A Primer

Discovery of Pathology Evidence

by James M. Wood

A personal injury or disease action can be won or lost by one overlooked, and literal, item of evidence. This particular bit of evidence, a piece of tissue stored on a hospital shelf, can often definitively establish the cause of a plaintiff's injury or disease. Tissue analysis is especially important in the burgeoning field of prescription drug product litigation. Pathology tissue must be evaluated in every case if it is available.
This article details methods that will help the trial lawyer to understand, obtain, and evaluate tissue samples and reports. The initial preparation of pathology slides is described, as is the procedure for obtaining duplicate slides for a consultant’s review. Professional societies and texts are identified to help the litigator find a potential expert witness or search for relevant and helpful medical articles.

**Need for Discovery and Review of Pathology Evidence**

In many prescription product cases the cause of disease or injury is often unawed only by an evaluation of the evidence found in a pathology slide. Cases involving injuries attributed to premature birth, AIDS, DES, and vaccines demonstrate the absolute necessity for existing pathology evidence to be carefully examined.


Here is another example. Plaintiffs’ lawyers’ decision to take a DES case depended on whether they were dealing with a primary cancer of the vagina or a primary cancer of the cervix. A statistical association between the development of vaginal clear cell adenocarcinoma in a young woman and in utero exposure to DES had at one time been suggested. A case controlled epidemiological study has investigated this specific association. However, the disease was often found to be a primary cancer of the cervix. No epidemiological study has been conducted that has shown a statistically significant association with DES and cervical clear cell adenocarcinoma. While the anatomical distance between the vagina and cervix often is a matter of millimeters, the Oncology Committee of the International Federation of Gynecologists and Obstetricians defined specific guidelines to be used for the classification of vaginal and cervical cancers. These guidelines, together with an independent review of the pathology slides in a cancer case, provided counsel with an important fact to defend the case.

As a third example, a viral link to other cancers has been discovered by oncologists and experimental scientists. See, e.g., Kaufman, et al., “Herpes Simplex Virus and Human Papilloma Virus in the Development of Cervical Carcinoma,” 29 Cl. Ob. Gyn. 678 (1986); Stremlau, et al., “Human Papilloma Virus Type 16 Related DNA in an Anaplastic Carcinoma of the Lung,” 55 Cancer 1737 (1984). Because of the growing awareness that viruses are a cause of cancer, premature birth, and other physical problems, the role of virus in a case must be examined. Special training techniques or electronmicroscopy can be used by a pathologist to identify the virus. To “ask the right question” one must know the answer.

In these cases, the disease is often rare or presents a histologic pattern seldom seen by a hospital pathologist. Thus, the hospital pathology report may miss or not comment on an important clue that appears only from an examination of the tissue. The trial attorney must, therefore, look beyond the hospital pathology report when evaluating the cause of a plaintiff’s injury or disease and turn to a qualified pathologist who can help evaluate the precise nature of the condition.

**Preparation of Pathology Slides**

When human tissue such as bone, skin, or organ is removed in a biopsy or surgical procedure, it is routinely sent to the hospital pathology department or an independent pathology laboratory. The gross tissue specimen is first processed, with the tissue embedded in a paraffin wax block. A micron-thin slice of tissue is cut from the block. This tissue slice, which is approximately one-tenth the thickness of a piece of paper, is laid upon a glass slide, stained, and examined through a microscope. From a typical gross tissue specimen, literally thousands of slides can be prepared.

After the initial slide is prepared, the remaining tissue block is saved so that additional slides can be prepared if needed. Pathologists frequently mail slides to each other for “second opinions,” but generally the primary pathologist always keeps the best slides as a matter of routine. The duplicate slides are cut from the wax tissue block in the same manner as the original slides.

However, evidence of the disease that is seen in the original slide may not be observed in the recut slides or only show up on a recut. An example of this is cancer. Malignant cells may be apparent in the original slide. However, because the cancer may not have invaded the next tissue layer, the cancer may not be seen in a recut slide. More importantly, if biopsy or surgical material is selected that discloses only clean tissue, the next section may show the presence of cancer. If there is ever any doubt as to the correctness of an interpretation of the recut slides, the original slides must always be reviewed.

To verify the original pathologist’s diagnosis in any case, it is important that the consulting pathologist be permitted to review and to analyze the original tissue slides and to inspect a sufficient number of additional slides, including performing additional special stains as indicated.

Staining and preparation of pathology

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Here is a compilation of resources to which the defense attorney can turn in learning more about pathology (and other medical fields) and understanding specific diseases or injuries, as well as finding specialists who can serve as consultants.

The list is from Medline Plus Health Information, http://www.nlm.nih.gov/medlineplus/databases.html. Each citation on this site is linked to the specific website.

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**Pathology Resources**

The College of American Pathologists has prepared a guide to understanding the categories in a pathology report. See http://www.cap.org/apps/docs/fact_sheets/pathrep.htm. The elements of the report described are the gross description, the microscopic description, the diagnosis and, if there is a malignancy, the tumor size and the tumor stage.

When the defense attorney decides that a pathology consultant should be retained, in searching for such a consultant he or she must remember that, like all other medical sciences, pathology has developed many subspecialties. He must become thoroughly familiar with the literature that describes the specific diseases, and he must consult with the appropriate subspecialists. The American Board of Pathology, Inc. recognizes such subspecialties as dermopathology, forensic pathology, hematology, immunopathology, medical microbiology, neuropathology, and radiosotopic pathology.

The American Board of Pathology is an important source for identifying potential consultants and experts. The mailing address of the Board is: Lincoln Center, 5401 West Boulevard, P.O. Box 25915, Tampa, Florida, 33622. Pathology departments at major medical schools or teaching hospitals are another fruitful source in finding specialists.

**MEDLINE Search** (National Library of Medicine): Access to more than 11 million references to articles published in 4,300 biomedical journals. Enter what you are looking for in the box at the top of the screen. http://www.ncbi.nlm.nih.gov/pubmed/

**NIH Consensus Statements** (National Institutes of Health): Provides reports from major conferences that produce consensus statements and technology assessment statements on controversial issues in medicine important to health care providers, patients, and the general public. http://consensus.nih.gov/


**Databases on the Food and Drug Administration Web site** (Food and Drug Administration): Latest regulatory information on food, drugs, biologics, cosmetics, medical devices, and radiological health. http://www.fda.gov/search/databases.html

**National Ag Safety Database** (National Institute for Occupational Safety and Health): http://www.cdc.gov/niosh/nasd.html


**Merck Manual** (Merck & Co., Inc.): http://www.merck.com/mrkshared/mmmanual/home.jsp


**National Rehabilitation Information Center** (National Institute on Disability and Rehabilitation Research): http://www.naric.com/search/

**Vaccine Info Database** (Vaccine Disease Information; State Vaccine Requirements for School Entry) (National Network for Immunization Information): http://www.immunizationinfo.org/search/index.cfm

**Virtual Hospital** (an on-line health sciences library created at the University of Iowa): http://www.vh.org
Pathology texts published from 1994 through 1999 continue to be valuable sources of information for the defense attorney wishing to learn more about pathology. The variety of resources listed above are collected and reviewed, and a consultant retained, counsel is well on the way to thoroughly identifying a cause of a plaintiff’s injuries or disease.

Compelling Hospitals and Laboratories to Release Pathology Evidence

In virtually any type of discovery proceeding, lawyers will try to prevent their opponents from obtaining important bits of evidence. Litigation involving pathology is no exception. The most common obstructive behavior in this type of litigation is the attempt to prevent opposing counsel from obtaining the original or recuts of the original pathology slides. As is often the case with portions of medical records, counsel may claim that the pathology slides are protected from review by rights of privacy or privilege. These objections can be effectively rebutted.

First, courts generally accept the relevancy and discoverability of pathology evidence. Oklahoma City v. Alvarado, 523 P.2d 1073

Courts have recognized the importance of a defendant’s independent access to pathology evidence. In Schindler v. Superior Court, 161 Cal.App.2d 513, 520, 327 P.2d 68, 73 (1958) (disapproved on other grounds in People v. Garner, 57 Cal.2d 135, 18 Cal.Rptr. 40, 44 (1961)), defendants in a murder case moved to obtain release of decedent’s tissue specimens for their pathologist’s analysis:

It may be that an independent examination of these specimens by another qualified pathologist may indicate that the death of the child was not due to the blows received, or at least may tend to refute that conclusion reached by the autopsy surgeon. These samples and specimens therefore should be made available to the petitioners.

Courts in other jurisdictions have also noted the direct relationship between access to pathologic evidence and fairness. Harrison v. State, 635 So.2d 894 (Miss. 1994) (failure to allow defendant access to pathologist and pathology evidence violated due process and was fundamentally unfair in criminal case); Deason v. State, 84 S.W.3d 793, 796 (2002) (a pathologist is necessary in a capital murder case to ensure a fair trial).

Second, many jurisdictions provide that the filing of the lawsuit constitutes a waiver of the privilege as to the injury involved in the case. The pathology evidence thus becomes discoverable. See, e.g., California Evidence Code, section 996; Annot., “Commencing Action Involving Physical Condition of Plaintiff or Decedent as Waiving Physician-Patient Privilege as to Discovery Proceedings,” 21 A.L.R.3d 912 (1968); and 81 Am.Jur.2d Witnesses §270. In other instances a motion may be required to have the court expressly determine that a privilege has been waived.

Once claims of privacy and relevance are overcome, defense counsel may next assert that the defense is entitled to the report of the pathologist consultant. A claim by the plaintiff that the examination of the pathology slides constitutes an “independent medical examination” must be rebutted, as well as an argument that unlike medical records, a review of the pathology slides is in fact a physical examination of a party. See, e.g., California Code of Civil Procedure, section 2032, and Rule 35 of the Federal Rules of Civil Procedure.

These arguments also can be defeated. First, the pathology evidence is existing physical evidence and is in fact no different than a discoverable X-ray or a medical record. Second, a plaintiff’s privacy will not be intruded upon nor will he or she be examined when the slides are reviewed through a microscope. Most of the statutes involved in an independent physical examination apply only where the plaintiff is required to submit to a medical examination by a physician. Third, the identities and opinions of a defendant’s confidential pathology consultants are protected from disclosure under the work product doctrine. See, e.g., South Tahoe Public Utility District v. Superior Court (CH2M Hill California, Inc.), 90 Cal.App.3d 135, 154 Cal.Rptr. 1 (1979). A defendant’s right to pretrial preparation includes the right to retain a consultant to examine existing physical evidence and to render a report which is protected from disclosure until the consultant is designated as a trial witness. Scotsman Manufacturing Co. v. Superior Court (Roberts Brass Manufacturing Co.), 242 Cal. App.2d 527, 51 Cal.Rptr. 511 (1966); Annot., “Pretrial Discovery of Facts Known and Opinions Held by Opponent’s Experts Under Rule 26(b)(4) of Federal Rules of Civil Procedure,” 39 A.L.R. Fed. 403 (1977); Annot.,

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nature of pathology slides, it is also recommended that the slides not be placed in the mail but be personally handled throughout the time that they are being reviewed.

Once the slides are received the practitioner must next retain a qualified specialist. Conclusion
The pathology evidence in a personal injury case must never be overlooked. When obtained during pretrial discovery the pathology slides can provide critical and often outcome-determinative evidence of the cause of a plaintiff’s injuries. Careful preparation includes accessing the resources available to understand the pathology evidence in a case, identifying the appropriate expert, and obtaining access to the slides through the court.

Proposed Stipulation for the Release of Pathology Slides

SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

ROBERT SMITH, ) No. AB 1234

Plaintiffs,

vs.

XYZ COMPANY, a corporation, et al. )

Defendants.

Plaintiff Robert Smith and XYZ Company, a corporation, through their respective attorneys of record stipulate as follows:

Upon request by Smith, Jones & Brown, Professional Corporation (“SJ&B”), attorneys for Defendant XYZ Company, the Custodian of Pathology of the following institution is authorized to release and transfer in the manner described in paragraph 4 below, any and all pathology slides of the plaintiff, as identified in the following Pathology Report (copy attached).


2. The pathologist at this hospital or laboratory is authorized to prepare up to five (5) additional slides (hereinafter referred to as “new slides”) from the tissue blocks prepared after surgery,
biopsy, or other procedure. Upon request by SJ&B, the Custodian of Pathology is authorized to release and transfer the new slides in the manner described in paragraph 4, below.

3. After obtaining custody of the new slides, SJ&B, or its designated representative, shall be permitted to retain custody of the new slides. If necessary, SJ&B will designate an individual to receive and review the new slides on behalf of XYZ. The identity and address of any such individual shall be subject to the confidentiality provisions of paragraph 5, below.

4. The new slides shall be transferred from the Custodian of Pathology to SJ&B, or its designated representative, by either of the following methods:
   a. They may be mailed by registered or certified mail directly to an individual designated in accordance with paragraph 3; or
   b. They may be transferred to SJ&B, or to its designated representative(s).

5: Confidentiality. If an individual is designated by SJ&B to receive and review the new slides referred to in paragraphs 1 and 2 on their behalf, and the name and address of that individual are disclosed to the appropriate Custodian of Pathology to permit the mailing of the slides in accordance with paragraph 4(a), the name and address of the designated individual shall be held in strict confidence by the Custodian of Pathology and shall not be disclosed to any other party, or its attorneys or representative(s).


By: ____________________________
    Attorneys for Plaintiff


By: ____________________________
    Attorneys for Defendant

IT IS SO ORDERED.


By: ____________________________
    JUDGE OF THE SUPERIOR COURT