From: Harry Fisch [redacted]
Sent: Wednesday, April 25, 2018 8:10 PM
To: Jeffrey Epstein
Subject: FDA advisory committee votes to recommend update to celecoxib safety labeling | Family Practice News

https://www.mdedge.com/familypracticenews/article/164177/rheumatoid-a=thritis/fda-advisory-committee-votes-recommend-update?channel=290&utm=source=News_FPN_br_042518_F&utm_medium=email&utm_content=BREA=ING%20NEWS:%20FDA%20advisors%20squash%20celecoxib%27s%20CV%20concerns <https://www.mdedge.com/familypracticenews/article/164177/r=eumatoid-arthritis/fda-advisory-committee-votes-recommend-update?channel==90&utm_source=News_FPN_br_042518_F&utm_medium=email&utm_con=ent=BREAKING%20NEWS:%20FDA%20advisors%20squash%20celecoxib%27s%20CV%20con=erns>

FD= advisory committee votes to recommend update to celecoxib safety labeling<=h1> SILVER SPRING, MD. <= style="max-width: 100%;">REPORTING FROM AN FDA ADVISORY COMMITTEE MEETIN=

– An FDA advisory committee voted (=5 yes, 5 no, 1 abstention) to update the safety information in the label of=celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), for use in patien=s with osteoarthritis (OA) and rheumatoid arthritis, on the basis of result= of the PRECISION trial.

A Joint Meeting o=the Arthritis Advisory Committee and the Drug Safety and Risk Management Ad=isory Committee was convened April 24-25 to address two issues, the first b=ing the consideration of Pfizer's application for celecoxib and the=second, to assess the safety of celecoxib and other common NSAIDs like ibup=ofen and naproxen.

The randomized controll=d PRECISION <https://clinicaltrials.gov/ct=/show/NCT00346216> (Prospective=Randomized Evaluation of Celecoxib Integrated Safety vs. Ibuprofen or Napro=en) trial compared celecoxib, naproxen, and ibuprofen and their cardiovascu=ar outcomes. The PRECISION trial was undertaken after another selective COX=2 inhibitor, rofecoxib (Vioxx), was withdrawn from the market because of as=ociated cardiovascular events. It compared the three drugs among more than 2=,000 patients with painful arthritis and elevated cardiovascular risk.

<= style="max-width: 100%;">Main results showed that the rates of cardiovas=ular events (cardiovascular death, myocardial infarction, or stroke) were 2=3% with celecoxib, 2.5% with naproxen, and 2.7% with ibuprofen during a fol=ow-up approaching 3 years, showing noninferiority for celecoxib.

In a post hoc analysis presented by Steven Nissen, MD <https://my.clevelandclinic.org/staff/1185-steven-=issen> , patients taking=ibuprofen and naproxen experienced adjudicated cardiovascular, GI, or renal=events 28% and 15% more than did patients taking celecoxib.

The results of the study could inform clinical strategy, s=id Dr. Nissen, chair of cardiovascular medicine at the Cleveland Clinic in O=io. "For arthritis patients who require NSAIDs to achieve an accept=ble quality of life, particularly those at high cardiovascular, GI, or rena= risk, the PRECISION trial suggests that a clinical strategy of starting pa=ients on celecoxib 200 mg daily may be the safest approach, reserving full t=erapeutic doses of ibuprofen and naproxen for patients who do not respond t= celecoxib."

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Sent from my iPhone

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