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Lawmakers: Drug trial disclosure should be mandatory

Drug makers may have to disclose pediatric trial data to get exclusivity

By Laura Gilcrest, CBS MarketWatch
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WASHINGTON (CBS.MW) -- Drug companies may be required to make results of all of their clinical trials - both favorable and unfavorable - available to the public, and such disclosure could even become a condition of firms' gaining market exclusivity.

The heated debate over whether drug companies should have to disclose results of studies showing that a drug doesn't work came to Capitol Hill Thursday at a hearing before the House Energy and Commerce Committee.

While advocates of the new policy say it should apply to all new drugs, the committee focused on pediatric trials of anti-depressant drugs due to an ominous trend in suicidal behavior in children and teens taking the drugs.

Committee members noted that the problem will only get worse, with one out of every six children in the United States reportedly taking a prescription anti-depressant.

Yet against that backdrop, the lawmakers pointed out, only three out of the 15 pediatric studies of anti-depressants done so far, showed that the drug actually worked in children. And it was only those three pediatric trials that were published in medical journals as "stand-alone" studies, the committee members said.

"People want to know, 'Where are the other 12 studies, why aren't they published?'" said Committee Chair Joseph Barton (R-Texas). He noted that the evidence of increased suicidal behavior in young people on anti-depressants was gleaned from "mostly undisclosed studies."

Also troubling is the fact that only Eli Lilly & Company's (LLY: news, chart, profile) anti-depressant Prozac is currently approved for use in children, but physicians more frequently prescribe other anti-depressants for their pediatric patients, Barton said. "Do these (other anti-depressants) work in kids at all?" he asked. Committee Vice Chairman

Dave Weldon (R-Fla.) agreed. Given the increased risk of suicidal behavior linked to the drugs, "If a sugar pill works just as well as an anti-depressant, should doctors prescribe the drugs off-label in kids?"

Barton and other committee members argued that so-called "no-effect" study results should be part of labeling for anti-depressant drugs. Some lawmakers went further, arguing that the problem is serious enough to rework the law granting drug makers six months of market exclusivity for conducting pediatric studies

Edward Markey (D-Mass.) -- who with Henry Waxman (D-Calif.) is sponsoring a bill that would make clinical trial registration mandatory - said that the exclusivity law should require "broad disclosure" of clinical trials as well as pediatric trial results in drug labeling.

However, industry representatives who spoke at the hearing argued that drug companies have been forthcoming in sharing trial data with FDA and the medical community, and that the process should remain voluntary. Caroline Loew, an official with the Pharmaceutical Research and Manufacturers of America, said that the clinical trial database that the trade group launched this week would contain "the results of all 'hypotheses-testing' clinical trials, regardless of outcome..." Loew said that the database would be most useful if administered by with PhRMA partner or an independent third party free of "government involvement at this time." .

Strongly advocating mandatory clinical trial disclosure, Richard Gorman of the American Academy of Pediatrics, told the committee that Congress has the task of "balancing the rights of the drug company with the needs of patients," Gorman said, noting that his group thinks more transparency in clinical trial data "should benefit children."

At Thursday's hearing, Barton also blasted FDA for what he called "stonewalling and incompetence" in response to the committee's request for agency data on the evidence of rising suicidal tendencies in children on anti-depressants. The Texas lawmaker referred to an internal e-mail sent by an agency staffer charged with responding to the committee's request,

instructing FDA employees to withhold from the committee draft notes and memos on pediatric studies of anti-depressants.

The FDA's lack of cooperation "makes me wonder if this is sheer ineptitude or something worse," Barton said. He told FDA official Janet Woodcock, who spoke at the hearing, to advise FDA Acting Commissioner Lester Crawford: "If you folks can't fix it, we'll fix it for you."

At the hearing, Woodcock told the panel that, "FDA welcomes a continued dialogue regarding the kind of information from clinical trials that would be useful to providers, patients and families so they can make meaningful treatment decisions." She added that the agency would also consider what further action might be necessary to assure the safe use of anti-depressant drugs in children.