Vioxx

Bone/Spine Repair/Healing Litigation issues

Approximate presentation time 15 minutes; detail likely to require off line or at other MDL meetings. Goals in red are necessary at meeting.

Goals

- **Awareness and Education of Bone/Spine repair/healing problems via Cox-2 inhibitors; Vioxx in particular.**
- **Describe how the existing PSC cannot represent bone/spine healing pre-trial & DISCOVERY.**
- **Request separate CLASS and separate PSC for bone/spine pre-trial & DISCOVERY.**
- **Why the public/ general legal field are not knowledgeable/ motivated, and why they should formally be.**
- **Provide reasons that the Statute of Limitations should be extended for bone/spine.**
- **Relate to the newer Cox-2 inhibitors seeking USA approval.**
- **Concurrent Cox-2 inhibitors (e.g. Vioxx)/ bio-phosphates (e.g. FOSAMAX); potential massive disaster?**

Presentation Methodology

- **In understanding this is first discussion of these issues and the meeting time is precious please:**

  Litigant Harrison respectfully requests to be allowed to provide entire presentation for all items FIRST – holding conversation at end in order to first provide "big picture" without halt and proceed problems. Halt and proceed will damage presentation and take inordinate amount of time from the very precious, and expensive, time of participants.

- **Summary - two phases:**

  - **I Very quick 1 minute overview.**

    II 10 minute overview of additional detail which is in RED.

  - **please read NON-RED as you see fit during presentation, group discussion or off-line.**

- **Group discussion: can't solve world hunger in one meeting.**

  - **Agreeing/resolving likely will not to be complete – items need at elast to be acknowledged, take notice, and work though.**
  - **Agreements can be between MDL meetings**
  - **It would be wise to utilize MDL meetings to provide status and present issues until a separate class is functioning is well underway, then the MDL should serve to ensure the two PSCs are working well together; and of course common PSC issues.**

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1 - **Heart/Cardiovascular DISCOVERY vs. Bone/Spine repair/healing DISCOVERY NEEDS.**

2 - **Bone/Spine – MUCH evidence by Independent Research; where are the drug companies?**

3 - **Can the existing Heart/CV PSC represent bone/spine issues effectively and fairly?**

4 - **Should a new LAWSUIT "CLASS" be created?**

5 - **Public Awareness: Should Public finally be made aware?**

6 – **STATUTE OF LIMITATIONS: Should it be extended for bone/spine repair/healing issues?**

7 – **Proposed new Cox-2 inhibitor(s) and existing one: danger ahead; here we go again?**

8 - **FDA as experienced by this litigant.**

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Bone/Spine Repair/Healing Litigation issues

1 - **Heart/Cardiovascular DISCOVERY vs. Bone/Spine repair/healing DISCOVERY NEEDS:**

a – **Allegations of Neglect, Deceit, Fraud; lack of fair warnings and education, etc. are** generally similar in the English meaning; but showing in heart/CV IS not sufficient to prove in bone/spine. Cannot be just generally similar, must also be specific to heart/CV and specific to bone/spine. However, consistency of intent and methods of deceit, neglect, and fraud may be synergistic in the whole.

b - causation: Cox-2 inhibitors heart (recovery esp.) and bone/spine some similarities, but not enough.

c - DISCOVERY by this PSC for Bone/spine repair problems likely to complicate and overburden even more.

d - separate class (and separate PSC) of litigants specifically for bone/spine issues would not complicate issues nor overburden the existing work load of the heart/CV CLASS and PSC. It would provide proper Federal pre-trial and common DISCOVERY. Current status of improper Discovery would encourage appeals, many when the bone/spine issue is commonly known.

2 - **Bone/Spine – <u>MUCH</u> evidence by Independent Research; <u>where are the drug companies?</u>**

a - A LOT HAPPENED TO SUPPRESS AND SUBDUE THE ISSUE; perhaps inadvertently AND also planned. Bone/Spine issues certainly did not and are not receiving fairness.

b - high profile of heart/CV; "lawsuit" templates, relative low cost/risk for lawsuits - has caused legal profession to very much prefer "heart" to "bone/spine". <u>Legal representation nearly impossible to gain.</u>

c – a great deal of Independent Research (IR) and Trials virtually all conclude bone/spine repair problems from Cox-2 inhibitors; Vioxx most often used as the drug mentioned. IR seems to attempt to fill the gap that Merck should have responsibly embraced – ***<u>and IR still is!</u>*** ***<u>Recent biopsies of corps even!</u>***

d - Merck notified of IR and studies/trials; Merck chooses to deny and ignore and takes no action; also, Merck knowledge of bone repair process, by itself, should have caused it to responsibly test, warn, educate, etc.

e – Merck continues to deny Cox-2 inhibitors, (e.g. Vioxx) MAY cause bone/spine repair/healing issues.

f - Merck motivation to suppress in beginning: $$$ at risk; competition; catching up; Celebrex already on market and doing well; short-term profits over long-term responsible ness and steady income; environment ripe for negligence/recklessness; deceit, fraud, . SHORT TERM PROFIT OVER LONG TERM STABILITY! <u>CREATION OF THE "VEIL OF SAFETY"</u>

g - Merck motivation to suppress now: enough heart/CV problems; owning up to bone/spine issues show consistency of motivation and be synergistic with heart/CV allegations. Likely thousands were damaged, maimed, and possibly death. New product(s) at risk.

e. excuses/reasons for not testing would be nothing but lame and designed to extend and buy time! – there are so many ways to test and make retrospective reviews from many resources. Intersection of bone/spine issues and Vioxx usage HAS to be very high. Studies, biopsies statistical analysis has much to offer!

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3 - Can the existing Heart/CV PSC represent bone/spine issues effectively and fairly?

a -NO

b - PSC has firmly repudiated confirmation of DISCOVERY representation by litigant Harrison; much time has been lost; litigant extremely concerned if PSC is "forced" to represent; and sees significant issues in a verbal PSC suggestion.

c - PSC could have embraced bone/spine issues and looked for synergies; too late now; potential neglectful environment by this PSC would place bone/spine at great risk.

d - similar general allegations (heart/CV and bone/spine); but litigant, as well as the thousands that SHOULD be seeking informed legal representation, need specific discovery results to bone/spine repair problems.

e - similar heart/CV and bone/spine allegations cannot be passively synergistic; must actively "tie" synergies. Certainly DOES NOT need the same PSC to do so. Same PSC will continue heart/CV bias. Need new PSC to want to drive the bone/spine DISCOVERY.

4 - Should a new LAWSIUT "CLASS" be created?

a - YES; so, so much evidence is mounting and accelerating – 000's likely impacted. Broken bone and spine problems intersect with Vioxx usage greatly.

b - PSC has already firmly declined to represent bone/spine repair DISCOVERY

c - if PSC now forced to do so, bone/spine may be in "hostile" environment and continue being neglected.

d - having existing PSC and Litigant both doing Discovery will lead to problems of bureaucracy and easily can lead to both PSC and Defense manipulation of environment and responsibilities, finger pointing, "run around", and playing "second fiddle".

The issue simply will not be litigated properly without focus. 000's most likely involved need focus!

e - avoids problems above; finally facilitates public notification and fair legal representation; may even help existing and proposed Cox-2 inhibitor makers (Merck, Novartis, Phizer) may finally take this issue seriously. "Cleanest" way. Need an enthusiastic new PSC working DISCOVERY as FIRST PRIORITY.

f - if NOT also would require effort to avoid anarchic environment; consistency and MDL charter items items at risk. Additional effort is, incrementally, not significantly more at this point.

g - existing PSC and great number of litigants within MDL experiencing law of "diminishing returns"? This would get worse with increased complexity; especially with thousands of probable additional lawsuits.

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5 - Public Awareness: Should Public finally be made aware?

a - YES; it is long overdue – past fairness is at risk; let alone current and future health of public! There is not sufficient means for individual discovery of the bone/spine issues by any means! Fortunately for plaintiff litigant, email article led him to investigate, refusal for legal representation resulted in "pro se", of which so, so many people do not have the resources to do so – especially the elderly and uneducated!

b - overwhelming Independent Research ("evidence is compelling – time to tell the public").

c - being so inundated with high profile heart/CV cases; neither public nor legal field understand depth and quantity of damaged individuals.

d – damaged likely to be in thousands; if not tens of thousands and still not knowing why! QUITE likely more DAILY via existing (Celebrex) and so many more at risk with new products attempting approval.

e - simple to Complex; delayed healing can be severe, maiming & possibly lead to death. Weak healing can also lead to problems and even death. Some cases of death can be years after – example would be weak cervical fusion required to prevent spine piercing brain and immediately shutting down breathing – weak fusion may not hold up in the litigant's otherwise natural lifetime.

f - issue is not just past/Vioxx but current Phizer/Celebrex and future Arcoxia/Merck and Prexige/Novartis; Incredibly the bone/spine issue(s) are not being addressed in new drug (Cox-2 inhibitor) attempts.

g - when withdrawn; Merck did not acknowledge or warn of potential bone/spine problem(s); The "WOW" effect has passed - to Merck's benefit and the Public's detriment. The Public and Physicians had no clue!

6 – STATUTE OF LIMITATIONS: Should it be extended for bone/spine repair/healing issues?

a - YES; certainly; public doesn't know what hit them!

b - when Vioxx taken off the market; only Heart/CV given as reason; still no bone/spine warning(s)!

c - association of problem with Vioxx is neither obvious nor readily derived. Also, after the fact.

d - "clock" has "ticked" very far with the bone/spine issues(s) unjustly concealed.

e - "clock" should only start when Merck finally acknowledges the possibility and notifies public.

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7 – Proposed new Cox-2 inhibitor(s) and existing one: danger ahead; here we go again?

a - Merck (Arcoxia) and Novartis (Prexige) amazingly also don't address the bone/spine issue(s).

b - separate bone/spine repair/healing CLASS will place proper pressure for the "new" drugs to be responsibly treated this time; as well as CELEBREX.

c - does not mean Cox-2 inhibitors can't be marketed – but need fair education and warnings of physicians and consumers; as well as follow-ups, etc. – let alone some reasonable testing!

d - there is a proper market for Cox-2 inhibitors; but must educate and warn when not to take, provide formal follow-ups; etc. and let educated physicians and consumers decide benefit/problem tradeoffs.

e - emerging FOSAMAX issues; SHOULDN'T THERE BE CONCERN ABOUT CONCURRENT USE OF C0X-2 INHIBITORS AND FOSAMAX; FOSAMAX STAYS IN BONES UP TO 10-15 YEARS.

IMPORTANT Special Note: There is even some evidence that long term use of Cox-2 inhibitors may harm male bones; combine this with evidence and theory that perhaps FOSAMAX, long term, creates denser, but more brittle bones! Both together interfere with the body's natural process of bone/spine repair, healing and/or regeneration. *This may be a recipe for long term, massive public disaster; yet – incredibly! the drug companies are not even addressing the issue on a hypothetical basis. Immediate study of concurrent FOSAMAX and Cox-2 inhibitor usage, as well as patient follow-ups must be done to protect the public. Independent R&D must play a significant role to reduce/eliminate bias.*

8 - FDA as experienced by this litigant.

a - lethargic; beaten down; not aggressive. Reporting system is "anecdotal"

b - incredibly, showed no interest in Independent Research or studies.

c - not interested in actively reviewing records (not conducive to review!)

d - mild reference to Celebrex warning of "bone problem" not understood by FDA; asked litigant to investigate!

e - FDA not helpful at all to litigant Harrison.

Supplement to Discussion

While much, much more detail exists – and litigant Harrison would be very willing to discuss as appropriate, some additional information is provided in the attached to help understand the Independent Research Studies, The PSC/litigant communication, and a sample of the litigant attempting to gain some commercial coverage, including concerns for the public at large. The litigant strews his sentences with "alleged" to ensure that the reader understands that this is what they – only alleged.

- Brief Statements from just some of the many, many articles.

- A full, recent article on some conclusions based upon corpses

Google Web Alert for: **cox-2 bone healing**
ORTHO SuperSite - NSAIDs and **COX-2** inhibitors impede tendon, **bone ...**
The upshot: **COX-2** inhibitors impair tendon and **bone healing**, ... Decreased prostaglandin may impair **bone healing**, and the **COX-2** enzyme is critical for ...

This once a day Google Alert is brought to you by Google.

- Subsets of communication between the PSC and the litigant Harrison

- The original communication (email) from litigant Harrison to the PSC

- An earlier overview of litigant's attempt to gain commercial press coverage

Just some example excerpts from virtually hundreds of articles:

February 02, 2005 - HSS Physicians Review Literature on the Safety of COX-2 Inhibitors...COX-2 inhibitors effect fracture healing and spine fusion... should never be used in spinal fusion...

December 23, 2002 - Bone Fractures...Cox-2 Inhibitors interfere with bone growth and, healing... Researchers at Stanford Univ. University Medical Center...COX-2 inhibitors also impede the new bone growth that normally helps heal a fracture or stabilize a joint implant...

May 21, 2002 - Journal of Bone and Mineral Research - COX-2 Decreases Bone Healing? ... mechanical testing revealed that COX-2 inhibitors...reduce bone strength...expression of COX-2 is critical for bone healing...essential for fracture healing...the inhibition of prostaglandin synthesis stops normal fracture healing.

Cox-2: Where are we in 2003? - The role of cyclooxygenase-2 in bone repair - Einhorn TA.
Professor and Chairman, Department of Orthopedic Surgery, Boston University Medical Center, Boston, Massachusetts, both non-specific and specific inhibitors of cyclooxygenases impair fracture healing - ***but that this is due to the inhibition of Cox-2 and not COX-1! Vioxx is a Cox-2 inhibitor.***_***"It's time to tell the public,"*** concludes Dr. Thomas Einhorn.

Journal of Bone Mineral Research 1999 Jun;14(6):969-79...initial immune response is crucial to fracture healing...

Reprinted from: www.usatoday.com/news/ ... ***"It's time to tell the public,"*** concludes Dr. Thomas Einhorn, Boston University's orthopedic surgery chairman. New research suggests some of the most widely used painkillers may delay healing of a broken bone... "If it were my fracture ... to me every day counts," he says. ***Vioxx and Celebrex are among the culprits....the makers of Vioxx and Celebrex deny any link.***

December 2002 New England Journal of Medicine...haven't lived up to their earlier promise... Even worse, the largest study ever done looking at joint-disease modification, published in the journal Arthritis & Rheumatism, found that people using 25 mg ***of Vioxx lost 0.27*** mm of cartilage in just one year. ***That number was expected to be 0.1 mm.***

"***Somehow, this study flew under the radar***," says Jason Theodosakis, MD, MS, MPH., author of The Arthritis Cure (St. Martin's Press 2004). This information **is unlikely to be broadcast by pharmaceutical companies**, he explains: "***It could affect the billions of dollars in sales of the COX-2 inhibitors if people knew they might be destroying cartilage while they're trying to relieve their pain***."

Komatsubara S et al. Spine 2006; 31:E528-34. "High-grade slippage of the lumbar spine in a rat model of spondylolisthesis: effects of cyclooxygenase-2 inhibitor on its deformity" (shows COX-2 inhibitor led to deterioration of bone healing which worsened vertebral slippage)

O'Keefe R et al. Ann NY Acad Sci 2006; 1068:532-42. "COX-2 has a critical role during incorporation of structural bone allografts" (findings indicate that COX-2 dependent PGE2 production in the early stage of bone healing is needed for efficient skeletal repair and is essential for bone allograft incorporation; COX-2 inhibitor (Celecoxib or Ketorolac) reduced bone formation and boney ingrowth)

Daluiski A et al. Orthopedics. 2006; 29:259-61. "Cyclooxygenase-2 inhibitors in human skeletal fracture healing" (study indicates that COX-2 is naturally lower in nonunion fractures that don't heal well, may reduce the bone-forming potential of precursor cells, and they note that limited use should be made of COX-2 inhibitors in patients with healing fractures since they need to mount an initial immune response in order to achieve fracture healing)

Li L, et al. Cytokine Growth Factor Rev 2006; 17:203-16. "Regulation of bone biology by prostaglandin endoperoxide H synthases (PGHS): a rose by any other name..." (this is a review article that includes some discussion of the importance of COX-2 (also known as PGHS-2) in bone fracture repair)

Hill K et al. Foot Ankle Clin 2005; 10:729-42. "The role of cyclooxygenase-2 inhibition in foot and ankle arthrodesis" (this article notes that COX-2 inhibitors are valuable to help control postoperative pain but may have deleterious impacts on bone healing in patients undergoing hindfoot arthrodesis)

Radi Z and Khan N. Inflamm Res 2005; 54:358-66. "Effects of cyclooxygenase inhibition on bone, tendon, and ligament healing"

See Other Side for recent article on study from corpses

NSAIDs and COX-2 inhibitors impede tendon, bone and cartilage repair

NSAIDs are not appropriate for neurogenic pain with no prostaglandin-mediated inflammation.

By Matt Hasson
ORTHOPAEDICS TODAY INTERNATIONAL 2006; 9:12

September 2006

INNSBRUCK, Austria — Recent biochemical research suggests that NSAIDs are appropriate for prostaglandin-mediated inflammation, not "neurogenic inflammation" associated with tendinopathy.

The upshot: COX-2 inhibitors impair tendon and bone healing, two leading experts said.

Physicians have typically treated patients with tendinopathy but no inflammation with NSAIDs. However, there are certain chemical and genetic factors that discourage NSAID use in some patients, said Hakan Alfredson, MD, of the University of Umea, Sweden.

"In earlier days, the only information we had to rely on was the information from biopsies," Alfredson said at the 12th ESSKA Congress, here. "And those biopsies showed us irregular fiber structure, high concentrations of matrix, vascular ingrowth but no inflammatory cell traits. But, despite that, we gave these patients tons of NSAIDs. ... We wanted to use a new method to try to evaluate whether there was any inflammation in these tendons."

In vivo microdialysis

Using in vivo microdialysis to study the biochemical properties of affected tendons, Alfredson and his colleagues tested 20 patients with tendinopathy and painful knee function. The control group included 12 patients with normal tendons and no pain. Another arm of the study focused on six patients with jumper's knee. The control group had six patients with normal tendons, Alfredson said.

"If you use NSAIDs together with proteins, certain NSAIDs virtually block the protein synthesis in the muscle."
— Hakan Alfredson, MD

The specialists also assessed patients for prostaglandin E2, which is "essential for a so-called chemical inflammation," Alfredson said. They found that prostaglandin E2 levels did not differ between the chronic painful tendons and the normal, pain-free tendons.

"So, the conclusion from those studies was that there is no prostaglandin-mediated inflammation inside those tendons," he said.

Studying 1,178 knees, Alfredson's group found that several pro-inflammatory cell proteins were not regulated in the tissue, again suggesting no prostaglandin-mediated inflammation in the tendons, Alfredson said.

"It cannot be justified to treat your patients with NSAIDs with this background," Alfredson said. "It's also important to remember that certain NSAIDs have negative effects on muscle protein metabolism. So, if you use NSAIDs together with proteins, certain NSAIDs virtually block the protein synthesis in the muscle, so that's another negative factor."

NSAIDs also inhibit tenocytes and, during exercise, decrease blood flow, Alfredson said. Other factors include heavy

vascularity and "neurogenic inflammation," as opposed to prostaglandin-mediated inflammation.

The benefits of prostaglandins

Norwegian specialist Sigbjørn Dimmen, MD, also noted the value of prostaglandins, which are "responsible for ensuring balance between bone resorption and bone formation." Decreased prostaglandin may impair bone healing, and the COX-2 enzyme is critical for fracture healing, he said.

Dimmen and his group tested how short-term doses of parecoxib, a COX-2 inhibitor, and indomethacin, a COX-1 inhibitor, affect long-bone fracture healing. The parecoxib and indomethacin groups had lower bone mineral density than the control group.

Also, mechanical testing showed the parecoxib group and control group demonstrated significant differences in all properties, Dimmen said. However, parecoxib proved more detrimental.

"So, our findings with parecoxib had the higher delay in the fracture healing than indomethacin, with the assumption that the COX-2 enzyme is responsible for impaired fracture healing," he said.

"Never give NSAIDs for stress fractures or for cartilage damage. NSAIDs hate chondrocytes."
— Sigbjørn Dimmen, MD

No prospective, randomized clinical trials or evidence-based measurements have addressed the effects of NSAIDs and COX-2 inhibitors on long-bone fractures, Dimmen said. Some data show NSAIDs and COX-2 inhibitors cause no nonunions in acetabular fractures, which "might indicate that you can't see any negative effects from NSAIDs or COX-2 inhibitors in fractures which normally heal well," Dimmen said.

However, he advised colleagues to avoid NSAIDs or COX-2 inhibitors when treating stress fractures or even when repairing cartilage.

"We know that prostaglandins are necessary for fracture healing," Dimmen said. "We know that COX-2 is critically involved in fracture healing in the first 3 weeks after a fracture. And NSAIDs and COX-2 inhibitors both impair fracture healing.

"I think one should probably avoid NSAIDs and COX-2 inhibitors in all shock fractures and also other fractures requiring unimpaired fracture healing," he added. "Never give NSAIDs for stress fractures or for cartilage damage. NSAIDs hate chondrocytes."

For more information:

- Alfredson H, Dimmen S. Non-steriodal anti-inflammatory drugs and tissue healing. Mini symposium. Presented at the 12th ESSKA Congress and 5th World Congress on Sports Trauma. May 24-27, 2006. Innsbruck, Austria.

My name is Dennis Harrison.
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badbonehealing@hvc.rr.com;
BLOG just started: http://badbonehealing.wordpress.com/

In Re: Possibly another alleged VIOXX problem on a large scale – the public should be aware!

Below is a Press Release "article" I created relating to my VIOXX usage and the alleged damage it did to me. I have an active "Pro Se" lawsuit. I believe publishing this article would also be a public service. The statute of limitations is ending - plus Cox-2 inhibitor(s) **still** exist with many unanswered questions and inadequate warning(s).

Also, there are an accelerating number of lawsuits and scientific evidence of alleged bio-phosphates (for example, Fosamax which MERCK also produces besides Vioxx) problems, – the dreaded DEAD JAW syndrome!

Thus, one cannot help but wonder about concurrent usage of Vioxx and Fosamax in the past or currently Cox-2 inhibitors and Fosamax. These "intelligent speculations" are at worst, potential allegations at this point. I hope to provide public awareness and gain information to provide a SUMMARY REPORT on several issues like these. The intention of this article, access to my Vioxx blog, and the provision of two email IDs is to both provide and collect information. NO detailed user identification data will be within in the SUMMARY REPORT – only summary data and some history excerpts (no user identification). My history summary here is about 2 pages long. A longer version is about 4 pages long (on the Vioxx blog) and includes more detail. Please visit the blog **http://badbonehealing.wordpress.com/** (and hopefully provide a relative amount of your history). I can also email you the 4 page version if you request via one of the two email ids.

I hope you are able to print this – it would be a public service, and from what I can tell, no-one is actively addressing these very important issues with an eye towards helping to resolve them, specifically.

Sincerely,

Dennis Harrison

VIOXX – (allegedly) MORE than breaking hearts… make no bones about it!

……Intro as a "PR" trying to obtain Commercial Press
……Several Examples (similar to other attachement, so no need here).

A Merck hired consultant , studying the bone/spine issue, allegedly stated ***"it's time to tell the public" and that the "evidence is compelling"***. Mr. Harrison questions if that information is included in their recently announced, seemingly self serving study of their internal affairs. Also, one would certainly feel that there was an internal reaction to those independent studies – and that should be in Merck's commissioned internal study…what were they?

The independent R&D tests of Cox-2 inhibition drugs, indicated deleterious impact on bone/spine healing. Allegedly warnings were provided to Merck and ***allegedly, Merck just denied/ignored the issue***.

Mr. Harrison alleges that ***Merck skillfully, artfully, and successfully planned and created a "veil of safety" perception. Allegedly, this "veil of safety"*** contributed very substantially to the thought process that it was one of the safest drugs around. Thus it is alleged; physicians and consumers were skillfully lulled into a false sense of security.

Not having any clue otherwise, Mr. Harrison continued to take VIOXX (he was a long term user – about 5 years, and took the maximum dosage of 50mg) while receiving several very important operations. The Plaintiff's bone/spine operations (other ones without Vioxx usage succeeded) failed. ***Routine leg (femur) operations failed, infections and sepsis set in; broken, infected internal hardware had to be removed. Some broken hardware, a significant amount, remains in his body.***

In the NY lawsuit (broken leg (femur)) – he waited, waited, and waited for some bone healing so that he could be operated on and walk again – but it did not happen after almost the eight months (his surgeons and physicians also were not aware of the

Vioxx bone/spine repair problem). ***Allegedly, surgeons and physicians were not made aware of the problem from Merck (no warnings, no education, etc.).*** They seemed puzzled as to why Mr. Harrison's bones were not healing even the minimal amount needed to "maintain an anchor" for the correcting operation(s). Their notes speculate on improper bone healing. Unfortunately, and allegedly the link to Vioxx was purposely not conveyed to them (by Merck).

Thus he ***spent almost a year in hospitals and nursing homes for what was supposed to be a routine 3-4 day hospital stay and about 6 weeks recovery!*** Mr. Harrison was wheel chair bound, except for ***"hopping" around on one foot*** and undergoing painful rehabilitation in an attempt to keep him strong enough - while he waited, and waited. Meanwhile, his home life and finances embarked and continued on a steep, downward spiral.

As Mr. Harrison waited and went beyond his medicare allowed days, his confidence was reduced to despair and depression. But he kept ***doing what he was asked to by his physicians and physical therapists.*** He became desperate and called a well-known surgeon in NJ for help. A method was devised to get around the issue(s) from Vioxx. Far from the plan of record, the most optimal solution (which utilizes bone healing to "anchor" it, as well the ability for the bone to "grow" into the implant) it was basically his only chance to walk and save his leg. The preferred methodology uses interweaved bone growth into the implant for strength and durability instead of glue. However, with glue utilized, it is likely to require replacing much sooner than would have been the case and is not considered as reliable as the plan of record. ***Mr. Harrison, with his health declining, hopes at that time he will be strong enough. – and there is to be wary of this.***

However, his trail to recovery was yet laden with more problems that he alleges simply would not have happened, ***if the "routine" operations in the beginning had just healed like they were supposed to!*** His last few months of hospitalization and nursing home experience (with a very brief time home) ***were plagued with excessive bleeding, infection, sepsis (twice) and obviously depression and ever diminishing hope.*** He alleges his whole life has been re-arranged, and NOT for the better!

POSSIBLE OTHER PUBLIC CONERNS!

While the following is based on facts, allegations, and "intelligent speculation" – Mr. Harrison raises several other potentially explosive issues that he feels, very strongly must be studied. He feels it is just not responsible, in any way, not to do so.

VIOXX, and all COX-2 inhibitor drugs, work by inhibiting the body's natural response to inflammation and bone repair/regeneration. Mr. Harrison indicates that (1) he ***would also have to wonder about other long-term effects on the bones (from Vioxx usage)***. Also, it begs other questions. (2) What might be the ***impact of FOSAMAX (also produced by Merck!) on bone healing***? It has already been alleged, and there are lawsuits pending, that it can prevent the jaw from healing after a tooth extraction ***(bone dies - the issue is called "Dead Jaw")***. (3) This should cause one to question - ***what about FOSAMAX's relation to other bones***? (4) Furthermore, ***what if some one took VIOXX, or another Cox-2 inhibitor, and FOSAMAX at the same time***? Since both work basically by ***interfering*** with ***the body's natural reaction of bone repair and healthy regeneration*** - could the problem be even worse with concurrent use – which did and does exist?

Also, what other bone problems may develop with the past concurrent (Cox-2 inhibitor VIOXX and FOSAMAX USAGE?) Incredibly, both drugs are/were produced by Merck! Shouldn't Merck (allegedly) have a formal opinion on this by now, as well as some kind of testing and Post Marketing followup? Also, since Celebrex exists today and it is also a Cox-2 inhibitor, what about current concurrent use (Celebrex and Fosamax)? Shouldn't maker of Celebrex (allegedly) also have a formal opinion about this, as well as some kind of testing and Post Marketing followup.

If you would like to review more of Mr. Harrison's history and gain more thoughts on your situation if similar, please visit the blog - http://badbonehealing.wordpress.com/. There is also a longer, more detailed history, not in the blog – but available by emailing and requesting. Furthermore, if you are a Professionnal or R&D person with an opinion on this matter - please provide input to the blog.

badbones@hvc.rr - for general bone concerns/history etc. potentially from medication(s)

badbonehealing@hvc.rr.com - for specific experience with bone/spine healing problem(s) and the use of a Cox-2 inhibitor medication.

Perhaps your emails and BLOG discussions will provide enough useful post-usage information that will ***fan the flames of fair warnings, "level the playing field", and encourage proper analysis and industry accountability. It's about time!***