nor anyone, did anything wrong, and no safety concerns now. The agency just says it screwed up internally and will rescind clearance.

"Chill U.S. Investors"

Bisbee says the FDA actions have unsettled the FDA regulatory community.

"It's unbelievable that after more than five years of review of this product—and after being told [by the FDA] to file two separate 510(k) submissions for this device as a surgical mesh—Dr. Shuren [current FDA device head] now says that they were wrong. This arbitrary and unsubstantiated intention is an example of why the investment community is increasingly wary of investing in companies with products requiring FDA approval."

The company says the FDA's decision that device clearances can be re-reviewed and rescinded..."Will chill U.S. investors' enthusiasm for investing in the development and distribution of new devices."

"After six years of unthinkable bias, mistakes and blunders, we are opting out of the FDA's administrative process and pursuing other legal options for continuing to market Menaflex to U.S. orthopedic surgeons and their patients," said Bisbee.

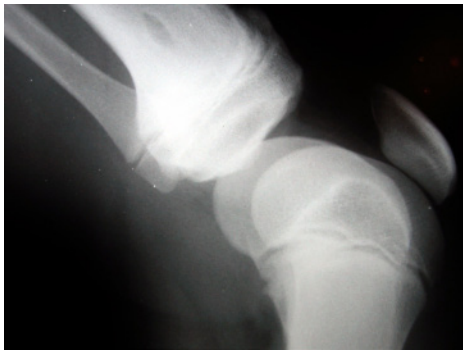
What those legal options are was not addressed in the company statement.

—WE (March 31, 2011) ◆

biologics

New Study Targets PRP for Knee Pain

Will platelet-rich plasma (PRP) relieve knee pain in patients with osteoarthritis? Researchers at Chicago-based Rush University Medical Center intend to find out. For years doctors have used PRP to promote healing after surgery, but results have remained inconclusive. PRP, which doctors have used to treat sports injuries in professional athletes, contains growth factors that promote cell proliferation. The substance is prepared from the patient's own blood.


Source: Clarita/morgueFile.com

The present standard of care for knee pain is either corticosteroid injections, which may provide relief for about three months, or synthetic lubricants containing hyaluronic acid, which can last for up to a year.

In the double-blind, randomized, controlled study of PRP, 100 patients will receive either hyaluronic acid or PRP. The PRP is prepared from 10 millimeters of the patient's own blood which is spun in a centrifuge to separate the platelets from the red and white blood cells. The platelets are then injected into the knee joint using ultrasound imaging to guide placement.

The patients receiving PRP will receive three injections over a three week period and will be monitored for two years. Physicians will assess pain and knee function. In addition, a teaspoon-size sample of the synovial fluid will be taken from around the knee joint to test for molecular changes that may indicate a shift in the balance of anabolic factors that increase the buildup of tissue and catabolic factors that break it down. An imbalance in these factors has been implicated in the deterioration of cartilage that leads to osteoarthritis.

"There have been few controlled clinical trials...but data so far suggests that it could be a promising treatment for healing in a variety of tissues," said Dr. Brian Cole, orthopedic surgeon, professor of orthopaedic surgery, head of the Cartilage Restoration Center at Rush and head team physician for the Chicago Bulls. "The therapy will not be a cure for osteoarthritis, but it could help put off the day when a patient will need to get a knee implant," he said. Rush is a not-for-profit academic medical center comprising Rush University Medical Center, Rush University, Rush Oak Park Hospital and Rush Health.

—BY (April 4, 2011) ◆

large joints

Wright Medical Group Inc.

Wright Medical in Turmoil

This morning Wright Medical Group Inc., the $520 million (revenue) manufacturer of extremity and large joint implants, announced that its popular and well regarded CEO, Gary D. Henley, CEO since 2006, had abruptly resigned "without good reason" before a meeting called to discuss management's oversight of the company's ongoing compliance program.

Because Henley's resignation is occurring "without good reason" he does not qualify, according to this morning's press release, for severance. Furthermore, in the same release, the company announced that the firm's Chief Technology Officer Frank S. Bono, was terminated for "failing to exhibit appropriate regard for the company's ongoing compliance program." What's that mean?

Wright Medical's employees, apparently, are learning about these changes from the press release that was issued this morning. As they and the rest of