

Pediatric Use

Safety and efficacy of HUMIRA in pediatric patients for uses other than juvenile idiopathic arthritis have not been established.

Juvenile Idiopathic Arthritis

In the juvenile idiopathic arthritis study, HUMIRA was shown to reduce signs and symptoms of active polyarticular juvenile idiopathic arthritis in patients 4 to 17 years of age. HUMIRA has not been studied in children less than 4 years of age, and there are limited data on HUMIRA treatment in children with weight <15 kg.

Safety of HUMIRA in pediatric patients was generally similar to that observed in adults with certain exceptions [see *Adverse Reactions*].

Geriatric Use

A total of 519 rheumatoid arthritis patients 65 years of age and older, including 107 patients 75 years of age and older, received HUMIRA in clinical studies RA-I through IV. No overall difference in effectiveness was observed between these subjects and younger subjects. The frequency of serious infection and malignancy among HUMIRA treated subjects over 65 years of age was higher than for those under 65 years of age. Because there is a higher incidence of infections and malignancies in the elderly population in general, caution should be used when treating the elderly.

OVERDOSAGE

Doses up to 10 mg/kg have been administered to patients in clinical trials without evidence of dose-limiting toxicities. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

PATIENT COUNSELING INFORMATION**Patient Counseling**

Patients should be advised of the potential benefits and risks of HUMIRA. Physicians should instruct their patients to read the Medication Guide before starting HUMIRA therapy and to reread each time the prescription is renewed.

- **Immunosuppression**

Inform patients that HUMIRA may lower the ability of their immune system to fight infections. Instruct the patient of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis and reactivation of hepatitis B virus infections.

- **Allergic Reactions**

Patients should be advised to seek immediate medical attention if they experience any symptoms of severe allergic reactions. Advise latex-sensitive patients that the needle cap of the prefilled syringe contains latex.

- **Other Medical Conditions**

Advise patients to report any signs of new or worsening medical conditions such as heart disease, neurological disease, or autoimmune disorders. Advise patients to report any symptoms suggestive of a cytopenia such as bruising, bleeding, or persistent fever.

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Lack of Health Insurance Linked to Texas Deaths

BY MARY ELLEN SCHNEIDER
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In 2006, more than seven working age people in Texas died each day due to a lack of health insurance, according to the consumer group Families USA.

Families USA released state-by-state estimates of deaths attributed to a lack of health insurance for individuals ages 25-64 years. The report builds on the work of the Institute of Medicine, which in 2002 released a report that found that approximately 18,000 individuals ages 25-64 years died in 2000 because they were uninsured. A more recent study from the Urban Institute found that approximately 22,000 people in that age bracket died in 2006 because they didn't have health insurance.

"Our inadequate system of health coverage condemns a great number of people to an early death simply because they don't have the same access to health care as their insured neighbors," Ron Pollack, executive director of Families USA, said during a teleconference. "A lack of health coverage is a matter of life and death for many."

In general, the uninsured are less likely to have a usual source of care outside of the emergency department, they often go without screenings and preventive care,

and they frequently forego needed medical treatment, Mr. Pollack said.

In Utah, where 19% of the 1.2 million working age people in the state were uninsured in 2006, on average 3 people died each week due to a lack of health insurance coverage. Between 2000 and 2006, more than 800 people died due to lack of health insurance, the group estimated.

In Massachusetts, about 12% of the 3.4 million people aged 25-64 years were uninsured in 2006. Families USA estimates that more than 6 working age individuals in the state died each week in 2006 due to a lack of insurance coverage. Between 2000 and 2006, more than 2,000 working age adults died because they didn't have insurance coverage, the group estimated.

The Families USA estimates are based on 2000-2005 state mortality and population data from the National Center for Health Statistics and the U.S. Census Bureau Current Population Survey data from 2000 to 2006. The group released 50 state specific reports but does not make state-to-state comparisons. The differing population size, mortality rates, and uninsured rates make it difficult to compare states, according to Families USA. ■

State figures are at www.familiesusa.org

Partisans Seek Compromise On Health Care Reform

BY JOEL B. FINKELSTEIN
Contributing Writer

WASHINGTON — The shaky state of the health care system appears to be driving a sense of urgency and compromise in the debate over comprehensive reforms, lawmakers said at the American Medical Association's annual advocacy conference.

Putting partisanship behind them, a group of senators has introduced a bill "built on the fact that both Democrats and Republicans have been right on key parts of the issue," said Sen. Ron Wyden (D-Ore.).

The Democrats have been right to insist that everybody be included, while the Republicans have been right about involving the private sector, the senator added.

The Healthy Americans Act (S. 334) would shift the responsibility, but not the cost, of purchasing private health insurance from employers to individuals in recognition of the need to modernize the employer-employee relationship. Employees want portable coverage that will follow them through jobs and employers are seeking better control over costs, he said.

"Ron Wyden has a good plan. There's a lot of it that I agree with; there's a lot I adamantly disagree with," said Sen. Tom Coburn (R-Okla.), a practicing physician. He also noted that a key principle is "to truly create access in this country."

Despite that seeming common ground, Sen. Coburn has sponsored a competing proposal, the Universal Health Care Choice

and Access Act (S. 1019), which would similarly disentangle employers from the business of providing health insurance for their workers. The bill would allow individuals to claim the tax benefit linked to purchasing health insurance and currently only available through employer-sponsored coverage. It would also create a tax credit to, in effect, subsidize the cost of health insurance for low-income people and cap the tax cut that higher-income people get.

"Today, the very wealthy get about \$18,000 worth of tax benefit and the very poor get about \$100 worth of tax benefit," according to Sen. Coburn.

Both Senators also called for increased emphasis on prevention and early detection through realignment of the reimbursement system.

The major area where the senators differed was over how much the government should be involved in setting standards both for individuals and the health care industry in general.

Sen. Coburn said that once the opportunity to access health coverage was created, it would be the responsibility of individuals to take advantage of that. In contrast, Sen. Wyden's bill would require companies to contribute to and workers to purchase health coverage. In addition, Sen. Wyden's proposal contains a guaranteed issue provision to make insurers offer coverage to all comers, whereas Sen. Coburn's preference is to rely on a free market to determine supply based on demand. ■