

Forum: CME May Falter Without Industry Funding

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WASHINGTON — Without pharmaceutical industry funding, continuing medical education is in danger of faltering, said a group of CME providers, several physicians, and a medical journal editor at a forum sponsored by the Center for Medicine in the Public Interest.

The forum—designed to educate Capitol Hill staffers—was sponsored by the

Center, a New York-based nonprofit organization, and the Coalition for Healthcare Communication, an umbrella group for advertising agencies and medical journal publishers.

The meeting was called in response to numerous efforts from senators, House members, and accrediting organizations for greater accountability for CME funding. In July, a task force of the Association of American Medical Colleges said that academic medical centers should discour-

age faculty participation in industry-sponsored speakers bureaus. A month earlier, the Accreditation Council for Continuing Medical Education proposed tightening restrictions on commercial support of CME, and possibly even banning industry funding.

Panelists at the CMPI forum warned that withdrawing such funding would undermine a well-run and much-liked enterprise. "CME in the U.S. is a great success story," said Dr. George Lundberg, a former

editor of JAMA and currently editor-in-chief at Medscape. CME changes knowledge, skills, and patient outcomes, he said, adding that surveys have shown that physicians are in favor of industry support.

Dr. Michael Weber, a professor of medicine at the State University of New York, Brooklyn, said that he views pharmaceutical company funding of CME as a mandate, "not a luxury." The manufacturers have a responsibility to educate clinicians on how to use their products, he said. The pressure for transparency is leading to what Dr. Weber called censorship. He said that he has had to alter presentations at the request of meeting leaders in this country, whereas a recent appearance at the European Society of Cardiology was completely within his control.

Another cardiologist speaking at the forum, Dr. Jack Lewin, said he had "serious, serious concerns about the recent attacks" on CME. Dr. Lewin, CEO of the American College of Cardiology, said that without industry funding, it would cost the ACC an additional \$2,000-\$3,000 per attendee at its annual meeting, for instance. The ACC has multiple steps to remove conflicts of interest from its professional and educational programs, he said. And, said Dr. Lewin, the ACC discloses its industry funding on its Web site.

About a third of that organization's \$97 million annual budget comes from outside sources (\$35 million), and 21% of that is from charitable contributions, he said.

Dr. Lewin said there had been abuses in the CME arena, but that the move to clamp down on those bad actors had professional societies and pharmaceutical companies running for cover, he said.

There is evidence to support his claim. Public Citizen's Health Research Group, in comments sent Sept. 12 to the ACCME on its proposal to limit or ban industry support of CME, said that, "Despite a quadrupling of commercial support for CME over the past 10 years, in 2007, the percentage of CME income provided by commercial interests actually decreased to 2002 levels."

Public Citizen advocates an end to commercially funded CME. Because CME is a condition of licensure, demand will remain, according to the group. "Shifting the burden of funding toward physicians (not exactly a group occupying the lower rungs of the earning ladder) would attenuate the effect of lost revenue."



UNIQUE NATIONAL
HCPCS CODE
J7323

BRIEF SUMMARY

Please consult package insert for full Prescribing Information.

INDICATION

EUFLEXXA® (1% sodium hyaluronate) is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).

CONTRAINDICATIONS

- Do not use EUFLEXXA® to treat patients who have a known hypersensitivity to hyaluronan preparations
- Do not use EUFLEXXA® to treat patients with knee joint infections, infections or skin disease in the area of the injection site

WARNINGS

- Mixing of quaternary ammonium salts such as benzalkonium chloride with hyaluronan solutions results in formation of a precipitate. EUFLEXXA® should not be administered through a needle previously used with medical solutions containing benzalkonium chloride. Do not use disinfectants for skin preparation that contain quaternary ammonium salts
- Do not inject intravascularly because intravascular injection may cause systemic adverse events

PRECAUTIONS

General

- Patients having repeated exposure to EUFLEXXA® have the potential for an immune response; however, this has not been assessed in humans
- Safety and effectiveness of injection in conjunction with other intra-articular injectables, or into joints other than the knee has not been studied
- Remove any joint effusion before injecting
- Transient pain or swelling of the injected joint may occur after intra-articular injection with EUFLEXXA®
- Do not use after expiration date
- Protect from light
- Do not re-use—dispose of the syringe after use
- Do not use if the blister package is opened or damaged

Information for Patients

- Transient pain and/or swelling of the injected joint may occur after intra-articular injection of EUFLEXXA®
- As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities or prolonged (i.e., more than 1 hour) weight-bearing activities such as jogging or tennis within 48 hours following intra-articular injection
- The safety and effectiveness of repeated treatment cycles of EUFLEXXA® have not been established

ADVERSE EVENTS

Adverse event information regarding the use of EUFLEXXA® as a treatment for pain in OA of the knee was available from two sources; a multicenter clinical trial conducted in Germany and a single center clinical trial that was conducted in Israel.

Multicenter Clinical Investigation

This clinical investigation was a prospective randomized, double blinded, active control (commercially available hyaluronan product) study conducted at 10 centers. Three hundred twenty-one patients were randomized into groups of equal size to receive either EUFLEXXA® (n=160) or the active control (n=161). A total of 119 patients reported 196 adverse events; this number represents 54 (33.8%) of the EUFLEXXA® group and 65 (44.4%) of the active control group. There were no deaths reported during the study.

Incidences of each event were similar for both groups, except for knee joint effusion, which was reported by 9 patients in the active control group and one patient in the EUFLEXXA® treatment group. A total of 160 patients received 478 injections of EUFLEXXA®. There were 27 reported adverse

events considered to be related to EUFLEXXA® injections: arthralgia – 11 (6.9%); back pain – 1 (0.63%); blood pressure increase – 3 (1.88%); joint effusion – 1 (0.63%); joint swelling – 3 (1.88%); nausea – 1 (0.63%); paresthesia – 2 (1.25%); feeling of sickness of injection – 3 (1.88%); skin irritation – 1 (0.63%); tenderness in study knee – 1 (0.63%). Four adverse events were reported for the EUFLEXXA® group that the relationship to treatment was considered to be unknown: fatigue – 3 (1.88%); nausea – 1 (0.63%).

Single Center Study

In a single-center, single-blinded, placebo controlled, prospective, two parallel treatment arm clinical trial a total of 49 (25 EUFLEXXA®, 24 placebo) patients were randomized into two treatment groups in a ratio of 1:1 EUFLEXXA® or placebo. A total of 65 adverse events were reported by 17 (68%) of the patients in the EUFLEXXA® group and 15 (63%) in the placebo group. Of the 65 total events reported, 20 were regarded as treatment related. Knee pain, hypokinesia of the knee, knee swelling, and rash were considered to be treatment related adverse events.

DETAILED DEVICE DESCRIPTION

Each syringe of EUFLEXXA® contains:

Sodium hyaluronate	20 mg
Sodium chloride	17 mg
Disodium hydrogen phosphate dodecahydrate	1.12 mg
Sodium dihydrogen phosphate dihydrate	0.1 mg
Water for injection	q.s.

HOW SUPPLIED

EUFLEXXA® is supplied in 2.25 ml nominal volume, disposable, pre-filled glass syringes containing 2 ml of EUFLEXXA®. Only the contents of the syringe are sterile. EUFLEXXA® is nonpyrogenic. 3 disposable syringes per carton.

This product is latex-free.

DIRECTIONS FOR USE

- Do not use EUFLEXXA® if the package is open or damaged. Store in the original package below 77°F (25°C). Do not freeze. Protect from light.
- EUFLEXXA® is administered by intra-articular injection into the knee synovial capsule using strict aseptic injection procedures. The full content of the syringe is injected into the affected knee at weekly intervals for 3 weeks, for a total of 3 injections.

Toll free number for providers and patients to call with questions: 1-(888)-FERRING (1-(888)-337-7464).

MANUFACTURED FOR:

FERRING
PHARMACEUTICALS

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MANUFACTURED BY:

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References: 1. IMS data. February 2008. 2. Kirchner M, Marshall D. A double-blind randomized controlled trial comparing alternate forms of high molecular weight hyaluronan for the treatment of osteoarthritis of the knee. *Osteoarthritis Cartilage*. 2006;14:154-162.

Improved Web Site: Healthfinder.gov

The U.S. Department of Health and Human Services has launched a more accessible version of healthfinder.gov, a federal Web site designed for professionals and consumers. The site features links to more than 6,000 government and non-profit health information resources on hundreds of topics. The site also contains "Quick Guide to Healthy Living," which uses everyday language to encourage users to adopt healthy behaviors, and includes personal health calculators, menu planners, recipes, and tips for caregivers.