Should patient have to ask for testing?

A man was tested by Dr. A and found to be a thalassemia carrier, but his wife was not tested. When she became pregnant and blood work at 6 weeks indicated anemia, no testing for thalassemia was performed by Dr. B. The child was born with thalassemia, a condition that affects the body's ability to produce hemoglobin, and will need blood transfusions throughout his life.

Patient's claim The mother would have had an abortion if she had known the baby would have thalassemia.

Doctor's defense Because the parents knew the father was a carrier, the defendants relied on the mother to be tested if she became pregnant. Also, the parents would not have chosen an abortion.

Verdict $14 million New Jersey verdict against Dr. B only.

Advice to deaf patient is disputed

The parents of a baby girl born with spina bifida were profoundly deaf. The mother's deafness since birth was due to the genetic disorder Waardenburg syndrome.

Patient's claim The physician failed to communicate the importance of 1) taking folic acid to prevent birth defects and 2) maternal serum α-fetoprotein (MSAFP) testing to determine if spina bifida was present. The physician also failed to determine what caused the mother's deafness so she could be referred for genetic counseling. They would have aborted the fetus if they had known of the spina bifida.

Doctor's defense When the defendant asked about genetic disorders in the family, she was told there were none. She discussed folic acid with the mother, who refused MSAFP testing when it was suggested. The couple also never brought a sign language interpreter with them. The defendant added that there was no scientific evidence that folic acid affects neural tube defects associated with a genetic syndrome such as Waardenburg.

Verdict Kansas defense verdict.

Deaths due to untreated thrombocytopenia?

A 34-year-old woman who was 27½ weeks pregnant presented at the hospital with burning in the chest, diarrhea, nausea, vomiting, and headache. She had protein in her urine, and an OB diagnosed a urinary tract infection and sent her home. In less than 24 hours, she returned by ambulance to the hospital, where she remained for observation. The defendant OBs did not come and no lab tests were ordered.

The following morning, lab results indicated HELLP syndrome or thrombotic thrombocytopenic purpura (TTP). Treatment for HELLP syndrome (delivery of the fetus—a problem because of its prematurity) and TTP (plasma exchange) could not be done at the defendant hospital, but the mother was not transferred to another hospital and consultations were not sought. A day later, an internal medicine physician was consulted, and he urged that a physician specializing in TTP also be consulted, but that was not done. Later, ultrasonography indicated the fetus had died.

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Fifteen hours after the stillborn baby was delivered, the mother suffered cardiovascular collapse and died.

Patient's claim The defendants were negligent in treating the woman's thrombocytopenia and not transferring her to another hospital in a timely manner.

Doctor's defense Not reported.

Verdict A North Carolina settlement, which included $1,325,000 from the OB defendants and $750,000 from the hospital defendants.

Doctor ignores lump, and patient delays

A patient reported a pea-sized lump in her right breast to her gynecologist after several weeks. When he examined her at a later date, she again reported the lump, but he did not order a sonogram, mammogram, or biopsy. Over a year later, the patient was examined by a family practice physician, who examined the lump and ordered a mammogram. Seven months later, a biopsy showed the presence of cancer. As the cancer had spread to her lymph nodes, she required extensive treatment.

Patient's claim The gynecologist was negligent for not diagnosing the cancer earlier.

Doctor's defense Not reported.

Verdict $1,275,647.61 gross verdict in Florida. The woman was found 34% at fault, and the ObGyn, 66% at fault.

Ureteral stricture follows oophorectomy

The cystic ovaries of a 59-year-old woman were removed by an ObGyn in a procedure that was uneventful despite the presence of scarring and adhesions from previous surgeries, including a hysterectomy years earlier. The operative report did not mention that the ureters were visualized, although other structures were noted. The day after surgery, the patient was discharged in satisfactory condition. Two weeks later she returned to her physician with severe left flank pain. She was hospitalized, and a radiologist and urologist were consulted. She was diagnosed with a left ureteral stricture. The urologist placed a nephroureteral stent, and the patient wore a urostomy bag for 1 month until an indwelling stent was placed. Over the next year, she underwent frequent stent changes under general anesthesia.

Patient's claim The physician failed to visualize the ureter during the surgery and was negligent in placing a staple in it, thus causing the injury.

Doctor's defense He had visualized the ureter and properly placed the staples. The stricture was due to scar tissue.

Verdict Three Virginia trials resulted in a hung jury, a mistrial, and finally a defense verdict.

Bladder injury during tubal ligation

A 25-year-old woman pregnant with her first child made plans with a family physician to undergo a tubal ligation the day after delivery. During the procedure, performed under general anesthesia, the woman's bladder was lacerated and a sudden gush of fluid contaminated the surgical site. A urologist was called immediately and repaired the damage successfully. After 2 days, the patient was discharged, but she returned 5 hours later with intense abdominal pain, the result of a ruptured bladder. Another repair was followed by further complications and more hospital visits.

Patient's claim Because of a lack of bladder control, she requires ongoing treatment, including the use of catheters to drain her bladder.

Doctor's defense A lacerated bladder is a known complication of tubal ligation. Because the patient did not urinate before the surgery as he instructed her, the bladder was distended and discharged an unexpected gush of fluid when it was lac-

erated. Her ongoing problems, however, are not a result of the laceration or repair.
Verdict Indiana defense verdict.

Sex impossible after too much surgery?

A 52-year-old woman underwent a hysterectomy, bladder neck suspension to repair a cystocele, and implantation of a synthetic suburethral sling, all performed by an ObGyn. Following surgery, the patient suffered erosion of the sling into the vagina, causing a chronic infection with discharge and pain. After undergoing further procedures, including debridement and resection of the vagina, she has vaginal scar tissue, muscle myalgia, chronic vaginal pain or irritation and discharge, and the loss of her vagina due to scarring and foreshortening. She and her husband can no longer have sexual intercourse.
Patient's claim The sling procedure was unnecessary. Also the physician mishandled the postoperative complications resulting from the sling, and he did not refer her to a specialist in a timely manner.
Doctor's defense The patient had complained of stress urinary incontinence, and the sling procedure was indicated because of a hypermobile urethra. Also the complications were handled properly.
Verdict $5 million Illinois verdict, including $1 million for the woman's husband for loss of consortium.

IUD in place while pregnant with twins

A month after giving birth to her first child, a 19-year-old woman underwent a Pap smear and had an IUD inserted for birth control. After reviewing the Pap results, the physician asked the patient to return for a cervical biopsy. During the colposcopy, the physician removed the IUD because it was partially expelled from her cervix. A week later he inserted a new IUD, but neither he nor the patient knew she was 2 weeks pregnant. When she suffered severe bleeding and cramping 2 months later, a pregnancy test indicated she was pregnant, and a sonogram revealed twins with the IUD in place. The string was not visible, so the IUD could not be removed. The patient was put on bed rest to avoid a threatened miscarriage. At a second facility, it was confirmed that the IUD could not be removed. The patient was diagnosed with an incompetent cervix and, following placement of a cervical cerclage, was told to remain on rest. Within a month, she miscarried.
Patient's claim The physician was negligent for inserting an IUD without determining if she was pregnant, and the IUD caused the miscarriage.
Doctor's defense A pregnancy test prior to insertion of an IUD is not the standard of care, especially when the patient reports regular periods. Also, the miscarriage was not related to the IUD.
Verdict Missouri defense verdict.

Was mother's brain damage avoidable?

A 27-year-old pregnant woman at full term presented at the hospital for labor augmentation. Her OB was Dr. A. Dr. B, the anesthesiologist, was called a few hours later to place an epidural. Later, the patient began vomiting and experiencing seizures and became unresponsive. Neither Dr. A nor Dr. B was present. Fetal bradycardia was diagnosed and an emergency cesarean section was performed. During the delivery, the mother experienced cardiac arrest, uterine atony, and disseminated intravascular coagulation. She was resuscitated, but suffered severe brain damage. She must use a wheelchair because of cognitive and neurological impairments.
Patient's claim Three things should have been done: earlier cesarean section, suctioning after the vomiting, and intubation.
Doctor's defense The patient had an unpredictable and untreatable amniotic fluid embolism.

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FOSAMAX® (alendronate sodium) for either two or three years. In these studies the overall safety profiles of FOSAMAX 5 mg/day (n=642) and placebo (n=648) were similar. Discontinuation of therapy due to any clinical adverse experience occurred in 7.5% of 642 patients treated with FOSAMAX 5 mg/day and 5.7% of 648 patients treated with placebo. In a one-year, double-blind, multicenter study, the overall safety and tolerability profiles of once weekly FOSAMAX 35 mg (n=362) and FOSAMAX 5 mg daily (n=361) were similar. The adverse experiences from these studies considered by the investigators as possibly, probably, or definitely drug related in ≥1% of patients treated with FOSAMAX 5 mg/day or placebo for the two- or three-year studies were *Gastrointestinal:* dyspepsia 1.9% and 1.4%, abdominal pain 1.7% and 3.4%, acid regurgitation 1.4% and 2.5%, nausea 1.4% and 1.4%, diarrhea 1.1% and 1.7%, constipation 0.9% and 0.5%, abdominal distention 0.2% and 0.3%; and *Musculoskeletal:* musculoskeletal (bone, muscle or joint) pain 0.8% and 0.9%, respectively. For the one-year study with FOSAMAX 5 mg/day and once weekly FOSAMAX 35 mg, corresponding values were *Gastrointestinal:* dyspepsia 2.2% and 1.7%, abdominal pain 4.2% and 2.2%, acid regurgitation 4.2% and 4.7%, nausea 2.5% and 1.4%, diarrhea 1.1% and 0.6%, constipation 1.7% and 0.3%, abdominal distention 1.4% and 1.1%; and *Musculoskeletal:* musculoskeletal (bone, muscle or joint) pain 1.9% and 2.2%, respectively. *Treatment of glucocorticoid-induced osteoporosis.* In two, one-year, placebo-controlled, double-blind, multicenter studies in patients receiving glucocorticoid treatment, the overall safety and tolerability profiles of FOSAMAX 5 and 10 mg/day were generally similar to that of placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in ≥1% of patients treated with either FOSAMAX 5 mg/day (n=161) or FOSAMAX 10 mg/day (n=157) or placebo (n=159) were *Gastrointestinal:* abdominal pain 1.9%, 3.2%, and 0.0%; acid regurgitation 1.9%, 2.5%, and 1.3%; constipation 0.6%, 1.3%, and 0.0%; melena 0.0%, 1.3%, and 0.0%; nausea 1.2%, 0.6%, and 0.6%; diarrhea 0.0%, 0.0%, and 1.3%; and *Nervous System/Psychiatric:* headache 0.0%, 0.6%, and 1.3%, respectively. The overall safety and tolerability profile in the glucocorticoid-induced osteoporosis population that continued therapy for the second year of the studies (FOSAMAX: n=147) was consistent with that observed in the first year. *Paget's disease of bone.* In clinical studies (osteoporosis and Paget's disease), adverse experiences reported in 175 patients taking FOSAMAX 40 mg/day for 3-12 months were similar to those in postmenopausal women treated with FOSAMAX 10 mg/day. However, there was an apparent increased incidence of upper gastrointestinal adverse experiences in patients taking FOSAMAX 40 mg/day (17.7% FOSAMAX vs. 10.2% placebo). One case of esophagitis and two cases of gastritis resulted in discontinuation of treatment. Additionally, musculoskeletal (bone, muscle or joint) pain, which has been described in patients with Paget's disease treated with other bisphosphonates, was considered by the investigators as possibly, probably, or definitely drug related in approximately 6% of patients treated with FOSAMAX 40 mg/day versus approximately 1% of patients treated with placebo, but rarely resulted in discontinuation of therapy. Discontinuation of therapy due to any clinical adverse experience occurred in 6.4% of patients with Paget's disease treated with FOSAMAX 40 mg/day and 2.4% of patients treated with placebo.
Laboratory Test Findings— In double-blind, multicenter, controlled studies, asymptomatic, mild, and transient decreases in serum calcium and phosphate were observed in approximately 18% and 10%, respectively, of patients taking FOSAMAX versus approximately 12% and 3% of those taking placebo. However, the incidences of decreases in serum calcium to <8.0 mg/dL (2.0 mM) and serum phosphate to ≤2.0 mg/dL (0.65 mM) were similar in both treatment groups. *FOSAMAX PLUS D™ (alendronate sodium/cholecalciferol):* In a fifteen week double-blind, multinational study in osteoporotic postmenopausal women (n=682) and men (n=35), the safety profile of FOSAMAX PLUS D was similar to that of FOSAMAX once weekly 70 mg.
Post-Marketing Experience. The following adverse reactions have been reported in post-marketing use with alendronate: *Body as a Whole:* hypersensitivity reactions including urticaria and rarely angioedema. Transient symptoms of myalgia, malaise, asthenia and rarely, fever have been reported with alendronate, typically in association with initiation of treatment. Rarely, symptomatic hypocalcemia has occurred, generally in association with predisposing conditions. Rarely, peripheral edema. *Gastrointestinal:* esophagitis, esophageal erosions, esophageal ulcers, rarely esophageal stricture or perforation, and oropharyngeal ulceration. Gastric or duodenal ulcers, some severe and with complications have also been reported (see WARNINGS, PRECAUTIONS, *Information for Patients*, and DOSAGE AND ADMINISTRATION). Localized osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported rarely (see PRECAUTIONS, *Dental*). *Musculoskeletal:* bone, joint, and/or muscle pain, occasionally severe, and rarely incapacitating (see PRECAUTIONS, *Musculoskeletal Pain*); joint swelling. *Nervous system:* dizziness and vertigo. *Skin:* rash (occasionally with photosensitivity), pruritus, rarely severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis. *Special Senses:* rarely uveitis, scleritis or episcleritis.

For more detailed information, please read the Prescribing Information.
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Verdict New York defense verdict, but post-trial motions were pending.

Depo-Provera is given to pregnant woman

When a 28-year-old woman with a history of alcohol and drug abuse requested contraceptive medication, she was prescribed 3 injections of Depo-Provera over 6 months. At each exam, she reported a weight gain, breast tenderness, and swelling of her breasts. The ObGyn said those were side effects of the medication. When she went to another physician 7 months after the first injection, it was determined that she was late in her seventh month of pregnancy. Unable to terminate the pregnancy, she delivered a child with significant, permanent disabilities. To care for the child, she quit her job and moved in with her parents.
Patient's claim The physician failed to rule out pregnancy before the first injection.
Doctor's defense The plaintiff had no damages.
Verdict $400,000 Massachusetts settlement.

Video supports claims of negligence

Shoulder dystocia occurred during delivery of the plaintiff's child. Because of brachial plexus damage, the child suffers from Erb's palsy and has undergone surgery to try to restore function to her arm, hand, and fingers.
Patient's claim The defendants did not tell her to stop pushing when shoulder dystocia was discovered, and were negligent for using the McRoberts maneuver, suprapubic pressure, and excessive traction. The plaintiff provided video documentation of the delivery.
Doctor's defense Negligence was denied.
Verdict $1 million Maryland verdict. ■

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