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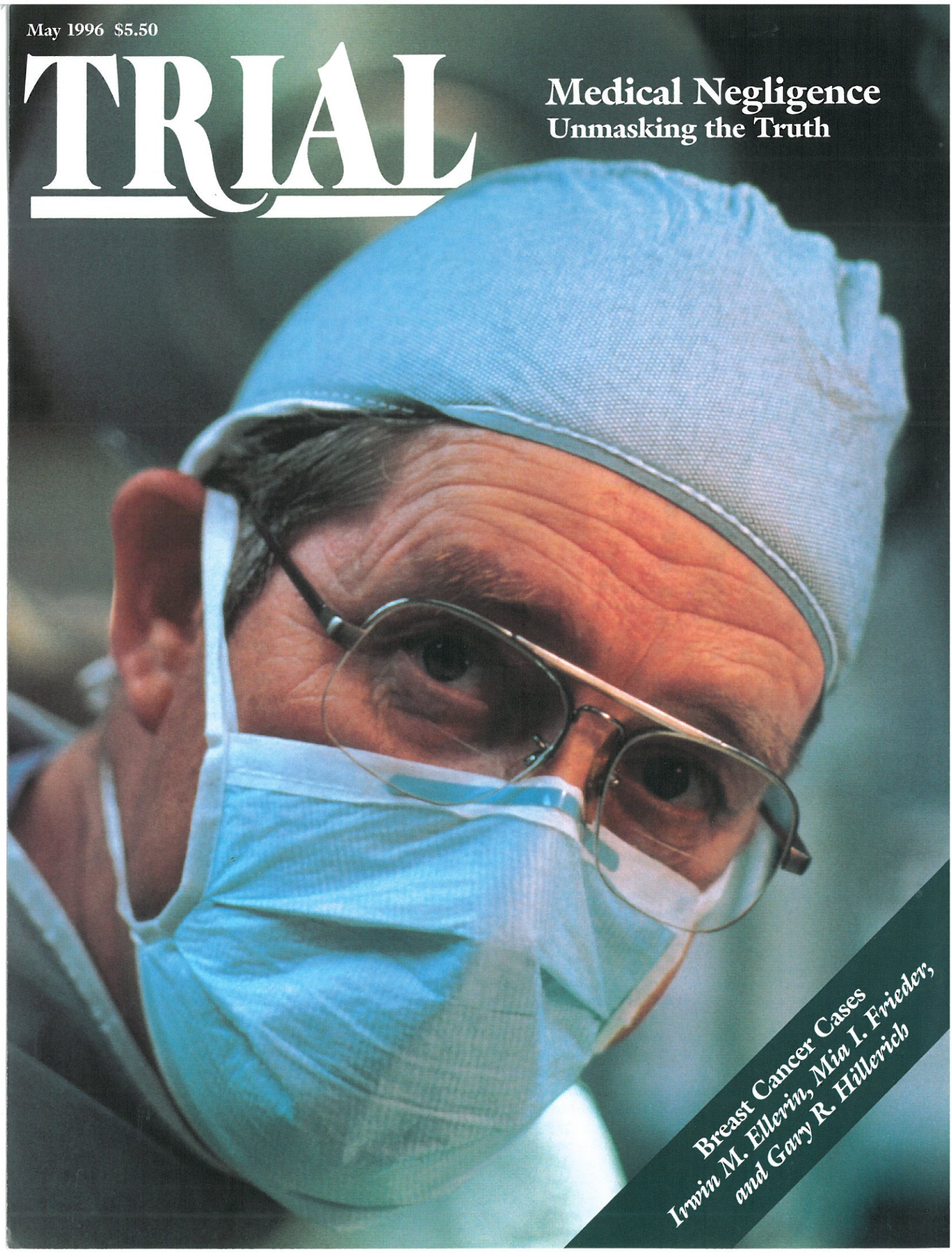
TRIAL

Medical Negligence
Unmasking the Truth



Breast Cancer Cases
Irwin M. Ellerin, Mia I. Frieder, and Gary R. Hillerich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Handling a Failure to Diagnose Breast Cancer Case

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Failure to diagnose breast cancer is the most frequently litigated medical negligence claim.[1] Unlike lung and cervical cancers, the risk factors associated with diagnosing breast cancer are not clear-cut, nor do these factors present an effective mechanism for control and treatment. In fact, 80 percent of women diagnosed with breast cancer do not have any of the known risk factors.[2]

Today, 50 centuries after it was first recognized, breast cancer remains the most common cause of cancer death in women.[3] Breast cancer constitutes 32 percent of all cancers in women and is responsible for 18 percent of deaths from cancer.[4]

This article discusses some basic elements of handling a failure to diagnose breast cancer case. The goal is to present a checklist of fundamental factors to consider; the article should not be considered all-inclusive.

Carcinomas of the breast are generally formed from the epithelium or lining of mammary ducts and lobules. These cancers are divided into two main groups: carcinomas of ductal epithelial origin and those of lobular epithelial origin.

Carcinomas of ductal origin are divided into non-invasive (duct cancer in situ) and invasive types. Carcinomas of lobular epithelial origin are usually divided on the basis of invasion, that is, lobular cancer in situ (or lobular neoplasia) and invasive lobular cancer. Although both types fall under the category of breast cancer, ductal and lobular carcinomas are two distinct histopathologic entities, having different clinical characteristics that may affect how they are treated.

A fundamental maxim of handling breast cancer cases is to learn as much as possible about breast cancer generally and your client's breast cancer specifically. This is a highly technical, specialized field. You must be both familiar with the concepts involved and fluent with the terminology.

For example, is the cancer estrogen/progesterone positive or negative and, thus, responsive to hormone therapy? What is the cancer's histology—that is, how much do the breast cancer cells resemble normal breast epithelium? Did the cancer have a high division or mitotic rate—an indication that the cancer was growing quickly?

It is also necessary to understand how cancer is staged.[5] Cancer staging is currently performed according to the tumor node metastasis (TNM) classification system. A breast cancer is assigned T, N, and M values based on the size of the primary tumor (T), the nodal involvement (N), and the presence of metastasis (M_0-M_1). Then the cancer is designated by a stage number, I through IV. For example, Stage I cancers—a tumor less than 2 cm (T_1), no nodal involvement (N_0), and no metastasis (M_0)—have the best prognosis.[6]

Stages are determined in two ways. Clinical staging, the first method, depends on the physician's physical examination. It is often inaccurate, especially regarding nodal involvement, when compared to pathological staging, the second method, which entails microscopic analysis of the actual tissue. Still, the TNM classification system pathologically is probably the best and most widely used system currently available.

To better understand this disease, read some of the leading texts on breast cancer.[7] At least one should be added to your library.

Also, consider retaining an oncologist early in the case for consultation. You should have this person review your client's entire medical file and assist you

This stamp, which becomes available next month, will likely increase public awareness of breast cancer, but sometimes medical practitioners miss the diagnosis.

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in identifying the strengths and weaknesses of your case. Ask the specialist to teach you about breast cancer and the treatments involved, to point out possible defenses, and to advise you on effective cross-examination of the defendant's medical experts.

Case Evaluation

The most common type of breast cancer case involves a small, painless lesion or mass that is found first by the patient. In fact, 25 percent of women who consult a physician do so because they are concerned about a lump or other abnormal finding in the breast.[8]

If the breast mass or lesion does not resolve within one menstrual period, a physician must rule out any possibility of cancer. This includes, but is not limited to, ordering a mammogram, performing a needle biopsy or aspiration, or referring the patient to a surgeon or other specialist to perform these tests. Follow-up care and documentation are essential.

However, in many cases, the doctor is unimpressed with the physical findings of the exam and sends the patient home without ordering additional tests. Several months later, either through the persistent presence of the mass or the development of other symptoms, the cancer is finally diagnosed. By this time, the cancer may have invaded the lymph nodes and possibly metastasized to other organs or the skeleton itself, effectively reducing or destroying the patient's chance of long-term survival.

The initial consultation with the doctor coupled with the delay in diagnosing and treating the cancer will form the cornerstone of your case. Statistics on breast cancer cases show the average delay in diagnosis is 14 months after the patient first discovers the mass.[9]

Generally, the longer the delay, the stronger the likelihood that the cancer could have been successfully treated at an earlier stage. Keep in mind that the key inquiry is when the cancer could have been diagnosed compared with when the cancer was diagnosed and treated.

When a patient presents with a breast mass approximately 2 cm or smaller (about the size of a dime), and no other associated symptoms, the breast cancer is usually Stage I.[10] There is only a 20 percent to 25 percent chance that a patient presenting with clinical Stage I cancer will progress to clinical Stage II if treated.[11] Moreover, Stage I carcinomas are associated with the highest rate of patient survival; with chemotherapy the five-year survival rate is higher than 90 percent.[12]

Although breast cancer is most common in older women, it can be most difficult to diagnose in younger women. This difficulty reflects the fact that younger women have denser breast tissue, which reduces the efficacy of mammography. Also, physicians often are less likely to suspect the disease because of a younger woman's age. This is why it is essential for a physician to aspirate a breast mass if it does not resolve in 30 days.

Generally, younger women are better plaintiffs because they have been deprived of a larger part of their average life expectancy (and therefore their expected income) and also because younger women are more likely to be survived by minor children. According to the most recent study of breast cancer claimants conducted by the Physician Insurers Association of America (PIAA), 31 percent of the 487 claims studied were brought by women under 40. However, 37 percent of the sums were paid on this group's behalf.[13] An earlier study of 40 breast cancer verdicts confirmed that the largest awards went to patients who were younger, pregnant, or had experienced the longest delay in diagnosis.[14]

The most common type of breast cancer starts as a painless lesion.

Know the History

In assessing a case, it is important to find out whether your client faced a higher-than-normal risk for breast cancer. Significant factors include a family history of breast cancer, especially in an immediate family member, and never having borne children.

Your client should have a thorough family health history and personal breast history documented in her record. If she is at an increased risk, the defendant physician will have a much harder time explaining a failure to rule out the possibility of cancer. If there are no notations in your client's medical records indicating an awareness or consideration of your client's history, it will appear that the defendant doctor ignored your client's increased risk for breast cancer associated with these factors.

You may also want to see if your client has had any prolonged exposure to environmental factors that are linked to breast cancer.[15]

It is important also to ask your client why she did not seek a second opinion. This question will burn in the minds of jurors, so make sure you address it. Find out if your client had considered the possibility of speaking to another doctor, and the reasons she ultimately decided against it. This will be especially important if your client consulted the defendant physician on only a single occasion as opposed to having a long-standing doctor-patient relationship.

Inquire about your client's routine regarding doctors' visits and breast self-examination. Is your client someone who visits a doctor on a regular basis, or does she wait until a crisis before consulting her physician? A client who takes responsibility for her own health through regular self-examination or yearly doctor visits may be viewed as a more attractive plaintiff.

Also, did your client follow her doctor's instructions? For example, was your client told to return for further study if there were any changes in the suspect mass? In this scenario, a client's failure to regularly examine the mass or report back to her physician after finding changes may make it more difficult to litigate since it can be construed as contributing to or causing the delay in diagnosis.

If your client sees her doctor regularly or has a condition, such as pregnancy, that requires routine office visits, the doctor's failure to diagnose the cancer will be more clear-cut.

If your client is pregnant, you will essentially be addressing two issues: failure to diagnose the breast cancer and failure to properly treat the baby.

In some, but not all, cases the doctor may need to abort the fetus to immediately administer chemotherapy and/or radiation. Or if the fetus is viable, it may need to be delivered prematurely by cesarean section before the mother's intensive treatment can begin.

There is a large body of information dealing exclusively with breast cancer and pregnancy.[16] How the pregnancy affects the breast cancer is a legitimate area of controversy, but most of the data suggest that breast cancer complicated by a pregnancy has a worse prognosis.[17]

The most common reason for the worse prognosis is that heightened hor-

mones and growth factors in a woman's body both during and after pregnancy can stimulate breast cancer growth. Another reason is that these changes make it more difficult to examine a woman's breast during pregnancy, which contributes to the delay in diagnosis.

Discovery

Cancer ravages a human being. The combined effects of the disease and its treatments are merciless and often devastate a person's appearance, demeanor, and ability to perform routine tasks.

Because the progression of metastatic disease can be quick, it is imperative to address the possibility that your client may not be alive at trial. You should have at least one videotaped evidentiary deposition of your client. The tape will chronicle pain and suffering and preserve for trial the harrowing effects of the cancer.

In this deposition, clearly establish the following:

- the date the mass was discovered and all examination dates;
- the size and location of the mass at each doctor's visit;
- what your client asked the doctor about the mass;
- who was present in the examining room on each visit;
- what was said and done by the doctor and any nurses on each visit; and
- whether breast self-examination instruction was given to your client.

You must obtain a complete set of medical records from all medical providers for at least five years before the cancer was found. These records will contain critical information for litigating the claim.

You will need to look for any notation in the records showing your client failed to comply with her physician's request for further diagnostic testing and follow-up appointments. You must secure your client's medical records early enough in the case to allow you and your experts time to sift through every piece of information and to glean every possible analysis.

All X-rays, mammograms, ultrasounds, and bone scans, both before and after the diagnosis, should be reviewed by an oncologist or radiologist specializing in reading films for cancer metastasis. Where mammography had been ordered, be certain to get the "call sheet," which details orders from the primary physician to the mammographer from the radiology department where the mammogram was performed. This could indicate that the referring physician suspected cancer or told the radiologist what to look for.

The records should support the chronology of the patient's chief complaint and contain a diagram or narrative by the primary physician indicating the size, location, and any other features of the breast abnormality. The records should also document further diagnostic studies, consultations, and follow-up instructions ordered by the examining physician.

If the abnormality is described in the records as a "lump" or a "mass," or is measured or drawn, by definition the patient has a dominant three-dimensional mass, and the standard of care dictates that this must be resolved by additional diagnostic studies.[18]

These studies include aspiration, fine needle aspiration, or open biopsy. In some cases, these diagnostic studies can also include a plan of action. The plan should be carefully delineated. An example is a recommendation for reexamination after a menstrual cycle.

Omission of one or more of these diagnostic studies from the medical records may be evidence of a deviation from the standard of care. Moreover, jurors may view incomplete records as evidence of the physician's failure to provide adequate treatment.

In addition to a complete set of medical records, you will need to secure your client's entire file from the pathology lab. Sometimes a pathology lab will run diagnostic studies in addition to those specifically requested by the physician. Therefore, in your subpoena for documents, be sure to request the results of all studies run on all tissue samples.

Preparing the Case

The most likely defendants in your lawsuit will be the gynecologist or internist who examined the abnormality or the radiologist who performed or read any mammograms. According to a 1995 study, radiologists were named most frequently as defendants in breast cancer cases, followed by gynecologists.[19] An earlier study of these verdicts and settlements identified gynecologists as the most likely subject of this type of claim.[20]

Although radiologists may have less direct patient contact, this shift in primary defendants may be due, in part, to the increased responsibility of the radiologist for the actual diagnosis of the cancer through interpreting and reporting the results of mammograms, X-rays, and bone scans, which can show metastatic growth.[21] Also, when reading the mammogram the radiologist has an obligation to obtain prior mammograms.[22] The American College of Radiologists publishes a set of standards for radiologists performing mammograms. Also, federal rules for mammography were promulgated in the Mammography Quality Standards Act.[23]

The elements of damages for your client will generally include past and future medical expenses (monitoring expenses, chemotherapy, radiation therapy, and bone marrow transplant); loss of earnings, earning capacity, and future earnings; past and future pain and suffering; loss of enjoyment of life (in some states); and mental anguish caused by awareness or fear of being terminally ill. If your state allows recovery for a spouse's or minor child's loss of consortium, these claims should be added to the complaint.

If your client dies before trial, you will be handling both a medical negligence action and a wrongful death action. The elements of damages for the wrongful death claim will be determined by your state's wrongful death act.

Litigating failure to diagnose breast cancer cases is costly, so be prepared to invest substantial resources in developing your case.

You will need to present at least one expert, usually an oncologist, to testify at trial to educate the jury on how cancer grows in the body, how it is treated, and what the survival rates are. This expert must be able to communicate the concepts involved both simply and directly to a lay jury. Experts specializing in clinic work and teaching often have a good blend of qualities for this task.

You will need another expert who practices in the same specialty as the defendant to testify about the standard of care. If the defendant is an obstetrician/gynecologist (ob/gyn), it may be common practice for this specialist not to perform needle aspirations or biopsies. Although it is perfectly acceptable for a practicing ob/gyn to refrain from these procedures, in many jurisdictions it is a deviation from the standard of care not to refer the patient to a specialist when appropriate.

In addition to medical experts, you will need an economist and possibly a psychologist or psychiatrist to attest to the effects of a terminal illness on a person with cancer and her family.

Read every publication your expert has written and every deposition your expert has given. To assist you in locating previous depositions, consider taking an ad in a legal publication for the plaintiffs' bar, such as the *ATLA Advocate*, to re-

quest depositions on a particular expert.[24] You might also contact a deposition bank, or the trial lawyers association in your expert's home state.

As previously noted, have your medical experts assist you in preparing for cross-examination of the defense. In breast cancer cases, the defense will commonly proffer an argument regarding doubling time[25] or the rate at which a cancer grows. Your expert should estimate the doubling time of your client's cancer. The doubling time for breast cancer ranges from a few days to more than a year.[26] Generally, 90 percent to 95 percent of all breast cancers grow with an average doubling time of 30 days or slower.[27]

Another prominent defense involves the assumption that even if the cancer had been diagnosed earlier, it would not have affected the outcome since the cancer was unresponsive to treatment. To combat this defense, have your expert interpret your client's blood chemistry levels after treatment such as chemotherapy. If the blood chemistry levels improved, this may be evidence that the cancer did, in fact, respond to treatment. Moreover, it can be argued that the cancer would have responded even better had there been less tumor in the body.

Going to Trial

Space limitations preclude an extensive discussion of all the relevant considerations of trying a failure to diagnose breast cancer case. Like most medical negligence cases, photographic blowups of important medical records will be essential to litigating your case. Enlargements of reports that contain an erroneous diagnosis of the mass or lesion are vital. These enlargements should be displayed where the jury can see them throughout the trial since they are evidence of the defendant's negligence.

You will need other demonstrative evidence to assist the jury in understanding the progression of breast cancer throughout the body. You will want to have a chart depicting a cutaway of the breast and a chart depicting the entire body front to back, especially if the cancer has metastasized. At least one of these charts should show the axilla lymph nodes (the lymph nodes in the armpit).

Using markers or a pointer, your expert can show the jurors how cancer grows and spreads in the body. More important, your expert will show the jurors how to recognize the warning signs of cancer at an early stage and point out the features of the mass or lesion that should have led the defendant to consider the diagnosis of breast cancer.

You also can use model spheres to allow jurors to see and feel the size of the tumor at various stages. A plastic model of the breast is also a good visual aid.

In a radiology case, get blowups of the mammogram with the mass that was missed. Some courts will even allow you to give a copy of the photo to individual jurors.

Today, there is as much written on jury selection as there is on actually trying the case. Although we do not purport to be jury experts, one general principle regarding obstetrical/gynecological cases is that older men may make more sympathetic jurors. Women can exercise harsh judgment on women plaintiffs, especially regarding the failure to seek a second opinion. Also, if your defendant is a male ob/gyn, be aware that some men harbor a general animosity toward male physicians who work in gynecology.

Failure to diagnose breast cancer cases is an area of medical negligence that is growing at a great rate. People with malignant tumors almost invariably bring these growths to the attention of their personal physician. These tumors can be diagnosed and treated at an early stage by physicians or radiologists who exercise reasonable care. □

Notes

1 Physician Insurers Association of America (PIAA) Study (1995).

2 American College of Obstetricians and Gynecologists, PRÉCIS V: AN UPDATE IN OBSTETRICS AND GYNECOLOGY 301 (1994) [hereafter PRÉCIS V].

3 Courtney M. Townsend Jr., *Breast Lumps*, 32 CLINICAL SYMPOSIA 3 (1980).

4 PRÉCIS V, *supra* note 2, at 301.

5 *See generally* AMERICAN JOINT COMMITTEE ON CANCER, MANUAL FOR STAGING CANCER (1992).

6 *Id.* at 149-52.

7 For an overview of breast cancer for the nonphysician, *see generally* CHARLES B. SIMONE, BREAST HEALTH (1995); STEVE AUSTIN & CATHY HITCHCOCK, BREAST CANCER: WHAT YOU SHOULD KNOW (BUT MAY NOT BE TOLD) ABOUT PREVENTION, DIAGNOSIS, AND TREATMENT (1994).

8 Townsend, *supra* note 3, at 3.

9 PIAA Study, *supra* note 1, at 14.

10 PRÉCIS V, *supra* note 2, at 304.

11 BARBARA FOWBLE & DONNA GLOVER, Locally Advanced Breast Cancer, *in* BREAST CANCER TREATMENT: A COMPREHENSIVE GUIDE TO MANAGEMENT (Barbara Fowble ed., 1991).

12 MARC E. LIPPMAN ET AL., DIAGNOSIS AND MANAGEMENT OF BREAST CANCER (1988).

13 PIAA Study, *supra* note 1, at 8.

14 Kenneth A. Kern, *Causes of Breast Cancer Malpractice Litigation: A 20-Year Civil Court Review*, 127 ARCHIVES SURG. 542 (1992).

15 For example, a recent study of female electrical workers concluded that electromagnetic radiation may cause cancer. Dana P. Lommis et al., *Breast Cancer Mortality Among Female Electrical Workers in the United States*, 86 J. NAT'L CANCER INST. 921 (1994).

16 *See, e.g.*, Jose E. Torres & Abe Mickal, *Carcinoma of the Breast in Pregnancy*, 18 CLINICAL OBSTET. & GYNECOL. 219 (1975); Thomas T. White, *Carcinoma of the Breast Associated with Pregnancy*, 57 N.W. MED. 477 (1958).

17 *Id.*

18 PRÉCIS V, *supra* note 2, at 306.

19 PIAA Study, *supra* note 1, at 4.

20 *See generally* PIAA Study, *supra* note 1.

21 *Id.* at 4.

22 American College of Radiology, *Guidelines for Mammography*, 38 AM. CANCER REV. BULL. 6 (1982).

23 21 C.F.R. §900.1

24 To place a notice in the *ATLA Advocate*'s Networking section, call (800) 424-2725, ext. 216, or fax notice to (202) 965-0030.

25 Discussion on overcoming doubling time objections is beyond the scope of this article. For additional information regarding this topic, *see* Ronald Citron, *Late Cancer Diagnosis: The Myth of Doubling Time*, TRIAL, May 1991, at 54.

26 *See generally supra* note 12.

27 *Id.*