Patient sues drug companies: "HT caused my breast cancer"

A WOMAN IN HER LATE 50S took a combination of Premarin and Provera for 6 years to treat menopausal symptoms. She was then switched to Prempro for 4 years until she detected a lump in her breast. Her physician diagnosed invasive ductal breast cancer and the patient underwent a left mastectomy. Cancer spread to her lymph nodes; she underwent chemotherapy and radiation treatments. She sued the drug manufacturers.

PATIENT'S CLAIM Years of combination hormone therapy (HT) caused her breast cancer. The pharmaceutical companies failed to adequately test the drugs despite knowledge of their cancer-causing potential. If the defendants had begun cancer studies in the early 1980s when they first learned about the cancer risk, the risk would have been discovered before she began taking HT in 1991. She provided letters dated as early as 1976 from the FDA, independent researchers, and internal drug company scientists urging that cancer risk research be conducted. She claimed the defendants intentionally restricted the publication of medical data outlining the cancerous effects of combination HT to physicians and patients.

DEFENDANTS' DEFENSE The FDA has reviewed the benefits and risks of HT for decades, always finding that the benefits outweighed the risks. Defendants cited 19 studies examining HT and breast cancer risk, the first published in 1959. The Women's Health Initiative reaffirmed the increased risk of breast cancer, available in the labeling for Prempro in 1995. Labeling for Premarin and Provera included FDA-approved warnings of the breast cancer risk. The physician and patient were adequately warned of risks before use.

VERDICT $34.3 million verdict was returned, including $28 million in total punitive damages against the drug companies.

These cases were selected by the editors of OBG MANAGEMENT *from* Medical Malpractice Verdicts, Settlements & Experts, *with permission of the editor, Lewis Laska (www.verdictslaska.com). The information available to the editors about the cases presented here is sometimes incomplete. Moreover, the cases may or may not have merit. Nevertheless, these cases represent the types of clinical situations that typically result in litigation and are meant to illustrate nationwide variation in jury verdicts and awards.*

Was hypertension properly treated in this stroke victim?

AFTER HEAVY VAGINAL BLEEDING was diagnosed in a 49-year-old woman, her gynecologist prescribed medroxyprogesterone acetate. Several months later, she underwent a dilation and curettage for continued bleeding. A year later, her blood pressure (BP) was 140/94 mm Hg, which the physician believed was "white coat" hypertension. The woman returned 10 months later, still complaining of abnormal uterine bleeding, but she refused surgical options; the physician prescribed birth control pills. She returned for a routine exam a year later, when her BP was again elevated. The physician continued the patient's oral contraceptive prescription and initiated treatment for high BP with triamterene. When the patient called to complain of excessive bleeding the next month, a nurse told her to take ibuprofen and call back if symptoms persisted. Shortly thereafter, the patient suffered a stroke. After rehabilitation, she regained use of her arms and legs, but suffered from foot drop and decreased fine motor skills.

PATIENT'S CLAIM The stroke was caused by uncontrolled hypertension and/or birth control pills. The physician should have initiated treatment the first time her BP was elevated, and it should have been checked more frequently. Birth control pills should have been discontinued when high BP was diagnosed because they are contraindicated in women older than 35 years whose BP is elevated.

PHYSICIAN'S DEFENSE The use of birth control pills was proper; the physician prescribed a low-dose combination medication commonly given to perimenopausal women to control abnormal bleeding. When high BP was first suspected, the physician commenced treatment.

VERDICT A defense verdict was returned.

Painful intercourse reported following incontinence surgery

EIGHT SURGERIES WERE PERFORMED to correct a 54-year-old woman's cystocele, enterocele, and retrocele. The patient's bladder, colon, and intestines had been pressing on her vaginal canal causing abdominal pain, painful intercourse, and urinary and fecal incontinence.

PATIENT'S CLAIM The procedures reduced the size of her vaginal opening and the length of her vaginal canal, causing constant pain as well as severe pain with intercourse. She was not informed that this was a risk of surgery.

PHYSICIAN'S DEFENSE The patient's vaginal opening did shrink due to the release of pressure placed on the vaginal canal by the other organs, but it is still within normal range of vaginal size. The procedures resolved the patient's incontinence issues.

VERDICT A defense verdict was returned.

Radiotherapy wrong for sarcoma; caused short bowel syndrome

FIBROIDS WERE MORCELLATED during a vaginal hysterectomy in a 56-year-old woman. The patient's pathology report indicated endometrial stromal sarcoma (ESS). She underwent open surgery for staging and to remove any residual cancer cells that could be identified. The gynecologist referred her to a radiation oncologist. After receiving radiotherapy for 4 months, the patient complained of bowel-related symptoms. Three months later, she sought treatment closer to home for diarrhea and gastrointestinal problems. A surgeon diagnosed radiation-induced short bowel syndrome causing inadequate nutritional absorption. The patient underwent two operations, during which large sections of her bowel were removed, a permanent colostomy was placed. She then required total parenteral nutrition tube feedings.

PLAINTIFF'S CLAIM The radiation oncologist was negligent for recommending and administering radiotherapy because of its limited value in ESS. Hormonal therapy should have been used instead.

PHYSICIAN'S DEFENSE Radiotherapy was necessary because of the patient's history and disease type. Morcellation during vaginal hysterectomy increased the risk of microscopic cancer cells remaining in the pelvis, supported by the finding of residual cancer cells during the second procedure. Radiotherapy was necessary to treat the residual cancer cells.

VERDICT A defense verdict was returned.

No response to alarm when fetal heart tones are lost

A WOMAN ATTEMPTED VAGINAL BIRTH after having one vaginal birth and one cesarean delivery in the past. Labor progressed slowly with inadequate contractions and lack of descent. After the mother pushed five or six times without

PRODUCT UPDATE

HYGREEN™ HAND HYGIENE SYSTEM WINS 2010 MEDICAL DESIGN EXCELLENCE AWARD

The HyGreen™ Hand Hygiene System, developed by Xhale Innovations, Inc., of Gainesville, Fla., has won the prestigious 2010 Medical Design Excellence Awards competition that recognizes superior medical product design. HyGreen is a wireless system that doesn't impede the workflow of busy health care workers. After using alcohol-based sanitizers (soap or gel), a worker places his/her hands under the HyGreen sensor. If the device senses the presence of alcohol, it sends an "all clean" message to a badge worn by the worker. A wireless monitor mounted above each patient's bed searches for the message—if absent, the badge vibrates, reminding the wearer to wash. All interactions are recorded in real-time.

FOR MORE INFORMATION, VISIT www.xhale.com/hygreen

SEW-RIGHT AND TI-KNOT DEVICES IMPROVE LAPAROSCOPIC SUTURING AND KNOT-TYING

Sew-Right SR-5 and Ti-Knot TK-5 are hand instruments for minimally invasive surgery designed to improve suturing procedures. The Sew-Right instrument allows a surgeon to remotely place sutures to approximate soft tissue precisely and with minimal trauma. The Ti-Knot device securely crimps sutures together using a compressible sleeve (titanium knot), and cuts the excess suture tails. These ergonomically designed instruments from LSI Solutions (Rochester, NY) are comfortable in either hand, and are completely operational using only one hand.

FOR MORE INFORMATION, VISIT www.lsisolutions.com/tk

MICROLINE SURGICAL AND CAMBRIDGE ENDO ANNOUNCE PARTNERSHIP

A new partnership for distribution and product development has been created between Microline Surgical (Beverly, Mass.), manufacturer of reposable instruments for minimally invasive surgery, and Cambridge Endo (Framingham, Mass.), producer of single-incision surgery devices. In the collaboration, Microline will serve as a distribution channel for Cambridge Endo's products, and the two companies will work together on new solutions and products for the laparoscopic market.

FOR MORE INFORMATION, VISIT www.microlinesurgical.com and www.cambridgeendo.com

CERVILENZ MEASURES VAGINAL CERVICAL LENGTH TO ASSESS PRETERM LABOR

Research has shown the length of a woman's cervix is a good indicator of imminent birth. Now clinicians can use CerviLenz® to measure vaginal cervical length objectively to assess preterm birth risk. When a woman presents with preterm labor symptoms, practitioners can evaluate a baseline measurement and monitor change with repeat measurements. CerviLenz is a low-cost, single-use, FDA-cleared medical device from CerviLenz, Inc. (Chagrin Falls, Ohio). OBs, nurse-midwives, and L&D nurses—any medical professional trained to use a speculum—can learn to use CerviLenz quickly and easily.

FOR MORE INFORMATION, VISIT www.cervilenz.com

progress, the OB left to deliver another baby. Because of lack of progression, the mother requested cesarean delivery, and the husband conveyed their concerns to the nursing staff. The nurses assured them that all was well but did not discuss the parents' concerns with the OB or other hospital personnel. One hour later, the mother's uterus ruptured, fetal heart tones were lost from the external fetal monitor, and an alarm sounded.

PLAINTIFF'S CLAIM The nursing staff failed to respond to the alarm immediately; when a response did come, a nurse allegedly stated with excitement that she was amazed that no one had responded. This statement was confirmed by the OB. After 9 minutes of signal loss, a fetal heartbeat of 60 was found, but it was severely bradycardic. The mother was rushed to the OR and the baby was delivered expeditiously. The child was born limp and without respiratory effort, and sustained hypoxic ischemic encephalopathy. At age 5, he had no purposeful movement of his extremities, could not communicate, and was wheelchair-bound, although he was not cognitively impaired.

DEFENDANTS' DEFENSE The OB offered full policy limits before trial. The hospital claimed that the 9-minute delay in detecting the loss of fetal heart tone and seeking the OB's intervention was not the proximate cause of the child's handicaps.

VERDICT A $4.9 million Michigan verdict was reached.

Untreated postpartum infection necessitated hysterectomy

AN 18-YEAR-OLD WOMAN was discharged from the hospital two days after the vaginal birth of her healthy child, although she claimed to not feel well. When a hospital-employed nurse visited her the next day, the patient reported abdominal pain and cramping. Five days later, she returned to the hospital in extreme pain. She was diagnosed with severe *Streptococcus A* infection, air-lifted to another hospital, and treated with antibiotics for 5 days. A hysterectomy was later performed.

PLAINTIFF'S CLAIM The physician, visiting nurse, and hospital failed to diagnose and treat the infection in a timely manner, resulting in a hysterectomy. Laboratory tests taken before the patient's hospital discharge showed an elevated white blood cell (WBC) count; the patient should have been prescribed antibiotics before leaving the hospital. The visiting nurse did not react appropriately when the patient reported pain. The hospital was responsible because the results of the WBC test were not entered into the patient's chart.

DEFENDANTS' DEFENSE The physician claimed that the elevated WBC count was not recorded in the patient's medical chart with other lab values. The hospital claimed that a high WBC count is common after childbirth; the test is rarely performed at that time. The only reason it was performed was that the technology automatically recorded WBC when it evaluated hemoglobin and hemocrit. Abdominal cramping reported to the visiting nurse is normal 3 days after childbirth. The patient did not have an infection at discharge or at the time of the nurse's visit.

VERDICT Suit against the physician was dismissed prior to jury deliberations. A $2.3 million verdict was returned against the hospital.

Did retained sponges lead to PID and gallbladder disease?

A 6-INCH VAGINAL LACERATION was discovered after a woman delivered a healthy baby. The ObGyn, who was covering for the patient's regular ObGyn because of a snowstorm, could not repair the laceration in the delivery room. He packed the patient's vagina with gauze sponges, and took her to the OR where he repaired the laceration. The next day, he removed sponges placed after surgery. The patient was discharged with instructions to follow-up with her regular ObGyn. Eight days after delivery, the patient complained to her ObGyn of severe abdominal pain and a foul odor. Antibiotics were prescribed, but she refused a vaginal examination because of the pain. Six weeks after delivery, four gauze sponges were removed from the patient's vagina.

PLAINTIFF'S CLAIM The physician was negligent in leaving the sponges in her vagina. He should have conducted the follow-up himself because he delivered her child. The infection caused chronic pain from pelvic inflammatory disease (PID), and necessitated the removal of her gallbladder.

PHYSICIAN'S DEFENSE Retained sponges can occur in the absence of negligence. It was proper for the patient to return to her own physician for postoperative follow-up treatment. The patient's PID and gallbladder problems were unrelated to the retained sponges.

VERDICT A defense verdict was returned. The defendant was granted costs and attorney fees exceeding $27,000.