proved in 1975 for the treatment of a synthetic hormone, was initially approved for use with calcitonin-salmon products. Subsequently, a number of specific changes to the labeling of these products’ labels were designed to capture cancer data systematically or link incidents of cancer to the administration of the drug, and patients weren’t screened at baseline for some of the cancers that were eventually detected.

And the variety of cancer types further complicated the effort to find a causal relationship between administration of the drug and a cancer diagnosis. “There are no consistencies with regard to tissue type, organ type,” he said, nor was there a dose–response relationship between calcitonin and a finding of malignancy.

Nevertheless, both FDA and Novartis found that cancers were more common in calcitonin-treated patients than in those given a placebo. FDA Medical Officer Theresa Kehoe said that because of limitations in the data, “we cannot assess the strength of the potential cancer signal with the data at hand—but it does appear plausible.”

FDA did not ask the advisers to vote on specific changes to the labeling of calcitonin-salmon products. According to FDA, calcitonin-salmon, a synthetic hormone, was initially approved in 1975 for the treatment of Paget’s disease of the bone. An indication for the treatment of postmenopausal osteoporosis was added to the labeling in 1984. Kehoe said an estimated 8 million women in the United States have osteoporosis. The condition increases the risk of fractures, with the most common types affecting the spine, hip, or forearm.

The postmenopausal osteoporosis indication for calcitonin-salmon was based on data showing that the drug increases total body calcium levels and improves bone mineral density. At the time, Kehoe said, those were considered acceptable surrogate endpoints for fracture prevention. But that’s not the case today. Of the five classes of FDA-approved drugs indicated for the treatment of postmenopausal osteoporosis, calcitonin products are the only ones for which fracture prevention data were not required for marketing approval. FDA began requiring such data in 1994 for a postmenopausal osteoporosis indication, according to the agency.

Kehoe said just one postmarketing study has been conducted to examine whether calcitonin-salmon prevents fractures. But only half of the expected 300 patients enrolled in the study, and half of them dropped out before the three-year endpoint. Problems with patient randomization and other issues affected the usefulness of the limited data gleaned from the study.

Kehoe said an FDA advisory committee in 1991 concluded that no conclusions could be made about the fracture data from the study.

Advisory committee member T. Mark Woods, clinical coordinator for pharmacy at St. Luke’s Hospital in Kansas City, Missouri, voted with the majority to exclude the use of calcitonin-salmon in postmenopausal women. “I really didn’t believe that there was sufficient efficacy data to support [this use], especially in view of the new data regarding the potential carcinogenic risk,” Woods said.

Woods said calcitonin-salmon is on the formulary at St. Luke’s but is used very infrequently—mostly for the treatment of Paget’s disease or for patients with painful compression fractures who cannot use other agents.

Woods encouraged pharmacists in outpatient settings to be familiar with osteoporosis. He said the profession has a role in helping to identify patients who are at risk for the disease and ensuring that they receive appropriate drug therapy and vitamin D and calcium supplementation.

—Kate Traynor
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**Appointments**

The Accreditation Council for Pharmacy Education has appointed Richard Artymowicz, Pharm.D., FCCP, BCPS, and Amir Emamifar, Pharm.D., M.B.A., to serve on the Continuing Pharmacy Education Commission through December 31, 2015. Artymowicz is the pharmacy services director at Cape Regional Medical Center in Cape May Court House, New Jersey. Emamifar is an associate administrator and the pharmacy services chief at Atlanta-based Emory Healthcare System.

**Diligence needed during transition in heparin products’ labels**

Labels on newly manufactured heparin products will prominently state the number of units of drug in the entire container once revisions to the United States Pharmacopeia monographs for heparin lock flush solution and heparin sodium injection go into effect on May 1.

This change, although intended to prevent medication errors, may initially present difficulties for health care professionals, FDA and the United States Pharmacopeial Convention (USP) have warned.

**New and old in coexistence.** According to FDA, manufacturers of Heparin Lock Flush Solution, USP, and Heparin Sodium Injection, USP, will have to use labels that “clearly state the strength of..."
the entire container of the medication followed by how much of the medication is in 1 milliliter."

The label on a 10-mL vial of heparin sodium 5,000 units/mL, in one example provided by FDA, will foremost state “50,000 USP units per 10 mL” followed closely by “(5,000 USP units per mL).”

As a result of this type of language on labels, health care professionals will no longer have to calculate the total amount of heparin in a container holding more than 1 mL, USP and FDA said.

Health care professionals may already have seen the new style of label on heparin products. FDA said in early March that it allowed manufacturers to ship heparin products with the new style of label before May 1.

As for products with the old style of label, FDA said those shipped before May 1 remain usable until their expiration dates.

Safety. To protect patients while both styles of label are in use, USP suggests that pharmacies and hospitals

- Consider separating heparin products with the old style of label from those with the new style and exhausting the supplies of the former before using the latter,
- Emphasize to practitioners that they should always look at the label on a heparin vial before doing anything with it, and
- Establish protocols, policies, and procedures, such as an independent double-check process, that highlight the change to labels on heparin containers.

Patricia C. Kienle, director of accreditation and medication safety at Cardinal Health Pharmacy Solutions, said now is “a great time for people to do a mini failure mode and effects analysis, an FMEA.”

Doing that type of analysis, she explained, gives people the opportunity to look for heparin products everywhere in the health care organization.

“They may be surprised” at what they find, Kienle said.

Procedural areas tied to the hospital likely have heparin products, she said. But so may a health system’s clinics, offices, and remote procedural areas. And don’t forget the dialysis areas.

“Often, dialysis [services] are contract services,” Kienle said. “And often, heparin is brought in by those contract services to be used in dialysis centers. And often, pharmacy isn’t aware of that.”

An FMEA of heparin products also presents the opportunity to ensure that the policies concerning high-alert medications are being followed, she said.

There is also the matter of size and strength.

“When I see people who have 10,000-unit/mL [vials] or have larger than 1-mL-vial sizes of heparin,” Kienle said, “it strikes a chord with me that, maybe, they haven’t looked at that whole safety perspective.”

Allen J. Vaida, executive vice president of the Institute for Safe Medication Practices, said his group for years has wanted hospitals to assess whether any area other than pharmacy truly needs to have heparin vials.

Take, for example, the patient care units.

If the pharmacy provides all first doses of heparin infusion, prepares all bolus doses of heparin, and stocks the units with standard premixed heparin solutions, Vaida said, then the nurses don’t need ready access to heparin vials.

“Use this as an opportunity and see if you can basically pull some product from the nursing units and [elsewhere] that maybe didn’t have to be up there in the first place,” he said.

Vaida said hospitals should also assess how their computerized prescriber-order-entry system, electronic medication administration record, and automated dispensing cabinets display heparin products onscreen.

Always a problem. Kienle said heparin products, even when all labels prominently state the entire strength in a...
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container, will remain problematic from a safety standpoint.

“There’s a lot of confusion with any drug that has a lot of zeros and/or has a ‘u’ for unit in their labeling,” she said.

Nonetheless, she said the new style of label is an improvement and will be particularly helpful in emphasizing that a small vial is not always a unit dose vial.

Vaida said USP’s decision to change the labeling section in the two heparin monographs corrects an oversight.

His group in 2002 told the USP Safe Medication Use Expert Committee about a variety of medication errors that had occurred because manufacturers’ labels did not prominently state the total amount of drug in a container. The eventual result, Vaida said, was a requirement for injectable drug products other than insulin to have a label prominently stating the total amount of drug in the container.

What was not realized until more recently, however, was that the heparin monographs contained overriding labeling requirements that prevented a label from stating the total strength in the container, he said.

Bona E. Benjamin, director of medication-use quality improvement at ASHP, agreed with USP’s decision to have the labels on heparin containers state the total amount of drug.

The total content of a drug container is an important piece of information, she said.

This change to the labels, she added, should reduce the risk of heparin errors.

—Cheryl A. Thompson
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PTCB plans major update to certification requirements

The group that has certified nearly 500,000 pharmacy technicians is introducing new requirements to the process of obtaining and maintaining the certified pharmacy technician (CPhT) credential.

“What we’re doing here is raising the bar,” said Everett McAllister, executive director and chief executive officer of the Pharmacy Technician Certification Board (PTCB).

“The goal is to always focus on the patients. That’s always the ultimate goal.”

PTCB’s certification requirements have been essentially unchanged since 1995, when the organization was founded. ASHP is one of the five pharmacy organizations that govern PTCB.

In general, McAllister said, the revised certification plan will allow technicians to assume greater responsibility for distributive processes, which will allow pharmacists to spend more time taking care of patients.

“When you free up pharmacists to do that, [we] believe it improves patient outcomes,” he said.

PTCB is accepting comments on its plan through May 2013. McAllister emphasized that his organization wants to hear from a variety of stakeholders, including pharmacists, pharmacy technicians, state pharmacy boards, professional associations, and employers.

Once the changes are fully implemented, new applicants for PTCB’s CPhT credential will be required to pass a criminal background check and complete an ASHP-accredited technician education program. PTCB has proposed a 2014 implementation date for the background checks and expects the training program requirements to be in place in 2020.

Recertification will undergo changes as well, including the phasing out of in-service education programs and a decrease in the number of continuing education (CE) hours obtained through college classes. Pharmacists technicians must recertify every two years to keep their CPhT credential.

For recertification starting in 2015, technicians will need to complete 20 hours of pharmacy technician-specific CE that includes 1 hour of pharmacy law—a current requirement—and, starting in 2014, 1 hour of medication safety CE.

Although CE programs must be based on Accreditation Council for Pharmacy Education (ACPE) principles, the programs are not required to be from an ACPE-accredited provider, according to PTCB.

McAllister said there are sufficient CE programs available now that PTCB considers technician specific, and he expects the number of such programs to grow.

He acknowledged that PTCB has much work to do to nail down the specifics of the CE requirements.

“As we write the rules, we’ll develop what the standards ought to be for acceptable hours. We’re not quite sure what it’s going to look like just yet,” McAllister said. “The comment period gives us a chance to gather information and sit down and craft good policy.”

The policy on background checks is also a work in progress. PTCB’s goal is to ensure that background checks harmonize with systems already used by employers and other entities in the health