

TNF Blockers to Include New Pediatric Warnings

BY ELIZABETH MECHCATIE

The cancer risk warnings associated with tumor necrosis factor blockers will be strengthened to include the increased risk of cancer identified in children treated with drugs in this class, a result of an analysis of 48 reports of cancer in pediatric patients who were treated with these agents, according to a Food and Drug Administration statement.

The boxed warning in the prescribing information for these agents will "highlight the increased risk of cancer in children and adolescents who receive these drugs," the statement said.

Information about reports of new-onset psoriasis during treatment with a TNF blocker will also be added to the prescribing information of these products, the FDA announced.

The adverse events section of the label will be updated to include information on reports of new-onset psoriasis associated with TNF-blocker therapy. Health care professionals should "be aware of the possibility and monitor for the emergence or worsening of psoriasis during treatment with TNF blockers, particularly pustular and palmoplantar forms of psoriasis," according to the agency statement.

The FDA reviewed 69 cases of new-onset psoriasis (2 were pediatric cases), which appeared "weeks to years" after TNF treatment was started in people who had not reported having psoriasis previously. Almost half (32 cases) were pustular or palmoplantar forms. In 12 cases, patients were hospitalized.

In most cases, psoriasis improved once treatment was stopped. Because of the number of reports and the temporal relationship between the initiation of TNF blocker treatment and the onset of psoriasis, the "FDA concludes there is a possible association between the development of psoriasis and the use of these drugs," the statement said.

The investigation of the malignancy re-

ports, first announced in June 2008 by the FDA, concluded that TNF blocker treatment in children and adolescents was associated with an increased risk of cancer after an average of 30 months.

Lymphomas accounted for about half of the cancer cases, according to the FDA. Information about the higher-than-expected rate of lymphomas in adults who were treated with TNF-blockers is already included in the prescribing information.

'Parents should be aware that they must balance a clearly very small risk of malignancy against the very large risk of damage from inadequately controlled' disease.

Pediatric rheumatologist Thomas Lehman said that he expects this warning to deter some parents and physicians from the use of these agents. Several concerned parents and physicians had contacted him within a few days of the FDA statement to discuss the warning. Some children who could benefit from these medications will not receive them because of fears provoked by the warn-

ing, Dr. Lehman said in an interview.

But he said it was important to note that the FDA statement says that the agency could not "fully characterize the strength of the association" between TNF-blocker use and development of a malignancy.

In addition, "parents should be aware that they must balance a clearly very small risk of malignancy against the very large risk of damage from inadequately controlled arthritis," said Dr. Lehman, chief of the division of pediatric rheumatology at the Hospital for Special Surgery in New York.

Physicians who were in practice before the anti-TNF drugs became available are familiar with the degree of pain and disability and the associated psychological toll that inadequately controlled arthritis takes on the child and family.

Dr. Lehman, who is also professor of clinical pediatrics at New York Weill Cornell Medical Center, is on the speakers bureau for Wyeth Pharmaceuticals and Amgen Inc., which market etanercept, and Abbott Laboratories, manufacturer of adalimumab. ■

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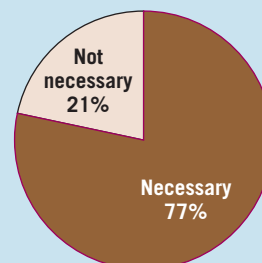


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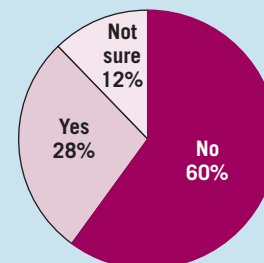


Note: Survey of 506 adults conducted July 31-Aug. 3; about 1% of respondents had no opinion.

Source: CNN/Opinion Research Corp.

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Note: Survey of 1,000 likely voters conducted Aug. 1-2.

Source: Rasmussen Reports