

COX-2 Uproar Will Alter Drug Trial Landscape

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Recent events surrounding selective cyclooxygenase-2 inhibitors will have far-reaching implications for future drug trials, Gary S. Hoffman, M.D., said at a symposium sponsored by the American College of Rheumatology.

Drugs under investigation for chronic diseases such as arthritis will require longer trials and follow-up than in the past, in part because of their likely long-term use among the patients who need them. "We can no longer endorse or not endorse these drugs based upon short-term studies, some of which have been as short as 6 weeks or 12 weeks and usually, certainly, less than a year," said Dr. Hoffman, a member of the Food and Drug Administration's arthritis advisory committee.

NSAID trials now will include cardio-

vascular and thrombotic events among the adverse events they monitor.

But this raises questions as to whether there are other adverse events (AEs) such as cancer, autoimmune effects, or neurocognitive dysfunction that are beyond our current knowledge, said Dr. Hoffman, professor of medicine and chair of rheumatic and immunologic diseases at the Cleveland Clinic Foundation.

"Are we looking at this with blinders on because of recent events or are there oth-

er important AEs that we should also be casting a broader net for?" Dr. Hoffman asked. "Perhaps there are increases in malignancies if you follow patients who take drug x, y, or z long enough. How long should those patients be studied in the context of randomized trials?"

Although answers to these questions are lacking, it's obvious that closer pre-market drug scrutiny will come at a greater cost, he said.

Forces such as the market, consumers,

and the medical community will need to determine how cost-effectiveness will be measured, and ultimately who will pay.

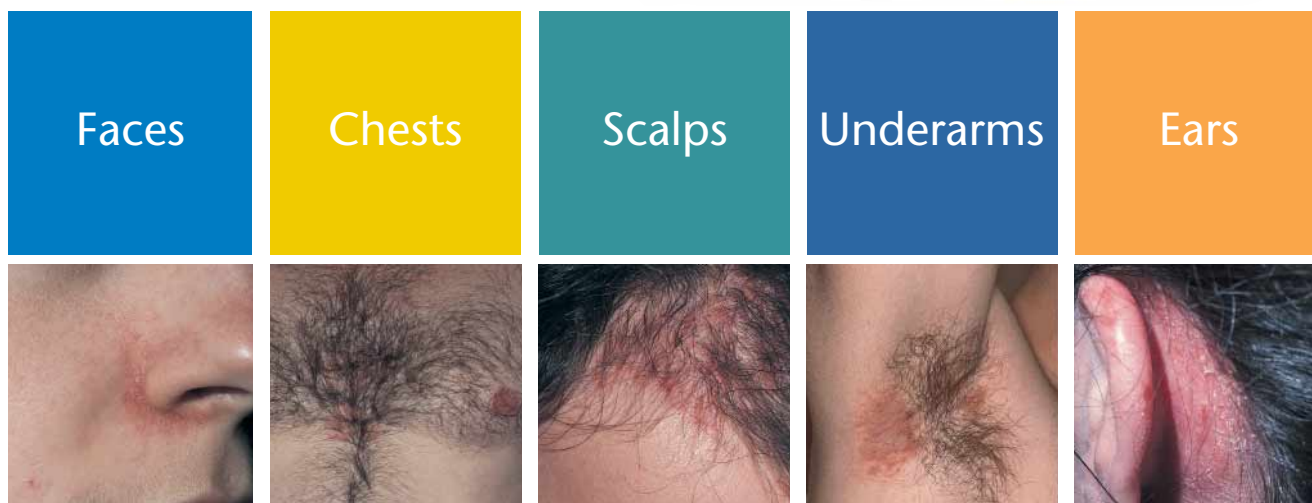
New strategies need to be developed to make new drug studies cost-effective.

Ironically, it was adverse events associated with non-selective NSAIDs that drove the COX-2 market in the first place, he noted. Research suggests that as much as one-third of every dollar spent on NSAIDs goes to managing adverse events. ■

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