information about an ADE from the section that asks a reporter to describe the event or problem—question 5 in the B section of the form.

Platt proposed the use of large automated claims databases to identify ADEs rather than spontaneous reporting systems.

Claims databases contain unbiased information, he said, adding that the databases provide an increasing availability to electronic medical records (EMRs).

Developers of EMR programs, he said, should include functions that prompt clinicians to record adverse events and other critical clinical information.

The use of EMRs to report ADEs can reduce the reporting burden and allow for the collection of real-time clinical information, he added.

Michael Katz from the patient advocacy group International Myeloma Foundation (IMF) said that adverse-event-reporting systems are too slow and ineffective to be relied on in today’s postmarketing environment where “drugs are innocent until proven guilty.”

“In a postmarketing setting, it’s not possible to prove causality without harming large numbers of people over long periods of time,” he said.

Consumer advocates, Katz said, need to work with clinicians and scientists to identify likely risks and “preemptively address them by promoting safer use of a drug or use of a safer drug.”

“When we do this, causality will likely never be proven, but fewer people will be harmed,” he said.

Katz recounted for IOM panelists how his organization helped to alert patients about dangerous adverse reactions associated with the use of bisphosphonates.

Shortly after Novartis began marketing zoledronic acid, or Zometa, in February 2002, Katz said, IMF started hearing anecdotal reports from subscribers to the organization’s listservers and from various support groups about patients with increased creatinine levels, some of whom were in renal failure.

Through discussions with patients, IMF was able to identify that patients who had previously been on pamidronate did not begin having the kidney ailment until their physicians had switched them to Zometa.

Novartis markets pamidronate under the brand name Aredia. But in 2001, the drug lost its patent protection, Katz noted, “and there was a broad-based, successful marketing push to switch patients from Aredia to Zometa.”

The suggested infusion time for Zometa was 15 minutes.

When IMF began advising patients to insist on an infusion time of 30 minutes for the drug, “kidney issues for Zometa dramatically declined,” Katz claimed.

IMF helped warn patients about another issue related to the intravenous use of Zometa and Aredia after hearing reports from two “alert” oral and maxillofacial surgeons, who reported an increase in cases of osteonecrosis of the jaw (ONJ) associated with the use of these drugs, Katz said.

IMF in July 2004 conducted an online survey to assess the risks of ONJ in myeloma patients and patients with breast cancer, he said.

Of 1203 patients who responded—904 with myeloma and 299 with breast cancer—62 myeloma patients and 13 patients with breast cancer had ONJ, Katz said. There were 54 suspicious cases of ONJ (SONJ) in myeloma patients and 23 reported cases of SONJ in patients with breast cancer.

Most of the patients with ONJ or SONJ had received Zometa, he added.

“When emergencies arise, advocacy organizations can take the initiative to quickly deliver meaningful drug safety data to patients,” Katz said. “Consumer advocates can’t afford to wait for the system to identify drug safety issues.”

Novartis revised its labeling for Zometa and Aredia in September 2004 to warn patients about the increased risk of ONJ, Katz noted.

—Donna Young
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News Briefs

• The Centers for Medicare and Medicaid Services canceled the Medicare Health Support pilot program that Visiting Nurse Service of New York was supposed to operate with the EverCare group of United Healthcare Services Inc. (see May 15 AJHP News). According to the government’s October announcement, the Medicare Health Support programs operated by Humana Inc., LifeMasters Supported SelfCare Inc., McKesson Health Solutions, and XLHealth Corporation involve pharmacists working either locally or by telephone.

• Lakeshea Harris, Pharm.D., a pharmacist at Southeastern Regional Medical Center in Lumberton, North Carolina, received the National Pharmaceutical Association’s Hospital Pharmacist Award in July. The award recognizes outstanding performance and achievements.

• Kurt Kleinmann, M.S., retired pharmacy director at Montefiore Medical Center in New York City, participated November 17 in a panel discussion of America’s 1934–45 rescue of Austrian children from the Holocaust. The Washington, D.C., event was a local promotion of the 2004 book Don’t Wave Goodbye: The Children’s Flight from Nazi Persecution to American Freedom, from the Greenwood Publishing Group. Born in Vienna, Kleinmann came to the United States in 1941 and lived with a foster family in Massachusetts.