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to issue warnings to physicians and dentists about the risk for the potential adverse effect. A letter published in the same journal in 2003 was the first report of a signal that ONJ was associated with bisphosphonates.<sup>3</sup>



**Michael Monheit**

The chief of the Division of Oral and Maxillofacial Surgery at LIJ, Salvatore Ruggiero, MD, DMD, or doctor of dental medicine, said they conducted the study after they noticed a cluster of cancer patients with necrotic lesions in the jaw, a condition they previously saw in only one or two patients a year. In conducting a review of the patients' charts, the doctors found that the 63 patients, diagnosed with ONJ over a 3-year period, shared one commonality, they all had received long-term bisphosphonate therapy.

Between February 2001 and November 2003, 63 patients were diagnosed and 56 of them were cancer patients who had received infusions of bisphosphonates for at least a year. Seven other patients had been receiving long-term oral therapy for osteoporosis.

"The patients developed ONJ after normal bone trauma," the press release said, "such as a tooth extraction, while receiving bisphosphonate therapy." Rather than healing, the bone began to die, and a majority of the patients required surgery to remove the diseased bone.

Another study released on April 4, 2006, found that more than 2,400 pa-

tients who were taking the injected form of bisphosphonate had suffered bone damage to their jaws since 2001. In addition to the 2,400 patients who were taking the injected form, the study found 120 patients taking the oral form of the drug who had been stricken with such incapacitating bone, joint, or muscle pain that some became bedridden and others required walkers, crutches or wheelchairs.

While the number may seem small when compared to the estimated 39 million oral prescriptions written in 2005, the problems still indicated a trend and may have signaled a serious problem for long term use of bisphosphonates.

"We've uncovered about 1,000 patients (with jaw necrosis) in the past six to nine months alone, so the magnitude of the problem is just starting to be recognized," Kenneth Hargreaves, of the University of Texas, told a newspaper.

#### THE FDA RESPONSE

In August 2004, the FDA's Office of Drug Safety issued its Postmarketing Safety Review on about four bisphosphonate drugs used to treat osteoporosis: Fosamax, Zometa, Aredia, and Actonel. The FDA report concluded that warning language about adverse events involving osteonecrosis should be added to the drugs' labels.

On September 24, 2005, Novartis issued a "Dear Doctor" letter regarding Zometa and Aredia, indicating that patients on injected bisphosphonate therapy should avoid invasive dental procedures, and that a dental examination should occur before initiating intravenous bisphosphonate therapy. The letter quoted the new precaution to be placed in the product label in August 2004.

#### Precautions

##### *Osteonecrosis of the Jaw*

Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth

extraction. Many had signs of local infection including osteomyelitis.

A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g.



**Tracy A. Finken**

cancer, chemotherapy, corticosteroids, poor oral hygiene). While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Actonel precautions changed in May 2005. Similarly, Merck changed its Fosamax precautions on July 20, 2005. The drug maker, said in a statement that in "all of our controlled clinical trials with Fosamax, which involved more than 17,000 patients, including some that were 10 years in duration, we had no reports of ONJ."

Merck stated it received a request from the FDA to update the label in January 2005.

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#### BISPHOSPHONATE LITIGATION STATUS

A class action lawsuit filed in early April 2006 in Florida alleges that Merck failed to change the package insert or label for Fosamax in a timely manner given what was known, and when, about the apparent connection or link between Fosamax and osteonecrosis of the jaw. As of May 9, 2006, Merck reported that 15 additional suits were filed. The company has cases pending against it in Tennessee, Pennsylvania, and Florida.

are known as osteocytes.

*How does the body make new bone?* In order to understand how a bisphosphonate works, one must next understand the process by which the body makes new bone and how it removes old bone. The process takes place with a third type of bone cell known as an osteoclast. Osteoclasts are cells that allow the body to resorb or take away the hard calcium structure that houses the mature and dying osteocyte.

An osteocyte cell, the mature cell inside the bone, has a normal life of 150 days. Therefore, after 150 days, the cell must be replaced with a new cell. The

new bone. Conditions like osteoporosis can also be caused by taking other prescription drugs, such as the birth control Depo Provera, which is known to reduce bone mass density.<sup>5</sup>

Hypercalcemia is a third condition treated by bisphosphonates. It is accompanied by tumors 20 percent of the time. Essentially, in hypercalcemia, the body has too much calcium in the blood flow. To reduce this, the bisphosphonate retards the osteoclast production—and the calcium simply stays in the bone matrix.<sup>6</sup>

#### BISPHOSPHONATE FUNCTION AND EFFECT

*How does a bisphosphonate work?* A common misperception is that bisphosphonates cause the body to make more bone. They do not. They simply slow down the process of removing the dead bone cells from within the matrix by inhibiting the production of osteoclast cells, or the cells that soften the bone. Thus, the body has more “hard” bone chambers than it would have, but it is at the cost of having fewer chambers housing healthy cells.

*How does bisphosphonate cause bone necrosis?* In the case of necrotic jaw bone disease, the body is left with a boney structure without new and healthy osteoblasts that are going to mature into osteocytes. Simply stated, more of the bone cells are like vacant apartments, or worse yet, apartments with a dead occupant. The result of not having healthy bone cells is that the blood flow through the bone is then reduced which can result in pervasive bone death – where all of the cells in the bone die because there is insufficient blood flow.

*Is it worth the risk?* In the case of cancer, taking bisphosphonate drugs may be worth the risk. But osteonecrosis of the jaw is not necessarily a foregone conclusion. Certain actions, as discussed below, can mitigate the risk. However, since there are currently no known ways of preventing certain cancer from spreading to bones, bisphosphonates provide an effective treatment. These drugs substantially reduce the risk of metastatic bone cancer.

However, in the case of osteopenia, a borderline osteoporosis condition, or even for osteoporosis, a range of alter-

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### **“In August 2004, the FDA’s Office of Drug Safety issued its Postmarketing Safety Review on about four bisphosphonate drugs used to treat osteoporosis: Fosamax, Zometa, Aredia, and Actonel.”**

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The Judicial Panel on Multidistrict Litigation consolidated in the Middle District of Tennessee federal litigation over Aredia and Zometa, two drugs used in cancer treatment that allegedly cause degradation of the jaw, *In re: Aredia and Zometa Products Liability Litigation*, W.D. Tenn., MDL No. 1760, April 18, 2006. The panel excluded litigation over Fosamax and Actonel, reasoning that because Zometa and Aredia are intravenous drugs, they had little in common with Fosamax and Actonel, which are oral medications. Judge Todd J. Campbell presides over the MDL.

#### THE SCIENCE BEHIND BONE STRUCTURE & GROWTH

*How are our bones structured?* Bone is a physical structure shaped like a honey-comb.<sup>4</sup> That is, our bones are not “solid” all the way through. Like a honeycomb, the bone is comprised of “chambers” which are occupied by living cells. These living cells, just like all cells in our bodies, require blood flow (oxygen, nutrients) to stay healthy. The bone cells, that occupy the bone matrix chamber, when mature, form a hard calcium, and other mineral, structure around them. The mature bone cells

osteoclast cells attach to the outside of the “chamber” and soften the chamber wall, allowing the old dying osteocyte cell to escape from the boney calcium matrix and form a new osteoblast, an immature osteocyte, cell to penetrate the chamber. As the saying goes, “Out with the old and in with the new.”

The osteoblast then matures, hardens up the chamber with new calcium and minerals, and lives there for the next 150 days, when the process starts all over again.

*What can go wrong?* The problems occur when any of the three types of cells begin to operate out of balance with the others. For example, in the case of certain cancerous tumors, the body is stimulated into producing more osteoclast cells. This causes the softening of the “body armor” that surrounds the osteocytes – the matter that makes up the hard calcium part of our bone. When the osteoclasts soften the bone, openings in the bone matrix are created. The cancer cells use these openings to penetrate and metastasize into the bones.

Problems also occur naturally with aging. Osteoporosis can occur when the body’s production of osteoblasts is unable to keep up with the demand for

natives exist, from 1) changes in diet, such as ingesting more calcium; lifestyle changes, such as giving up smoking; 2) exercise, i.e. weight-bearing exercise to stimulate bone growth; and 3) other effective medications that use a different mechanism. For example, Forteo, manufactured by Eli Lilly and Co., is an injection that works by bone surfaces stimulation of osteoblastic activity.<sup>7</sup> 4) Other measures can be taken to prevent the onset of osteoporosis. For example, despite other side effects, hormone replacement therapy (HRT) has been shown to help prevent osteoporosis.<sup>8</sup>

#### ONJ ONSET

*How does ONJ occur?* The bisphosphonate inhibits osteoclast production. As a result, when the osteoclast is unable to soften the outer shell of the bone cell (the part of the bone that makes it hard), then there is no way for the new osteoblast cell to get into the bony structure to replace the dying mature osteoblast (osteocyte).

When the mature cells die in the bone they can no longer maintain the Haversian canals and the blood flow through those openings ceases. The Haversian canals consist of a central hole surrounded by rings of bony tissue arranged concentrically around the central bone canal.<sup>9</sup>

When the periosteal blood flow, or blood within the bones, ends, then soft tissues around that bone and within the bone itself, which depend on that blood flow for health, also begin to die (or fail to heal).

*How long is a patient at risk after taking bisphosphonates?* The half-life of bisphosphonates in the body is 10 years. The mean-time to a necrotic event is 3 years after administration/ingestion of the bisphosphonates, leading to significant latency.<sup>10</sup>

Dental surgical procedures play a significant role in ONJ cases. For example, 27 percent of all necrotic jaw events related to bisphosphonates are "spontaneous," meaning there was no trauma, especially including no dental procedure that would bruise the jaw bone and tissues surrounding the jaw bone and teeth. However, 73 percent of these events involved a trauma or dental

procedure precipitating the necrosis.<sup>11</sup>

Thus, a dental procedure may cause bone damage, cutting off sufficient blood supply due to the osteoclast inhibition caused by the bisphosphonates. As such, instead of blood flow carrying oxygen and other nutrients needed for the tissue/bone to heal, the procedure causes bone and tissue death.

In addition, it appears that bisphosphonates can cause a widening of the ligament around a tooth. When this occurs, it can be seen on an x-ray as a radiolucency between teeth. Under ordinary circumstances, a dentist would remove that tooth. If the tooth is retained, food or worse yet, bacteria can enter the space next to the tooth and cause decay or disease. However, with a patient who was on bisphosphonates, extraction may not be an option. In fact, doctors recommend against removal

sphosphonates, and a surgical procedure would tend to worsen the situation. On the other hand, a doctor might simply remove the necrotic tissue and bone and stimulate the tissues to promote the tissue or bone to grow back for a patient who did not take bisphosphonates.

#### HOW TO SCREEN FOR A BISPHTHOSPHONATE CASE

To determine whether a potential bisphosphonate case exists:

1) Consider the reason why the bisphosphonate was prescribed. If the client has cancer and was prescribed a bisphosphonate to prevent metastatic cancer, you may question whether a plaintiff or her physician would choose to heed a warning about the potential for ONJ. Since the adverse event is a class effect, a reasonable alternative may have been missing.

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**“Consider the length of time that the plaintiff was on the treatment before developing ONJ.”**

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and simply perform a root canal or other procedure to remove only the top of the tooth.

To counter this risk, three tasks may be undertaken. 1) If a patient is treated with bisphosphonates, they must have all currently required or anticipated dental procedures completed before they begin their bisphosphonates treatment. They must then wait at least one month after such procedures before beginning their course of bisphosphonates. 2) While taking bisphosphonate drugs, patients must tend to their dental hygiene. 3) A root canal instead of tooth extraction lessens the amount of trauma.

*Why the Jaw?* The jaw is vascular, which may account for a higher quantity of bisphosphonates reaching that bone. In addition, its high need for blood flow may explain the significant impact on the jaw when blood flow is diminished.

*What can be done once ONJ has occurred?* The key is to prevent ONJ. Surgery cannot reverse the damage for a patient who was treated with bispho-

A countervailing consideration is that a warning could have caused the plaintiff's physician to ensure that all dental work needed was completed before the bisphosphonate therapy began and that the plaintiff was carefully instructed on good dental care and the increased risks associated with poor dental hygiene while on bisphosphonates.

2) You must determine for each individual patient whether the dental problem or procedure that led to the ONJ could have been avoided by good dental hygiene or could have been performed before the initiation of treatment.

3) Consider the length of time that the plaintiff was on the treatment before developing ONJ. Due to the mechanism of action (preventing bone take-away), bisphosphonates will need time to set up the structures that are susceptible to infection leading to ONJ.

4) Consider the drug regimen, since many chemotherapy drugs can lead to a weakened immune system, making

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claimants. Vioxx case development equates to shooting at a moving target. Developing plans for collecting and managing the massive amounts of data must be the first priority for those engaging in Vioxx litigation.

**INITIAL INTAKE**

Each potential claimant must be screened to establish his medical history, his family history, risk factors, Vioxx consumption, his baseline activity, and employment status, his Vioxx-related injury, then subsequent related and unrelated medical course. The adequacy of this initial data collection will deter-

mine the efficiency with which the case can proceed.

The first issues regarding the intake process include determining who is best suited to perform the intake and how this information is obtained. Many firms who started using paralegals and legal associates to obtain the initial intake information found that the project could be streamlined if they used registered nurses with cardiovascular backgrounds to perform the intake. Nurses anticipated the medical historical information that would have meaning in subsequent case analysis and development, and could more readily screen and exclude patients with too many medical confounders

right at the first interview.

For the initial screening of clients, many firms started by providing potential clients with questionnaires. Others found that skilled interviewers, who could alter the intake questioning to meet the client's needs and his case scenario, were more efficient in both screening and in collecting meaningful data. Interviewing clients also provides an opportunity to evaluate whether the potential plaintiff had the stamina and personality befitting a desirable client.

Once a client meets the criteria for inclusion, then the data collection can proceed to identify the claimant's

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infection more likely.

5) In the non-cancer patient, you must consider the length of use. You may be unable to sustain a case where the exposure to the drug was less than three months. Actually, the longer the exposure, the better is the case. If the plaintiff has been on the drug for a substantial period of time, the fact that the patient went off the drug and then developed ONJ does not mean that a case does not exist. Bisphosphonates have a long half life. For example, Fosamax has a half-life of 10 years. In cases of cancer patients with injectable bisphosphonates, the warning must have a meaning, so the dental procedure should be one that could have been prevented by adequate precautions or avoided altogether.

6) You must consider the degree of osteoporosis for which the client was prescribed a bisphosphonate. If the client had a very high fracture risk, they may have decided on the Fosamax anyway, because severe osteoporotic fractures are associated with a high mortality, quoted as high as 20 percent. On the other hand, if the use of a bisphosphonate was merely preventative on a patient with osteopenia, the case may be stronger.

7) You must also consider when the bisphosphonate was prescribed in relation to the warnings. If first prescribed

after the change in the warnings, there is very little chance a case could be sustained. If problems first arise after the warning dates, a viable case may still exist, because earlier warnings may have given the patient and her physician a choice on whether to use the drug.

Bisphosphonates may be another example of a drug marketed as a near panacea for the scourge of osteoporosis and a great aid in the treatment of cancer, but it lacks adequate after-market monitoring to protect the public from the inevitable adverse events.

Presently, lawyers who are willing to take on "Big Pharma" when drugs go bad constitute the only real protection for the public. Hopefully, in the future, drug companies will honor their ethical responsibility to assure the drugs' safety before initiating the huge sales push that accompanies the launch of new drugs.

In addition, a stronger FDA can help prevent the unnecessary injuries and deaths associated with prescription drugs which in the last decade are sold as any other consumer product instead of as their status as specialty medical products.

**Notes**

1. The press release can be seen in its entirety at <http://www.northshorelij.com/body.cfm?id=204&action=detail&ref=682>
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4. YOU: The Owner's Manual: An Insider's Guide to the Body that Will Make You Healthier and Younger, by Mehmet Oz, Michael F. Roizen. (Page 107). ISBN: 0060765313 HarperCollins
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11. *Ibid.*

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providers, past and present. Only then can the daunting task of collecting the medical records, pharmacy print-outs, itemized statements, and other documents to illustrate the elements of the Vioxx case begin.

Each case analysis starts with the tedious process of organizing the records, numbering and tabbing them. Many "paperless" offices scan the organized hard copies then all subsequent reviewers can use the electronic versions of documents.

**RISK FACTOR IDENTIFICATION**

For each claimant or Vioxx user whose criteria might fit protocols for inclusion as a claimant, the litigation team would compile databases identifying the patient's age, sex, ethnicity, medical history and risk factors. Data collection is often organized under the following headings and the number of risk factors is calculated<sup>2</sup>:

- Past cardiovascular medical history.
  - ♦ Prior evidence of hypertension, ischemic events (e.g., angina or angina-equivalents), cardiovascular, cerebrovascular, or other vascular events.
  - ♦ History of atrial fibrillation or other arrhythmias.
  - ♦ Evidence of hyperlipidemia, left ventricular hypertrophy, left ventricular thrombus, and/or heart failure.
  - ♦ Adequacy of medical management of pre-existing cardiovascular conditions.
    - ❖ Blood pressure medications prescribed & refilled accordingly.
    - ❖ Serial blood pressure measurements.
- Other co-morbidities.
  - ♦ Documented medical issues could have lead to hypercoagulability (e.g., pregnancy, cancer, recent trauma to a vessel wall, and disease processes that increase the risk of clotting, e.g., polycythemia, Antithrombin C deficiency, Factor V deficiency . . .).
  - ♦ Presence and duration of concurrent pathophysiologies may have accelerated the arterioscle-

rotic process (e.g., poorly managed diabetes mellitus, hypertension, renal disease).

- ♦ Complex medical history that may confound the case.
- ♦ Adequacy of general medical management or evidence of neglect or self abuse.
- Laboratory data.
  - ♦ Lipid studies.
  - ♦ Serum glucose and A1C levels (*Hemoglobin A1C levels reflect blood glucose levels over the prior six to eight weeks, so are a better measure of general diabetes management than random glucose checks*).
- Family history.
  - ♦ Any evidence or documentation of a familial predisposition to vascular or thrombotic conditions.
- Social history.
  - ♦ Tobacco, alcohol or recreational drug use or abuse.
  - ♦ Involvement in body building where anabolic steroids might have been used.
  - ♦ Recent dehydration and/or immobility, e.g., long plane rides, hospitalization, or other reasons the Vioxx user was immobilized and placed at risk for developing deep vein thromboses.
- Medication history.
  - ♦ Use of birth control pills, hormone replacement, steroids, or other medications that increase the risk for clotting.

**DOCUMENTING THE HISTORY OF VIOXX USE**

The objective documentation of this most important part of each claimant's history poses the biggest challenge, since patients may have taken varying doses over time, stopping and starting, using different pharmacies, sharing prescriptions with other family members, etc. The goal in obtaining a Vioxx history is to document:

- Whether the person took Vioxx in the four days immediately preceding the thrombotic event.
- The start and stop dates of each episode of Vioxx usage.
- The dosage prescribed.
- The dose taken.
- The total length of time Vioxx was used.

• Evidence of compliance with the prescribed regimen.

• Concurrent medications, particularly nonsteroidal anti-inflammatory drugs, steroids, and other Cox-2 inhibiting drugs, e.g., Celebrex (*celecoxib*) and Bextra (*valdecoxib*), which are a group of drugs whose anti-inflammatory actions come from inhibiting prostacyclin, which inadvertently causes abnormal clotting by inhibiting prostacyclin's inhibition of platelet clumping<sup>3</sup>.

- ♦ *The recent Canadian study did not provide conclusive evidence of an increased risk of MI for celecoxib, but it may be related to the low doses being consumed by the study sample, since it is also a Cox-2 drug.*<sup>4</sup>

Typically, the litigation support team who performs this massive task of data collection is composed of legal nurse consultants (LNCs) and paralegals. These individuals will mine the records and supporting documents to determine whether they illustrate the essential elements to build a viable case.

Data collectors compile Vioxx usage histories from a number of sources, such as pharmacy printouts, physician's order sheets, prescription labels, billing statements, insurance documents, and physician and nursing notes.

Medication histories, for as much as six months to a year prior to the start of Vioxx use, can be helpful to evaluate for the confounding effects of other medications, or for discovering other case-confounding disease processes. Vioxx histories that might confound or negate a causal connection between the claimant's injuries and his Vioxx use may include: lack of evidence that claimant took Vioxx on the four days before the event, and/or weak or nonexistent proof of Vioxx ingestion generally. For example, there is no evidence that the drug was ever prescribed for him or there is no pharmacy record of having the prescriptions filled and refilled.

*A Nurse's Perspective, cont. from Page 7*

#### MEDICAL CHRONOLOGIES

Once the medical records are in hand and the intake interviews are complete, timelines are developed. Timelines cite event dates and times, direct excerpts, interview summaries, medical records and documents with citations of where the information was obtained. The timelines should demonstrate the patient's baseline status prior to his Vioxx use, his status and events during the acute injury, and his chronic status following the acute injury caused by Vioxx use.

Microsoft Word or Word Perfect tables, Microsoft Excel spreadsheets, or specialty software, such as CaseMap by CaseSoft are all used to perform the same job. Each has pros

found in the medical research before filing suit.<sup>5</sup>

Inadequate evidence exists to causally connect injuries, such as transient ischemic attacks, gastrointestinal problems, heart failure, angina, hypertension, renal injuries, deep vein thromboses, and other thrombotic and ischemic events, to Vioxx usage for litigation purposes.

Injuries must be clearly documented through standard medical diagnostic studies performed by qualified physicians. They must be temporally linked to Vioxx usage as per the criterion that the law office deems appropriate.

Myocardial infarctions must be established via laboratory studies (e.g. cardiac markers such as elevations of select enzymes and/or tro-

ponins), EKG, echocardiographic, or other evidence. Thrombotic strokes, likewise, must be demonstrated via radiographic and symptomatic evidence.

#### MAKING DATA ACCESSIBLE

The data format may be set forth in table form or narrative style depending on its application. The narrative may be a simple statement of the case facts that can be cut and pasted into the complaint, or to be used to orient the expert physicians reviewing the case. A narrative also might be a complex instructional document laid out with explanations of the pathophysiology of Vioxx and the patient's unique history and injuries with medical literature and illustrations to orient the attorney to the medical issues at hand.

Defining the information to be collected, taking the time and foresight to develop the interview form, and devising the data collection tools at the onset of the project will streamline the initial case investigation. Good data management tools are critical to expedite re-reviews of each patient's facts, as inclusion criterion expand or contract.

Firms who are geared up to do mass record reviews are more likely to be more efficient in devising data management tools, because they are able to pull spreadsheets and questionnaires from one type of case to the next, making minor modifications to accommodate the next project.

Too often though, as in this Vioxx litigation, the rules change as new information becomes available. The May 2006 release of data is certain to generate a flurry of data re-reviews. Predictably, many short term Vioxx users, and people who suffered events in the year after they discon-

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**“...the litigation team must comprehend the case elements long before the records fall into an expert's hands.”**

---

and cons and will be chosen due to user familiarity and idiosyncratic needs for data management.

Likewise, users will dictate the degree of detail entered into each chronology. Every doctor's visit, hospitalization, procedure, or medical event will be listed in more or less detail; every prescribed medication will be entered. The patient's history will be made available for reference and for remodeling to fit the needs of the multiple legal documents and exhibits that will be developed over the life of the case.

#### DOCUMENTING THE INJURY

Myocardial infarction and stroke are the only injuries well documented as being caused by Vioxx use. While a causal connection to pulmonary emboli (PE) is biologically plausible, to date no study demonstrates an increased risk of PE from Vioxx. When screening cases, many law firms tentatively accept selected PE cases to determine whether stronger evidence of causation is

found in the medical research before filing suit.<sup>5</sup>

Any other injury, like pulmonary embolism, if the law firm deems it a viable injury for litigation purposes, should also have objective evidence, like CTs, laboratory studies [e.g., D-dimers (a non-specific indicator of thrombosis) or arterial blood gases] EKG changes, along with documented signs and symptoms with rule-outs to exclude other possible diagnoses, in order definitely establish the injury occurred.

#### INJURIES AND CAUSATION

As the other databases are being fleshed out, the injury or list of injuries will be compiled. The litigation team will evaluate the compiled data to establish a causal link to the Vioxx use and identify the confounding factors that might make causation problematic.

Medical conditions thought to con-

found or negate the causal connection

*continued on Page 9*

# Discovery Strategy: Effective Use of Rules 30(b)(5), 30(b)(6) and 34

## *An ATLA Exchange Litigation Packet Preview*

Understanding the interplay of Federal Rules of Civil Procedure 30(b)(5), 30(b)(6), and 34 is crucial when establishing whether the documents received in discovery are complete.<sup>1</sup>

Rule 34 provides for the actual production, inspection, and copying of documents by parties prior to a lawsuit.<sup>2</sup> It identifies the categories of documents to be produced. Rule 30(b)(5) provides a mechanism to compel the opposing party to produce requested documents at the deposition.

Rule 30(b)(6) requires an organization to designate and prepare a person to speak on behalf of the organization with respect to the requested documents and how those documents were located.<sup>3</sup> By designating this person, the organization or corporation establishes that this person has authority to speak not only with respect to facts but also to his or her subjective beliefs and opinions.<sup>4</sup> By using Rule 30(b)(6) in conjunction with Rules 30(b)(5) and 34, one can determine whether the documents requested are complete and, if not, the 30(b)(6) witness can be ques-

tioned as to why the requested documents were not made available at the deposition.<sup>5</sup>

The Litigation Packet is designed as a resource tool to assist ATLA members in understanding how Rules 30(b)(6), 30(b)(5), and 34 can work together to ensure complete production of documents at deposition. The Exchange created this resource with the assistance of ATLA plaintiff members who continue to develop new strategies in this area. The packet includes a sampling of documents that will assist members with discovery requests and document production including:

- Notices of 30(b)(6) depositions pursuant to Fed.R.Civ.P. 30(b)(5), 30(b)(6), and 34;
- Deposition outlines, guidelines, summaries, and transcripts;
- Court documents (notices, interrogatories, motions, deposition transcripts, and orders) from an interstate trucking case and a nursing care facility case that illustrate how to use Rules 30(b)(6), 30(b)(5), and 34 in conjunction with one another; and

• ATLA Education speaker papers outlining the interplay of these rules and how to get what you are entitled to in discovery.

*This article is an excerpt from an ATLA Exchange Litigation Packet. Working closely with ATLA members, the Exchange develops Litigation Packets, which contain comprehensive, practical material on "hot" litigation topics and trial advocacy issues.*

*For a detailed Table of Contents, log onto the Exchange at [www.exchange.atla.org](http://www.exchange.atla.org), click on "Litigation Packets," select "Advocacy" and "View" the Discovery Strategy: Effective Use of Rules 30(b)(5), 30 (b)(6) and 34 packet description, along with the "Table of Contents." Or call the Exchange at (800) 344-3023.*

### Notes

1. Mark R. Kosieradzki, *It's All in the Documents: Strategic Use of Rules 30(b)(5), 30(b)(6), and 34*, ATLA's Trial Advocacy College: Depositions (January 14 - 17, 2005). For more information on ATLA Education's upcoming Depositions Colleges, please visit <http://www.atla.org/Education>.
2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.*

### *A Nurse's Perspective, cont. from Page 8*

tinued Vioxx use, who were excluded based on the old study data, can now be reevaluated as potential claimants. Users who have suffered injuries, other than myocardial infarctions and thrombotic strokes, are unlikely to be named as claimants, at least at this point in time.

Each of the approximately 11,500 Vioxx lawsuits already filed will need to be reexamined to determine how this newly released research affects the facts of each individual case. As if that didn't pose enough of a challenge to involved plaintiffs' attor-

neys, countless additional cases are certain to emerge from this new data release.

Attorneys will have to modify their data collection and data analysis techniques, in order to keep up with evolving criteria defining which Vioxx users should become claimants in this litigation. Vioxx litigation is sure to continue for years and will continue to evolve as we gain a better understanding of the drug's pharmacologic effects.

### Notes

1. Levesque, LE, et al. (2006). Time variations in the risk of myocardial infarction among elderly users

of COX-2 inhibitors. *Canadian Medical Association Journal*. 174, (11);

2. Donati, M. (2006). *Defending a Giant: Vioxx®*. *Journal of Legal Nurse Consulting*. 17, (2). 16-17.
3. Donati, M. (2005). *Defending a Giant*. *LiNC*. 13, (2). 3, 9-10
4. Levesque, et al, online pg 6.
5. PowerPoint Presentation: *Vioxx Case Management and Case Selection* presented by Vioxx Joint Prosecution Alliance (Hill Peterson Carper Bee & Deitzler, Charleston, WV; Clark Perdue Arnold & Scott, Columbus, OH; Hill Williams, Wheeling, WV; Anapol Schwartz Weiss Choan Feldman & Smalley, Philadelphia PA & Cherry Hill, NJ), October 24, 2005.

**Nursine Jackson, M.S.N., R.N., 915 Miami Ave, Pittsburgh, PA 15228, T: 917/407-3192, [nursine@jacksonlaw.net](mailto:nursine@jacksonlaw.net); supporting the Law Offices of Mark R. Bower, PC, and plaintiff attorneys across the nation.**

# \*Spotted on the STEP List Server\*

## A Ruling in the Celebrex and Bextra Cases

By Gerie Voss, Washington, D.C.

To S.T.E.P. Members -

On August 16, 2006, the U.S. District Court for the Northern District of California, presiding over multidistrict litigation concerning Celebrex and Bextra, issued an order dismissing the Celebrex failure to warn claims without prejudice, with leave to amend. In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, N.D. Cal., MDL No. 05-1699, 8/16/06.

The district court found that the FDA's interpretation of the preemptive effects of its regulations (as stated in the drug labeling rule preamble) is entitled to deference. According to the court, although the FDA's current view of the preemptive effect of its labeling is a reversal of its prior position, the Supreme Court has recognized that an agency's view of the preemptive effect

of its regulations may change over time.

The court summarized the FDA's position as follows: "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." The court found that the plaintiffs' failure to warn claim poses an obstacle to the full accomplishment of the objectives of the Federal Food and Drug Act.

The court rejected Pfizer's additional argument that federal law preempts claims that the company falsely contended that Celebrex has fewer complications than other similar drugs. Pfizer had submitted its challenged advertisements to the FDA, which did not pose any objections. The court found that the FDA's silence with

respect to preemption of suits challenging false claims in prescription drug advertisements "suggests that the FDA does not intend its review of promotional materials to preempt false advertising claims."

The court's Memorandum and Order dismissing the failure to warn claims against Celebrex will be included in the ATLA Preemption Library.

Please let me know if you have any questions.

Thanks,  
Gerie

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*Gerie Voss is Regulatory Counsel at ATLA. Washington, DC, 202-965-3500 x748, or 800-424-2725 x748, F: 202-342-5484, gerie.voss@atlahq.org. You can join the ATLA STEP List Server by going to <http://www.atla.org/Lyris/Lists.aspx>.*

## How to Sign Up for Section List Servers

How can you increase your networking opportunities and case referrals? By participating on the ATLA Section list servers. ATLA has 18 topic-specific list servers available to Section members, which offers instant access to more than 2,500 of your fellow ATLA members.

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Follow these steps to take advantage of this FREE Section Member benefit:

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For information on posting or responding to a message, visit [www.atla.org/listservers](http://www.atla.org/listservers), and click on "FAQ Page," or contact ATLA staff at 800-424-2725, ext. 290, or send an e-mail to [listserversupport@atlahq.org](mailto:listserversupport@atlahq.org).

# The Preemption Document Library

**A**TLA Exchange recently announced the establishment of a document library for the sharing of preemption materials in a secure online environment.

Formerly the STEP Section Document Library, it has been renamed the Preemption Document Library. The document library contains sample briefs and ATLA Education materials.

All documents in the Preemption Document Library are available at no charge to ATLA Regular, Sustaining, Life, and President's Club members who are also members of any ATLA Practice Section.

## How to Contribute to the Document Library:

Members can submit their materials directly to the Exchange, or can upload electronic documents to the library by logging into the Exchange and selecting "Send Your Documents."

How to Use the Document Library:  
To access and obtain documents from the document library:

- Go to <http://www.exchange.atla.org>.
- Click on "Section and Litigation Group Document Libraries."
- Click on "Search Your Group's Library."
- Sign in with your ATLA Web site user name and password.

- Search by selecting Preemption Document Library or by search term.

- Click "Download Now" to download the document in Adobe PDF format.

For more detailed instructions for searching, downloading, and uploading documents, please visit <http://www.atla.org/Networking/Tier3/DocLib.aspx>.

ATLA encourages members to use and contribute documents to the library.

For more information on contributing to or accessing the Preemption Document Library, please contact the Exchange at 800-344-3023, or 202-965-3500, ext. 615.

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**Super!**

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