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AALNC

AMERICAN ASSOCIATION OF LEGAL NURSE CONSULTANTS

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The Journal of Legal Nurse Consulting

Purpose

The purpose of the journal is to promote legal nurse consulting within the medical-legal community; to provide both novice and experienced legal nurse consultants (LNCs) with a quality professional publication; and to teach and inform LNCs about clinical practice, current legal issues, and professional development.

Manuscript Submission

The journal accepts original articles, case studies, letters, and research. Query letters are welcomed but not required. Material must be original and never published before. A manuscript should be submitted with the understanding that it is not being sent to any other journal simultaneously. Manuscripts should be addressed to JLNC@aalnc.org.

Manuscript Review Process

Submissions are peer-reviewed by eminent professional LNCs with diverse professional backgrounds. Manuscript assistance can be provided upon request to the editor. Acceptance is based on the quality of the material and its importance to the audience.

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Features

Departments

Networking

It was great seeing my colleagues again from all over the country and meeting new members at the 17th National Educational Conference in Atlanta. We have an amazing membership of talented, educated, and experienced nurses. The outstanding benefit for me is the networking, collaboration, and support, both at the national level and within the local chapters. I just wish you all lived nearer to me so we could network even more. In a profession where "nurses eat their young," I was proud to observe our seasoned members taking the time to answer questions from the "newbies" or giving them their business cards with the offer to call or e-mail them with any other questions or for assistance and mentoring.

Betsy Turner, from Greenville, South Carolina, confirmed my thoughts when she e-mailed Headquarters to "thank all of you who worked on the National Conference in Atlanta. I only attended one day, and quite frankly that was a lot of information to process. I was so glad I joined your professional organization. Even though I am new to the profession, I was so impressed by the nurturing of all those I met. I would be happy to recommend your conference to all my colleagues (of course I don't have any, but after attending your conference, I feel sure I will get some). Your work team was so well organized and helpful." So now I challenge the new generation to continue paying forward this tradition.

Kevin Davidson, MSN RN, a nurse paralegal and consultant from Arizona, also e-mailed Headquarters about the Winter 2006 issue. He wrote, "I was delighted to read the excellent Q&A regarding: Nurse Paralegal/Legal Nurse Consultant: Similar Work Product... I wanted to congratulate you on a fine journal, and please pass along my compliments to the authors." Thank you Betsy and Kevin for your kind words.

We also received feedback about the mistake on the cover of the Winter issue. Being good legal nurse consultants with attention to detail, readers noticed "Bloodless Care" listed as a featured article, then scoured the pages in search of it. Our efficient production staff members at Headquarters were ahead of themselves by one issue. We apologize for the error and are pleased to present Kathleen Yhlen's and Kathleen Ashton's article in this issue.

Vaccines are intended to protect those who are vulnerable, especially our infants and children. The Centers for Disease Control and the American Academy of Pediatrics periodically update the recommended immunization schedules, and the pharmaceutical companies continue to develop combinations of vaccines to decrease the number of injections. Adversity accompanies any intervention, however, and Liz Holakiewicz describes the importance of the life care plan when an injury results from a vaccine.

Similarly, it is only the beginning of what could be a long history with the hundreds of pending Vioxx® cases. At the time of this writing, only one trial has resulted in favor of the plaintiff and two for the defending manufacturer, Merck. Debra Pritts presented at the 17th National Educational Conference the Legal Nurse Consultant's role in a pharmaceutical case and follows up with her article. To complete the topic, the Pittsburgh Chapter Board of Directors granted permission to reprint Melanie Donati's defense article, which was published in the chapter's newsletter.

In the Questions & Answers column, Greater Baltimore Chapter member Molly Feliciano analyses the types of certifications, which might be particularly interesting for new members. Finally, Eileen Croke reviews a book that should be in every consultant's library, and it is one of the references in a future article.

Until we meet again, keep on networking and submitting articles to The Journal.

Holly Hillman

Holly Hillman, MSN RN
Editor, *The Journal of Legal Nurse Consulting*

Bloodless Care: When Blood Transfusion Is Not an Option

Kathleen Yhlen, BSN CNA CAN & Kathleen Ashton, PhD APRN BC

KEY WORDS
Bloodless Care, Blood Transfusion, Jehovah's Witnesses

As a means of respecting the diversity of patients, as well as their differing religious beliefs and medical preferences, hospitals around the country have formalized bloodless care programs to offer patients alternatives to blood transfusions when making health care decisions. Bloodless care is the strategy of delivering high quality patient care while minimizing blood loss and eliminating the use of blood transfusions.

Reasons for choosing bloodless care vary with each individual. Historically, the Jehovah's Witnesses community was the driving force that led hospitals to create these types of programs, and these patients are still the majority who do not accept transfusions of blood. Jehovah's Witnesses interpret the Bible literally and refuse blood products based on biblical passages. According to Smith (1997), Jehovah's Witnesses believe that once blood has left the body it may not be returned; violation can lead to loss of eternal life. More recently, Cogliano and Kisner (2002) suggested that even patients who do not have religious reasons for refusing blood transfusions are also looking for alternatives due to shortages in the nation's blood supply, transfusion reactions, medical errors, and fear of disease transmission. Risks of blood transfusion may include, but are not limited to, transmission of viral infections such as HIV or hepatitis, bacterial infections, immune or allergic reactions, and problems caused by human error (Spiess, 2004).

Regardless of their reasons for refusing blood, patients need to be knowledgeable about alternatives to transfusions when making health care decisions. Michael (2002) stated that competent adults have the right to refuse medical care based on constitutional law, which grants the right to privacy and religious freedom, and common law, which guarantees the right to self-determination. Patients need to be informed about their conditions and treatment options, including the risks and benefits of planned treatment.

Responding to Demand: Introducing a Bloodless Care Program

Cooper University Hospital in Camden, New Jersey, formalized a bloodless care program in 1997 in response to consumer demand. The goal of the program is to respect patients' wishes in a consistent manner. Cooper University Hospital named a nurse coordinator to develop and manage the first and only bloodless care program of its kind in southern New Jersey. The program assists with referrals, consent forms, advanced directives, education, and follow-up care. A multidisciplinary team was established to create a seamless program to give patients, families, and hospital staff the security that patients' wishes would be respected. The team consists of physicians, nurses, and representatives from risk management, blood bank, perfusion, admissions, pharmacy, pastoral care, and patient relations. After a year of planning and education, the Bloodless Care Team developed patient guidelines, a bloodless care consent form (Figure 1), chart identification labels, a referral phone number, a nursing consult mechanism in the hospital's computer information system, and written educational information for the patients and their families.

Figure 1: Bloodless Care Consent Form.

BLOOD DIRECTIVE

I _____ hereby state that I REFUSE to have major blood products (whole blood, red cells, white cells, platelets and plasma) administered to me.

With respect to minor blood fractions or products containing minor blood fractions,
I ACCEPT: [please initial the appropriate line(s)

_____ a. NONE
_____ b. ALL
c. SOME (Those that I have initialed below)
_____1. Albumin
_____2. Human derived clotting factors (such as Factors VII, VIII, IX, XII)
_____3. Recombinant clotting factors (manufactured without using blood)
_____4. Immune Globulins (such as Rh immune globulin, gamma globulin, horse serum, snake bite antivenins)
_____5. Products that may contain small amounts of albumin (such as Erythropoietin, Streptokinase, Interferon, and some radio nuclide preparations)
_____6. Cryoprecipitate Antihemophilic Factor
_____7. Other _____

1) I understand that I have been hospitalized primarily for _____ (List condition or name of procedure)
and that my illness, my planned procedures and/or unexpected complications or emergencies may lead my doctor(s) to believe that I need to receive major blood products and/or minor blood fractions. I UNDERSTAND THAT MY REFUSAL TO ACCEPT MAJOR BLOOD PRODUCTS AND/OR MINOR BLOOD FRACTIONS, IF ANY PHYSICIAN DETERMINES THAT I NEED THEM, COULD CAUSE ME TO GO INTO SHOCK OR A COMA, SUFFER OTHER VERY SERIOUS HARM, OR EVEN DIE.

2) I have considered the potential benefits of the administration of major blood products and minor blood fractions, and I have fully thought about the possible consequences of refusing the administration of major blood products and/or minor blood fractions. I hereby REFUSE THE ADMINISTRATION OF MAJOR BLOOD PRODUCTS AND/OR MINOR BLOOD FRACTIONS EXCEPT FOR THOSE ACCEPTED AND INITIALED ABOVE UNDER ANY AND ALL CIRCUMSTANCES, EVEN FOR EMERGENCIES OR COMPLICATIONS THAT CANNOT BE ANTICIPATED OR PREDICTED AT THE PRESENT TIME, AND EVEN IF I COULD BE SAVED IF THE MAJOR BLOOD PRODUCTS AND/OR MINOR BLOOD FRACTIONS WERE ADMINISTERED TO ME.

3) I hereby release Cooper University Hospital and any and all physicians or other persons involved in my care or treatment from any and all liability from any harm that may come to me as a result of the failure to administer major blood products and/or minor blood fractions to me, including, without limitation, any claims for wrongful death.

4) If I have accepted the administration of any minor blood fractions the risks of the administration have been fully explained to me including the potential of a serious or even fatal reaction. I have also been advised of the possibility that I could contract a serious and/or potentially fatal disease, specifically serum hepatitis, AIDS, and West Nile Virus from the administration of some minor blood fractions. I understand, however, that the blood products used at Cooper are procured from sources that test for the presence of hepatitis B, West Nile Virus and the virus that causes AIDS, so that the risk of transmission of these diseases through the administration are low compared to the risk of serious injury or death if a needed blood product is not given to me.

5) I have signed this form freely, voluntarily, and without any pressure from anyone. I fully understand the consequences of my refusal. I have adequate information to make this decision, and all questions I have asked have been fully answered to my satisfaction.

_____ (Date/Time)
Signature of Patient (or Legal Authorized Representative)

_____ (Date/Time)
Witness (as to signature only)

_____ (Date/Time)
Signature of Informing Physician

The nurse coordinator is responsible for the overall management and coordination of the program. The coordinator acts as a liaison between patient, family, and staff by providing education, facilitating referrals, collecting statistics, coordinating multidisciplinary team meetings, and offering consultation services. The nurse coordinator refers patients to the appropriate physician and often facilitates the transfer of patients from other health care facilities. Once the patient is admitted, the nurse coordinator is consulted to visit with the patient and family to educate them about the alternatives to transfusion and make the appropriate recommendations for their care regarding their refusal of blood products. The patient is asked to sign a "blood directive," a specific type of consent form that allows the patient to refuse blood products. The blood directive is placed in the patient's chart. In addition, the nurse coordinator educates physicians, nurses, and other health care providers regarding the alternatives to blood transfusion in order to develop an appropriate plan of care for the patient.

Since the inception of the program, various issues have surfaced. One situation involved a physician who did not understand why the patient was refusing a blood transfusion in a very critical situation. The nurse coordinator intervened on behalf of the patient and family to educate the physician about the alternatives that the patient might accept. In another situation, a nurse was carefully and respectfully explaining to a patient who had refused a transfusion that she might recuperate more quickly if she would consider accepting a transfusion. When the coordinator encounters situations like this, she provides support and education for nurses to effectively care for patients who decline blood. The goal is to enable nurses to provide education, to be sensitive to patients' wishes, and to support their decisions.

Educating nurses and physicians is vital to the success of the program. Because of an increasing number of women requesting bloodless care when giving birth, the nurse coordinator of the program presented an educational seminar for obstetricians and gynecologists. As a result, the information discussed at the seminar and an increase in awareness of the program, the number of consults for bloodless care increased.

Strategies to Reduce Transfusions

All health care facilities have the capability of providing bloodless care to some extent. Approaches to bloodless care include a variety of strategies and techniques that may dramatically reduce the need for blood transfusions. First, a comprehensive evaluation of the patient is needed to determine the most appropriate alternatives to blood transfusion. Aggressive treatment is another critical strategy. All measures should be taken to stop bleeding as soon as possible and not take a "wait-and-see" approach. Noninvasive and minimally invasive techniques such as lasers, endoscopy, and interventional radiology also help to drastically reduce blood loss. Next, eliminating all unnecessary phlebotomy and the use of micro-containers to evaluate blood samples conserves the patient's own blood supply (Waters, 2004). The use of pharmacologic agents helps to rebuild one's own blood supply. Finally, encouraging the patient to provide a copy of his or her advanced directive and signing consent forms allow the medical team to develop an individualized plan of care.

Advances in technology benefit patients who refuse blood. One example is the use of a cell saver, a device that collects shed blood during surgery and re-infuses it to the patient (Waters, 2004). Other devices available are a harmonic scalpel that uses vibration to cut and cauterize at the same time, electrocautery, and lasers to minimize blood loss during surgery.

Other alternatives include pre-operative autologous blood donation. While not acceptable to all patients, this technique enables patients to pre-donate their own blood prior to surgery. The blood is then available, if necessary, during the procedure. While limited to elective procedures, this technique is gaining popularity.

According to Ford and Mastoris (2004), pharmaceutical agents play an important role in bloodless care. For example, epoetin alfa is a drug that stimulates the bone marrow to produce red blood cells. The issue with this medication is that it is prepared with a small amount of albumin, a minor blood fraction, so patients must consent to its use. The use of iron, folic acid, and multivitamins are also prescribed to support red blood cell production.

The Patient's Role

Patients themselves play a major role in the bloodless care program. They are encouraged to seek treatment as early as possible, find a physician who will comply with their wishes, discuss their treatment options with health care providers, and complete an advanced directive. Cooper University Hospital patients are asked to sign a bloodless care consent form. This consent allows the patient to refuse major blood products (whole blood, white cells, red cells, platelets, and plasma) and to accept minor blood fractions (albumin, clotting factors, and immune globulins) if it is in accord with their beliefs.

It is important to keep in mind that the bloodless care consent form implies certain intentions. Patients are aware that refusing to accept blood transfusions of any kind might impede and/or endanger their lives and that, regardless of this, they release the hospital, nurses, other employees, and all physicians associated with their care from any liability for respecting their wishes.

Patients retain a right to standard medical care. They have no objection to medical care in general and do not willingly accept death or disability. The refusal of blood is not the exercise of the right to die. Patients are simply seeking good medical care without blood.

Legal issues that can arise include but are not limited to the care of minors. Parents are educated about the legal constraints on the physicians if the life of a minor is at risk. The physician may seek a court order to transfuse blood products if all alternatives to transfusion are exhausted. The

court order is usually just for the administration of blood products. In this situation, if time allows, a family conference is coordinated with the health care team to discuss the plan of care. If there is an emergency, two licensed physicians may document that there is a life-threatening situation and a blood transfusion may be administered.

Advanced directives play an important role when the families' wishes are not the same as those of the patient. Patients are encouraged to complete advanced directives, a copy of which is placed in their charts. Advanced directives empower the patient to choose or decline medical care. All questions and concerns need to be addressed.

The Educator's Responsibility

It is the responsibility of health care providers to ensure that patients are making informed decisions. Informed consent involves educating patients about their plan of care, including the risks and benefits of the proposed treatments.

Respecting the diversity of patients and their families is an important goal. Just as no two patients are alike, each patient's diagnosis and treatment options are different. It is important to educate patients, families, and health care professionals about the alternatives to blood transfusion. Nurses play an increasingly important role in informing the public of available options and assuring that patients' wishes are respected when receiving care.

Legal nurse consultants (LNC) share in the role of educators, specifically regarding the legal community. The LNC interprets the wishes of the patient in deciding against blood transfusions when working with attorneys and juries. Explaining the concept of bloodless care to attorneys can assist in examining a case for merit. A case may turn on the issue of self-determination.

Most important in reviewing cases is to determine the presence of detailed documentation of the patient's decision and the education leading up to it. There should be evidence through documentation that the nurse presented all alternatives to the patient and the family, and that the nurse ensured that the patient and family understood the available options.

Although patients essentially release providers from liability for respecting their wishes, bloodless care programs pose a lawsuit risk. When outcomes are not as expected, patients—or their families—may point a finger at the medical or nursing staff. The LNC plays an important role in separating the facts of the case and measuring the care provided against the standards of care.

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The Life Care Plan and the Vaccine Injury Compensation Program

Liz Holakiewicz, RN BSN CCM CNLCP

KEY WORDS
Life Care Plan, Vaccine Injury Compensation Program

The life care plan is now utilized and endorsed as a damages tool within a variety of settings: civil litigation (personal injury and medical malpractice); reserve setting by insurance companies; managed care, workers' compensation, facility discharge planning, estate planning, and trust management; and the Vaccine Injury Compensation Program (VICP). In perhaps a lesser-known venue, the U.S. Court of Federal Claims obtains the information necessary to establish a VICP award by utilizing a life care plan, presented by both the petitioner (injured party) and respondent (U.S. Department of Health and Human Services represented by the U.S. Department of Justice), or, on occasion, an agreed-upon, single life care planner. In the VICP setting, the life care planner's role, as allowed by the Special Master, is adaptable, open, and supportive to the goal of "…a swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation" (Office of Special Masters Homepage, 2005).

Today, childhood vaccines protect against 11 diseases. Smallpox has been eradicated in the United States, and the last indigenous transmission of wild poliovirus in the U.S. occurred in 1979. According to the 2003 National Immunization Survey, more than 93% of children 19 to 35 months of age in all races received three or more doses of any diphtheria, tetanus toxoid, and pertussis (DPT) vaccines (Morbidity Mortality Weekly, 2004).

In the early 1980s, the safety of the DPT vaccine was called into question, as harmful side effects from the vaccine began to evidence themselves. Lawsuits were filed against the vaccine manufacturers and the health care providers administering the vaccines, and vaccination rates declined. Companies producing the vaccines began to leave the marketplace, causing a shortage in the vaccine supply and culminating in a serious potential threat to the nation's health.

In response to this impending public health issue, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) and subsequently created the Vaccine Injury Compensation Program (VICP) in October 1988. The Vaccine Act protected vaccine manufacturers and health care providers from liability and stabilized the vaccine market. Additionally, an adverse event reporting system was developed as a component of the Vaccine Act, to facilitate the research and development of newer and safer vaccinations.

Covered Vaccines

The VICP was designed as a no-fault system to resolve vaccine injury claims and to compensate those injured as a result of vaccinations recommended by the Centers for Disease Control (CDC). According to the Department of Health and Human Services (HHS), vaccines currently covered under the VICP are: diphtheria, tetanus, pertussis, (DTP, DTaP, DT, TT, or Td), measles, mumps, rubella (MMR or any components), polio (OPV or IPV), hepatitis B, Haemophilus influenzae type b, varicella (chicken pox), rotavirus, pneumococcal conjugate, and hepatitis A (Fact Sheet, 2005), whether administered alone or in combination.

On December 1, 2004, hepatitis A was added to the Vaccine Injury Table under Category XIV. Trivalent Influenza vaccines were added to this same category, effective July 1, 2005 (Table 1). Anthrax and smallpox vaccines are not covered under VICP. If injury or death results from the administration of one of the covered vaccines, the individual, a parent, guardian, or a trustee on behalf of a child or incapacitated person can file a claim/petition for compensation.

The escalating incidence of autism and its alleged relationship to Thimerosal, the mercury preservative in vaccines, has been hotly debated in the medical literature and in the news, as recently as June 2005 in Gardiner and O'Connor's *On Autism's Cause, It's Parents v. Research* (Gardiner and O'Connor, 2005). The VICP saw a dramatic increase in petitions, from 18 to 768, alleging this relationship between 2001 and 2002, and peaking in 2003 with 2,438 petitions filed (Post-1988 Monthly Statistics Report, 2005). The Court consequently established a special procedure for dealing with claims that allege vaccines or Thimerosal cause child autism or a similar disorder. The "Omnibus Autism Proceeding" essentially groups autism claims together (Autism Update, 2005).

VICP Claims Process

The process of claims resolution through the VICP is intended to be less adversarial and more efficient than a civil lawsuit. The HHS, the U. S. Court of Federal Claims (Court) and the U. S. Department of Justice (DOJ) co-administer the program. The claims process follows this course:

1. File a petition for compensation with the Court and with the Secretary of HHS identified as defendant.
2. The VICP/HHS physician reviews the petition to determine whether it meets the medical criteria for compensation and makes a recommendation on compensability.

3. The HHS physician recommendation is provided to the Court through a report filed by the DOJ, although it is not binding.
4. A DOJ attorney represents the HHS position in hearings before a "Special Master" who makes the initial decision for compensation under the VICP. The Court appoints Special Masters. The Office of Special Masters consists of one chief and five associates who are appointed for four-year terms. The Special Master is responsible for conducting all proceedings,

   > …including requiring such evidence as may be appropriate, in order to prepare a decision, including findings of fact and conclusions of law, determining whether an award of compensation should be made under the Vaccine Act and the amount of any such award. The Special Master shall determine the nature of the proceedings expeditious, flexible and less adversarial while at the same time affording each party and full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision [sic] (Vaccine Rules, 2002).

5. Decisions by the Special Master may be appealed to a judge of the Court, then to the Federal Circuit Court of Appeals, and then finally to the Supreme Court.

The Rules of the Court are very specific and must be strictly followed throughout the process. Though an attorney is not required, one may be advisable. The Vaccine Act does provide for recovery of reasonable attorney fees and costs.

Compensation through VICP

In order to qualify for compensation through the VICP, it must be proved that: (a) an injury found on the Vaccine Injury Table (Table 1) occurred; or (b) the vaccine caused the condition; or (c) the vaccine significantly aggravated a pre-existing condition.

Table 1: The Vaccine Injury Table, effective 12/1/04 and modified w/ 7/1/05 update.

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (e.g., DTaP, DTP-Hib, DT; Td, or TT)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Brachial neuritis	2-28 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	0-72 hours
	C. Any acute complication or sequela (including death) of above events	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	5-15 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days
	B. Any acute complication or sequela (including death) of above even	Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	0-6 months
	C. Any acute complication or sequela (including death) of above events	Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio	
	— in a non-immunodeficient recipient	0-30 days
	— in an immunodeficient recipient	0-6 months
	— in a vaccine-associated community case	Not applicable
	B. Vaccine-strain polio viral infection	
	— in a non-immunodeficient recipient	0-30 days
	— in an immunodeficient recipient	0-6 months
	— in a vaccine-associated community case	Not applicable
	C. Any acute complication or sequela (including death) of above events 4	Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
VIII. Hepatitis B antigen- containing vaccines	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines)	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Vaccines containing live, oral, rhesus-based rotavirus	A. Intussusception	0-30 days
	B. Any acute complication or sequela (including death) of above event	Not applicable
XIII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIV. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage.—see b, c below	A. No condition specified for compensation	Not applicable

b On December 1, 2004, the Secretary published a notice in the Federal Register announcing the addition of hepatitis A Vaccines to the Vaccine Injury Table under Category XIV with an effective date of December 1, 2004. (69 Fed. Reg. 69945-46 (December 1, 2004)).

c On April 12, 2005, the Secretary published a notice in the Federal Register announcing the addition of Trivalent Influenza Vaccines to the Vaccine Injury Table under Category XIV with an effective date of July 1, 2005 (70 Fed. Reg. 19092-19093 (April 12, 2005)).

In the VICP, compensation may be awarded for vaccine-related death or injury. These awards are funded from a trust fund created by an excise tax of $.75 on every dose of covered vaccine that is purchased, if the vaccine was administered on or after October 1, 1988 (How is VICP Funded?, 2005). For a vaccine-related death, an award of up to $250,000 may be provided to the estate of the deceased if the claim is filed per instructions and time guidelines. Within 36 months after the first symptoms from a vaccine appear, the Vaccine Act indicates that a claim can be filed for vaccine-related injury (Guidelines & VICP Compensation, 2004). The symptoms must have lasted for at least 6 months after the vaccine administration, or the injury must have resulted in inpatient hospitalization and surgical intervention. Reasonable compensation for past and future "nonreimbursable" [sic] medical, custodial and rehabilitative costs, $250,000 (cap) for actual and projected pain and suffering, lost earnings, and attorney fees and costs may be awarded for vaccine injury. Should a claim be determined non-compensable by the VICP, or the award be rejected, the petitioner still has the option to sue the vaccine administrator or manufacturer.

Statistics from the Health Resources and Services Vaccine Injury Compensation Program indicate that awards have ranged up to $9.13 million but average $974,393 (Post 1988- Monthly Statistics Report, 2005). The range of awards is influenced by diagnosis, but specifically by the services included in an individual plan. The need for ongoing supportive or nursing care is one of the largest dollar figures in any life care plan. For instance, the need for 6-8 hours of daily attendant care, at $16.50/hour, amounts to $42, 157 per year. Over a 20- to 30-year life expectancy, this attendant care alone totals $1,053,957. As a point of comparison, physician care—though higher-priced per unit—is not required at the same frequency and regularity and, consequently, represents a lower annual and lifetime figure in the life care plan. Quarterly visits with a physiatrist (at $100/visit) amount to an annual figure of $400, which for the same 20- to 30-year life expectancy translates to $10,000. Injuries such as autism, paralytic polio (Table 1, Item VI-A), and encephalitis (Table 1, Item III-B) are examples of vaccine injuries that may warrant the need for attendant care or nursing services. Conversely, a brachial neuritis from a tetanus vaccine (Table 1, Item I-B) may result in a loss of function in the affected extremity, requiring intensive acute care and treatment, but later resolve to require some adaptive aids, housekeeping assistance with aging, and periodic physician follow up: roughly $3,000 a year, or $75,000 for the same 20-30 year life expectancy previously mentioned.

The Life Care Plan

The life care planner's role in the VICP setting, as in the civil litigation environment, is to aid in assessing damages and establishing the level of compensation necessary for an injured individual. The VICP, Office of Special Masters Damage Order defines the damages process and specifically mentions, "In Vaccine Act cases, damages issues are typically resolved by a process in which petitioner, begins by obtaining a 'Life Care Plan' that sets forth petitioner's future needs" (Damages Order, 1997).

> A life care plan is a dynamic document based upon published standards of practice, comprehensive assessment, data analysis and research, which provides an organized, concise plan for current and future needs with associated costs, for individuals who have experienced catastrophic injury or have chronic health care needs (Weed, 2004).

Through review of pertinent medical records, direct assessment and observation of the petitioner, and collaboration with treatment providers and experts, the life care planner identifies and researches recommended services or equipment required for the individual, when such services or equipment are required, and for how long. Subsequently, the cost and cost sources are researched and identified. Though not all-inclusive, common categories of need outlined in a life care plan include: physician care, therapy, counseling, medications, diagnostic testing, durable medical equipment, supplies, home modifications, transportation needs, residential/attendant care, future surgeries or procedures, and potential complications.

In other settings, the rationale and basis for each of the life care planner's recommendations are typically attained through expert deposition or trial testimony. In the absence of expert testimony, the VICP life care plan must clearly define these details, as well as the manner in which the costs were attained. The Office of Special Masters Damage Order specifies the details required in the life care plan. Background information on the injured person includes the sources of information used to determine the level of care: conversations with the family, past level of care, physician recommendations, and school assessments. The current treatment plan is documented, and, if future care recommendations differ from the current treatment plan, the rationale for those recommendations is clarified in the report.

Documenting Care Options

Residential and attendant care recommendations in the VICP life care plan are accompanied by a thorough explanation as to how the level of care was determined for a particular individual and why that level of care is necessary. For nurse life care planners, determining this level of care is multi-factoral. The nursing process is utilized to assess an individual through medical record review, direct client interview and observation, and contact with the current care providers or expert physicians. Specifics about the individual's need for assistance with activities of daily living, hygiene, medication administration, behavior management, safety needs, and skilled nursing tasks are thus determined, and the appropriate nursing diagnosis assigned. The family's preferences regarding who provides the care and where care is provided are also taken into consideration. Attendant or nursing care hours are delineated in the plan, with specifics

about potential care providers. The number of care hours is determined by assessing the number of tasks, the time entailed in each task, the timing of the task during a given day, the availability of services within a geographic area, and the potential restrictions imposed in the community by agencies as to minimum number of hours. Finally, the skill level is determined by interpreting these issues within the confines of the nurse practice act and community care legislation of an individual state.

If residential care is recommended, a list of local residential care facilities providing the recommended level of care is noted with price, and details of the services are included for the noted price. Additionally, the life care planner must provide documentation of the specific dialogue used to identify the injured party to the facility, so it is clear that the level of care and cost has been accurately defined. This is necessary because disputes about facility care have typically centered on the issue of the descriptive information provided to the facility to establish the level of care (Damages Order, 1997). For instance, a recommendation for a low-cost facility that does not offer the intensity of care needed for the disabled individual could result in such a circumstance. If a facility is rejected as an option, the rationale for that rejection is also provided in the life care plan.

Collateral Sources

Since the VICP provides "reasonable compensation for past and future nonreimbursable [sic] medical, custodial and rehabilitative costs" (National Vaccine Injury Compensation Program: Compensation, 2005), the petitioner's planner must make note of insurance benefits anticipated for each of the services recommended in the life care plan, as well as the availability of state or local benefits. Noting these collateral sources of reimbursement, in essence, leaves the plan with only those expenses for which there is no anticipated reimbursement—or the bottom line, for the VICP.

As an example, the state of California requires that Regional Center and California Children's Services benefits are noted to offset the recommended services. Additionally, the VICP requires the life care planner to make note of therapy or services that are provided by the school district, another collateral source of reimbursement, through the Education of Individuals with Disabilities Act (Damages Order, 1997). If the school district does not provide services, the plan should explain why this is not occurring. Any other sources of financial aid currently or potentially available to offset the requested costs should also be noted in the plan. Conversely and proportionately, the effect of a VICP award on these benefits should also be included in the plan.

In the VICP environment, the petitioner and respondent life care planners work on a relative equal footing as compared to the plaintiff and defense planners in civil litigation. Both planners within the VICP have access to the injured person and the current providers. In one case example, the DOJ planner visited directly with providers outside of the plaintiff planner's presence. In another example, phone conference calls were recorded with both planners questioning the providers. This constitutes a significant variation from the civil arena, where the defense planner often does not have direct access to the injured person or the providers who treat him/her. Because the respondent planner is afforded this access, issues of dispute between plans can be directly addressed and potentially resolved with the providers.

The character of the dialogue between the provider and the life care planner directly affects the logic and methodology of how conclusions are derived for the plan. The types of questions posed, the manner in which the questions are asked, and the way the planner responds to the provider's comments or recommendations with additional questions to clarify all affect the outcome of the discussion and ultimately the life care plan. In one case example, teleconferences with treating physicians and providers were arranged and mediated by the petitioner's planner for the respondent planner. Both planners then participated in the dialogue with the provider, one after the other, and thus heard the same information. Areas of ambiguity were cleared up quickly.

The Office of Special Masters specifically encourages expert-to-expert dispute resolution. In one case, the petitioner and respondent planners reviewed their plans, noted areas of disagreement, developed plans for compromise, and resolved the differences in a collaborative fashion via teleconference. This process minimizes the adversarial atmosphere and thereby brings an expedited resolution of damages issues. In the instance where residual differences cannot be resolved, the Special Master may call a hearing in order to reach a decision.

Conclusion

The goal of "…a swift, flexible, and less adversarial alternative" dispute resolution (Office of Special Masters Homepage, 2005) in the Vaccine Injury Compensation Program provides an opportunity for the life care planner to function in a less typical and expanded capacity. It requires the planner to be thorough and creative in the approaches undertaken to present the life care plan and resolve differences. The flexibility offered by the Special Master to resolve differences directly between experts provides an interesting model for consideration in other arenas.

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Vioxx®… More to the Story

Debra Pritts, RN LNCC

KEY WORDS
FDA, Liability, Litigation, Merck, Pain Management, Pain Medications, Vioxx

On July 14, 2005, opening arguments were given in Ernst v. Merck, the first Vioxx®-related lawsuit to reach a jury. Mark Lanier represented the widow of Robert Ernst, who died in May 2001at age 59, after taking Vioxx® for 8 months. The coroner's report indicated that Ernst died of an arrhythmia. Lanier pointed out that the Merck Manual of Medical Information states that arrhythmias are associated with heart attacks 90% of the time (Keller, 2005). The trial was held in Angleton, Texas, with the 23rd District Court Judge Ben Hardin presiding. After 5 weeks of testimony, the jury realized not only how early Merck knew of the cardiovascular effects of Vioxx® but how they continued to aggressively market the drug despite these devastating effects. A seven-man, five-woman jury deliberated for 10 1/2 hours over 2 days before returning a verdict for the plaintiff.

On August 19, 2005, *Ernst v. Merck* ended in a $253.4 million verdict for the plaintiff, making it apparent just how egregious the Angleton, Texas, jury felt about the liability of Merck. The award included punitive damages of $229 million and $24.4 million in actual damages. The jury did not pick the $229 million dollar punitive damage award randomly: This was the exact amount that Merck made by delaying the changes to the warning label after the Vioxx® Gastrointestinal Outcomes Research (VIGOR) study showed results of a 5-time increase in heart attacks over Naprosyn® (Keller, 2005). VIGOR was a study initiated by Merck & Co. Inc., in January 1999 to evaluate the incidences of gastrointestinal (GI) events that included but were not limited to obstructions or bleeding in the upper gastrointestinal tract. Merck submitted the VIGOR results to the Food and Drug Administration (FDA) in June 2002. Merck delayed the changes in the labeling, and the FDA cannot order label changes. Under Texas law, punitive damages of $229 million will be reduced to $1.6 million. The jury's verdict is only a small percentage of the profits that Merck enjoyed by hiding the dangers of Vioxx® (Smith, 2005).

The case drew national attention from everywhere, including pharmaceutical companies, lawyers, additional plaintiffs, consumers, and stock analysts, as a signal of what lies ahead for Merck. Through the trial in Texas, the jurors and the rest of America learned that Merck executives knew the cardiac risks of Vioxx® as early as 1997 but nevertheless continued to aggressively market the drug as safe. Merck claims that patients showed a higher rate of heart attacks among Vioxx® users because naproxen, another drug to which Vioxx® was compared, offered a protective effect, and not because Vioxx® increased cardiovascular risk.

On November 3, 2005, the second Vioxx® trial ended in a state court in New Jersey, where Merck is based. By an 8-1 vote, the jury found that Vioxx® had not caused Frederick Humeston, a 60-year-old Idaho postal worker, to have a heart attack. Humeston, who survived and testified in his case, had a heart attack in September 2001 after taking Vioxx® for only 2 months and skipping some doses during that period. Dr. Benedict Lucchesi, a professor at the University of Michigan, testified at the trial on September 19, 2005, that intermittent use or even a day's use of Vioxx® could be enough to cause a heart attack or stroke (Livingston, 2005).

The first federal trial regarding Vioxx® opened in Houston, Texas, on November 29, 2005. This case concerned Richard "Dicky" Irvin, who suffered a fatal heart attack in May 2001. This St. Augustine, Florida, resident had been taking the drug for about a month to alleviate back pain, when his co-workers found him dead at his desk. Attorney Andy D. Birchfield, Jr., representing Irvin's surviving spouse, told jurors that taking the pain reliever for 1 month was enough to cause the 53-year-old man's heart attack. Merck argued that studies conducted before the painkiller's introduction in 1999 showed no evidence of causing heart attacks with short-term use and that heart disease, not Vioxx®, led to Irvin's death. The case ended in a mistrial and will be retried again in February 2006 (Agovino, 2005).

Early Studies

In the *Ernst* trial, Lanier questioned the plaintiff's expert, Dr. David Egilman, about how Merck may have manipulated its study data to hide Vioxx®'s cardiovascular risks. In one of Merck's pre-clinical studies, completed in 1996, patients taking Vioxx® experienced a higher rate of cardiovascular events than patients taking placebo. According to Egilman, this study "signaled" to Merck that Vioxx® might be associated with an increased risk of cardiovascular events and should have prompted Merck to perform further cardiovascular studies—but instead of studying cardiovascular risks, Merck simply omitted that study data from its future analyses of Vioxx®'s cardiovascular risks (Keller, 2005).

In February 1997, 2 years before Vioxx® went on the market, an internal Merck e-mail warned that a proposed trial might show Vioxx® causes blood clots. "Would allow low dose aspirin – I know this has been discussed to death, but real world is everyone is on it, so why exclude AND without Cox-1 (Cyclooxygenase 1) inhibition, you will get more thrombotic events and kill the drug" (Mathews & Martinez, 2004).

Mechanism of Action

To better understand the mechanism of action, it helps to have a basic understanding of how pain is felt. When tissue becomes damaged, chemicals called prostaglandins (PGs) are released to make the nerve endings register the shock sent to the brain even more strongly. Cells in the damaged tissue make PGs by using an enzyme called Cyclooxygenase-2 (Cox-2). In addition to the pain, PGs also produce swelling or inflammation in order to bathe the damaged tissue in fluid to protect and promote healing. Pain and inflammation remind that the tissue is damaged and caution use until healing takes place; however, pain does not necessarily accompany an actual injury, in instances such as headaches, arthritis, or menstrual cramps (Neseliler, 2002).

Table 1: Two Forms of Cyclooxygenase.

COX-1	COX-2
• Produces prostanoids that mediate homeostatic functions • Constitutively expressed	• Produces prostanoids that mediate inflammation, pain, and fever • Induced mainly at sites of inflammation by cytokines
Especially important in: ❍ Gastric mucosa; small- and large-bowel mucosa ❍ Kidney ❍ Platelets ❍ Vascular endothelium	**Constitutive expression in:** ❍ Brain ❍ Kidney (mainly animal data) ❍ Female reproductive tract

(DuBois, 1998)

There are two forms of cyclooxygenase: Cox-1 and Cox-2. PGs are involved in diverse functions, including blood clotting, ovulation, initiation of labor, bone metabolism, nerve growth and development, wound healing, blood vessel tone, and immune response (DuBois, 1998). Because of the many roles that PGs play in the function of the human body, it is not unpredictable that suppressing PG synthesis by inhibiting COX can lead to unwanted side effects. In particular, individuals taking non-steroidal anti-inflammatory drugs (NSAIDS) for even short periods of time can experience GI and renal side effects (DuBois, 1998).

Prostacyclin, a member of the family of lipid molecules known as eicosanoids, is produced from endothelial cells by the action of Cox-2 and results in vasodilation, decreased platelet aggregation and a decrease in smooth muscle proliferation (Mukherjee, 2001). Prostacyclin also mediates pain, inflammation, and fever (DuBois, 1998). If Cox-2 secretion is inhibited, prostacyclin secretion is also inhibited, thereby decreasing pain, inflammation, and fever. Prostacyclin acts mainly to prevent platelet formation and clumping involved in blood clotting and also is an effective vasodilator. Prostacyclin interacts quite the opposite to thromboxane, another eicosanoid. This implies a mechanism of cardiovascular homeostasis (Table 2) between the two hormones in relation to vascular damage (Prostacyclin, 2006). Thromboxane, produced in platelets, is a vasoconstrictor and aids the clumping of platelets. Thromboxane is named for its role in clot formation (thrombosis) (Thromboxane, 2006).

Table 2: Cardiovascular Homeostasis.

Platelets		Endothelial Cells
COX-1 ↓		COX-2 ↓
Thromboxane A_2 • Vasoconstriction • Increased platelet aggregation • Increased vascular smooth muscle proliferation	**Balance** ↔	**Prostacyclin** • Vasodilation • Decreased platelet aggregation • Decreased vascular smooth muscle proliferation

(Mukherjee, 2001)

FitzGerald (2001) names three broad classes of cyclooxygenase inhibitors that have emerged:

1. Aspirin;
2. Indomethacin and other NSAIDs; and
3. The first selective cyclooxygenase-2 inhibitors: the coxibs (e.g., celecoxib and rofecoxib).

Traditional NSAIDs and aspirin have effects on both Cox-1 and Cox-2 and are, therefore, considered non-selective. They work on both sides of the Cox-1 and Cox-2 pathways. They inhibit Cox-2, which helps reduce inflammation, pain, and fever, but they also inhibit Cox-1. Cox-1 is constituitively expressed, meaning that we always express it. This helps to thicken and provide a rich protective lining on the gastric surface. When taking aspirin or NSAIDs, Cox-1 is inhibited, causing the development of gastric irritation and bleeding as the gastric lining becomes thinner (FitzGerald, 2001).

NSAIDs are widely used to treat arthritis, menstrual pain, and headache. Although effective, their long-term use is limited by gastrointestinal effects such as indigestion, abdominal pain, and, less often, gastric or duodenal perforation or bleeding. A new group of anti-inflammatory drugs—the "coxibs"—were developed due to these unacceptable side effects. Both groups of drugs inhibit prostaglandin synthase; however, where NSAIDs inhibit both Cox-1 and Cox-2, the coxibs are selective inhibitors of only Cox-2. The inhibition of Cox-2 has been more directly implicated in relieving inflammation, whereas the inhibition of Cox-1 has been related to adverse effects in the gastrointestinal tract. It was hoped that coxibs would be better tolerated than NSAIDs but equally effective (FitzGerald, 2001).

Table 3: Net Effect of Cox-2 Inhibition Favors Cardiovascular Effects.

Platelets		Endothelial Cells
COX-1 ↓		COX-2 ↓
Thromboxane A_2 • Vasoconstriction • Increased platelet aggregation • Increased vascular smooth muscle proliferation	**Unbalanced** <	**Prostacyclin** • Vasodilation • Decreased platelet aggregation • Decreased vascular smooth muscle proliferation

(Mukherjee, 2001)

The potential mechanism underlying the increased cardiovascular risk in patients taking selective Cox-2 inhibitors involves their differences in actions of Cox-1 and Cox-2 on platelets and endothelial cells. Platelets are a major participant in the formation of obstructive clots in acute myocardial infarction. They also produce thromboxane A2 (a substance that results in vasoconstriction), increase platelet aggregation, and assist vascular smooth muscle proliferation, a process that results in re-stenosis in coronary arteries after angioplasty. Prostacyclin, on the other hand, is produced from endothelial cells by the action of Cox-2 and results in vasodilation, decreased platelet aggregation, and a decrease in smooth muscle proliferation (Mukherjee, 2001).

Cox-2 selective agents inhibit prostacyclin but do not inhibit thromboxane. This decreases pain and inflammation, and maintains the protective lining of the gastric mucosa; however this also provides the setting that may lead to increased pro-thrombotic activity, thereby increasing cardiovascular events. If there is an associated risk of thrombosis with Cox-2 selective inhibitors, it is thought to be small because of the presence of other substances that protect against thrombosis. Thrombosis would be expected to occur in patients who are already at an increased risk because of underlying conditions (FitzGerald, 2001). Many factors also determine the clinical response to a Cox-2 inhibitor. The genetic variability in individuals, interactions between drugs, characteristics of the patient such as a history of peptic ulcer, and pharmacokinetic and pharmacodynamic features of the drug may all influence both the efficacy and the adverse effects of Cox-2 inhibitors (FitzGerald, 2001).

Individual Causation

The general causation issue of whether Vioxx® increases the risk of adverse cardiovascular events has been answered, as all thirty-two members of the FDA advisory committee voted that Vioxx® is cardiotoxic. The specific causation issue, of whether Vioxx® was a cause of an adverse event in a given individual, is what needs to be determined. Risk factors are included in the many factors that may influence the clinical selectivity and safety of Cox-2 inhibition of any individual.

Initially determining individual causation involves concluding if an individual had an ischemic event while taking Vioxx®. The Vioxx® should have been taken for at least 4 days. As with multiple dosing, it would take this length of time to reach steady-state conditions. The 18-month period touted by Merck is the time at which increased risk of cardiovascular adverse events became statistically significant, but this time period may be irrelevant in the context of individual causation. In addition, the last dose should be no more than three days before the event, based on the figure that the half-life of Vioxx® is 10-17 hours, and it would take approximately five half-lives to clear the system (FitzGerald, 2001).

Once those criteria are met, determining further individual causation requires factoring in all of the individual risks, in order to look at the whole picture. The number of risk factors is essentially irrelevant because of the wide variation in how any risk factor presents itself and assessing the degree or severity of each of the risk factors. A rational rule in evaluating just how these risk factors play in the outcome of an individual case is that an excessive state of any risk factor is worse than if only having a mildly increased state or mildly abnormal result. It is believed that persons with underlying conditions are the exact people who could expect thrombosis to occur. Therefore, it may be argued that these individuals should not have been given Vioxx® (FitzGerald, 2001).

Risk Factors in Cox-2 Inhibition

One might conclude that individuals with a history of a cardiovascular event—including myocardial infarction, stroke, transient ischemic attack, or other clotting event such as a pulmonary embolism—would create an increased risk of having another of those events naturally. How much risk does the consumption of Vioxx® add to this individual in causing another cardiovascular ischemic event?

One cannot change the risk associated with a history of an earlier event, but what if the conditions precluding the earlier event were remedied with lifestyle changes, such as losing weight, quitting smoking, controlling blood pressure and cholesterol with medication, changing dietary habits, and exercising (Risk Factors and Coronary Heart Disease, n.d.)? If these conditions were improved, wouldn't the history-based probability of another event be greatly reduced? How much risk does the consumption of Vioxx® add to this individual in causing another cardiovascular ischemic event?

In addition to a previous personal history, other risk factors that cannot be modified include age, race, gender, and heredity (Risk Factors and Coronary Heart Disease, n.d.). How much risk does the consumption of Vioxx® add to these individuals in causing a cardiovascular ischemic event? Because these individuals have risk factors that they cannot modify, should they have been treated with Vioxx®? Should they have been offered other NSAIDs or some other alternative? Because these risk factors cannot be controlled, it is even more important to assess how these individuals controlled any other risk factors they may have had.

Assessing the modifiable risk factors requires more than just including if these are present. These risk factors include, but are not limited to, smoking, hypertension, hypercholesterolemia, physical inactivity, obesity, diabetes, and the use of alcohol or illegal drugs (Risk Factors and Coronary Heart Disease, n.d.). Instead of simply noting that an individual has one or more of these risk factors, one needs to evaluate the degree of the risk. Did the individual have a history of smoking that ceased 10 or more years ago? Or did he/she continue smoking two packs per day? Is the total cholesterol 200 mg/dL or 300 mg/dL? What are the levels of high density lipoproteins (HDL) and low density lipoproteins (LDL)? Is blood pressure 150/90, or 180/110, or is it controlled at 120/80 on an anti-hypertensive medication? Is the individual's weight 200 pounds on a 5'9" frame or 300 pounds on a 5'2" frame? In evaluating each case on an individual basis, the medical expert needs to

opine to a reasonable degree of medical certainty that Vioxx® significantly increased the person's risk above his/her baseline risk factors and was a major contributing factor in triggering the cardiovascular event.

The FDA Warns

Thomas W. Abrams, Director of Drug Marketing, Advertising, and Communications at the FDA, issued a Warning Letter dated September 17, 2001, to Merck CEO Raymond V. Gilmartin, relating to "promotional activities and material for the marketing of Vioxx® (rofecoxib) tablets" (Abrams, 2001) that minimized the potentially serious cardiovascular findings observed in the VIGOR study. The letter requested a response containing a corrective action plan, called for immediately ceasing all violative promotional activities or dissemination of violative promotional materials for Vioxx®, and ordered the issue of a "Dear Health Care Provider" letter to correct false or misleading impressions and information (Abrams, 2001).

This "Dear Health Care Provider" letter was not sent out until April 2002 (Yates, 2002). The information concerning the adverse cardiovascular effects was contained on pages two and three, following the reporting of favorable information about the decreased joint pain and tenderness in patients suffering from rheumatoid arthritis and the reduction in the risk of development of peptic ulcer and bleeds (PUBS). Merck finally changed the label to include mention of the cardiovascular risks, in April 2002, but did not include a black box warning. The information is not listed under "Warnings," but instead under "Precautions" as "Cardiovascular Effects" (Yates, 2002).

Continuing Blame

Merck continues to be blamed for deceiving the medical community, the FDA, consumers, and its own researchers into believing that Vioxx® was safe, by allegedly training sales representatives to dodge questions about Vioxx®'s cardiovascular risks, while safety data about cardiovascular adverse events was supposedly buried inside boxes of documents dumped onto the under-resourced FDA. Merck's Vioxx® ads purportedly never warned consumers about Vioxx®'s cardiovascular risks, but Merck argued that they are only required to warn doctors. Additionally, instead of adding a warning about cardiovascular risks in the package insert, Merck buried its description of cardiovascular adverse events in the least critical section of Vioxx®'s package insert, the adverse events section. Merck eventually added a warning about cardiovascular risks in June 2001, more than 14 months after receiving the results of its VIGOR study, which showed an increase in cardiovascular events (Keller, 2005).

An FDA analysis, based on data from a Kaiser Permanente study, projects that 27,785 heart attacks and sudden cardiac deaths "would have been avoided" had Celebrex been used instead of Vioxx® (Graham, 2004). More than 80 million people in the United States took Vioxx® between its introduction in 1999 and its withdrawal in 2004, and annual sales topped $2.5 billion for Merck (Topol, 2004). While Vioxx® was beneficial for a much smaller group of patients who suffered gastrointestinal complications from older drugs, Merck promoted Vioxx® to a substantially larger group of people with no better efficacy. Although realizing that all drugs have some risk/benefit ratio, consumers can only make smart choices about those risks when drug manufacturers are truthful, allowing physicians and patients to make their correct choices.

Merck allegedly placed profits over people in failing to provide critical information to consumers and physicians. During the Ernst trial, Lanier repeatedly raised his theme of empowering the jury to send a message to Merck by doing what the FDA couldn't do: "Punish Merck" with a big-money verdict—"Merck money" (Donald, 2005). The Humeston trial that ended in a defense verdict may discourage plaintiffs' lawyers from filing some marginal cases against Merck, especially in instances where patients took the drug for only a couple of months before suffering a heart attack. Still, both sides agree that many more trials are coming, with plaintiff attorneys vowing to move forward with other lawsuits and Merck vowing to defend every lawsuit against the company.

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Defending a Giant: Vioxx®

Melanie Donati, RN

The recent trend of drug liability claims has made pharmaceutical companies shudder—and for good reason because they have been targeted, with increasing intensity, in the latest round of class action lawsuits. Billboards, TV commercials, radio spots, Internet advertisements, and direct mailings remind the American public about the purported wrongdoing and injuries from the drug companies' misdeeds. This litigation has created a need for legal nurse consultants (LNCs) on both sides of the argument. LNCs are vital elements in the Vioxx® litigation arena. In the interest of presenting both sides, JLNC is pleased to include this article presenting insights primarily from the defense perspective of this encounter, originally published in Volume 13, Issue 2 (Fall 2005) of LiNC, the Official Publication of the Pittsburgh Chapter of the American Association of Legal Nurse Consultants. JLNC thanks the Pittsburgh chapter for their permission to reprint this article.

Vioxx® was approved in May 1999 for the reduction of signs and symptoms of osteoarthritis, the alleviation of acute pain in adults, the treatment of dysmenorrhea, and the relief of signs and symptoms of rheumatoid arthritis in adults and children. Merck & Co., Inc., informed the Federal Drug Administration (FDA) on September 27, 2004, that the Data Safety Monitoring Board conducting an on-going long-term study of Vioxx® had recommended that the study be stopped early due to safety reasons. The study showed an increased risk of cardiovascular events in patients on Vioxx® compared to those receiving the placebo, particularly those who had been taking the drug for longer than 18 months.

On September 28, 2004, Merck informed the FDA that they would be voluntarily removing Vioxx® from the market. On September 30, 2004, Merck and the FDA each announced the voluntary withdrawal of Vioxx® from both the U.S. and worldwide markets. With nearly 20 million people in the United States ingesting Vioxx® between 1999 and 2004, the circumstances under which Vioxx® was withdrawn have created a landslide of allegations. Being a legal nurse consultant (LNC) for the defense, while it is under such a harsh attack, creates an intense and stimulating work atmosphere, as strategies are developed to analyze the data and then construct a defense for the company's actions.

Having a clear understanding of the individual injuries alleged and causation problems is mandatory for LNCs on both sides of this litigation. Cardiovascular injuries comprise the bulk of those claimed; however, there are also gastrointestinal problems, renal failures, and various other injuries that claimants attempt to attribute to Vioxx®. Merck claims that patients showed a higher rate of heart attacks among Vioxx® users because naproxen, another drug to which Vioxx® was compared, offered a protective effect, and not because Vioxx increased cardiovascular risk.

While attorneys have the key role in determining whether the pharmaceutical companies were negligent in their marketing and distribution of Vioxx®, the major focus of the LNC is in determining whether the claimants' injuries are objectively substantiated within the medical records and whether the etiology of the injuries is supported by the records. In the experience of this author, many plaintiffs' claims are not substantiated by the medical records at all. Injuries claimed may not be evident, and documentation from health care professionals causally connecting the alleged injury to Vioxx® does not happen often. The LNC must mine all available records and documents to verify the presence or absence of these elements.

Data Collection

A major role of the LNC is to perform organized data collection with concurrent analysis of each individual case to help determine the likelihood of a causal connection between Vioxx® and the injury identified in the claim. The LNC's investigation includes analyzing the significance of plaintiff's:

- **Past medical history**. Determine whether the plaintiff had a prior history of angina, cardiovascular, cerebrovascular, or other vascular events which may have been documented or addressed.
- **All co-morbidities**. Identify pathophysiologic states such as diabetes or renal disease that accelerate the arteriosclerotic process; or processes that make clotting more likely, such as pregnancy, cancer, polycythemia, or other evidence of clotting abnormalities.
- **Family history**. Investigate for evidence of a familial predisposition to cardiovascular, cerebrovascular, or other conditions.
- **Social history**. Note cigarette use, alcohol and/or recreational drug use or abuse (e.g., cocaine use may have caused or significantly contributed to an injury such as myocardial infarction), involvement in activities like body building where anabolic steroids might be used, or recent long plane flights or other events that predisposed the individual to deep vein thrombosis and related pulmonary embolic events.
- **Factors that may have contributed to hypercoagulability or damage to a vessel wall**. Look for evidence of immobility, dehydration, use of hormones (including birth control pills) and steroids, and/or recent trauma.

Data Collection Tools

Data collection tools to illustrate the claimant's medication history generally include columns noting:

- The period that Vioxx® is claimed to have been taken;
- Documentation available supporting that Vioxx® was taken;
- Dosage prescribed;
- Dosage taken;
- Length of time taken;
- Evidence of compliance with the prescribed regimen; and
- Concurrent medications ingested, particularly NSAIDs and other Cox-2 inhibiting drugs, i.e., Celebrex® and Bextra®.

A history of Vioxx® use may be gleaned from pharmacy printouts, physicians' order sheets, prescription labels, billing statements, and physician and nursing documentation. Such documentation may establish the facts that support or refute each claimant's patterns of drug use. Understanding and developing a comprehensive medication summary (as much as "6 months prior to Vioxx® use" or "concurrent with Vioxx® use") to assess confounding effects of the other medications being used and to establish a pattern of compliance or noncompliance is critical—and always difficult. Charting an accurate timeline of Vioxx® ingestion and dosage can be tricky at times but is indispensable in establishing causation.

Making Data Accessible

Tables and graphs are ultimately translated into reports, and summaries need to make data more accessible. Several different formats for presenting information include:

- **Overview of the presenting case**. These documents give critical details including demographic information; allegation information; case classification (positive or negative product identification; dosage information; duration, allegation category); past medical history; past medical diagnoses related to the allegation category; past medical testing related to the allegation category; comprehensive medication history including a thorough Vioxx® ingestion history, concomitant medications, medications taken 6 months prior, and medications taken that are known to interact with Vioxx®; overview of alleged event; report of current status; and any special notes to include information with relevance to the case.
- **Chronology of the plaintiff**. This breakdown of the plaintiff's medical history should include relevant information related to the allegation category. It is presented in a detailed chronological fashion, beginning with the earliest available medical records and progressing through every doctor visit, hospitalization, or medical event, with every prescribed medication and diagnostic procedure noted.
- **Executive summary**. This narrative-style document tells a more detailed story than the overview summary and may go into explanations of the causal connections and some analysis of issues relevant to the case.

In addition to assessing the presence of the claimants' injuries and identifying the factors that affect the strength of the causal connection to the use of Vioxx®, the LNC is valuable in illustrating damages and permanent disabilities. A baseline status must be gleaned from the medical records, depositions, and other discovery to illustrate employment, recreational habit, and social status. This baseline is used to establish, as objectively as possible, which damages, if any, flowed from the injuries caused by Vioxx®. Understanding the plaintiff's level of functioning post-allegation will be an area on which both sides focus significant resources, in order to establish the value of each case.

Medical Negligence?

There always is the possibility that there may have been a deviation from the recommended administration of Vioxx®, such as dosages beyond the recommended amount, or beyond the recommended amount for the person's size, co-morbidities, etc. Should this be the case, the potential liability may then need to be shared with those who incorrectly prescribed, dispensed, and/or used the Vioxx®.

Conclusion

With the unleashing of thousands and thousands of Vioxx® claims, LNCs have excellent opportunities to apply their unique skills to illustrate the elements of these drug cases. The facts revealed in the review of countless medical records, and the means by which these facts are illustrated to the public, will affect the public's perception and may even affect the destiny of the seriously maligned pharmaceutical companies. Working as LNCs for the defense, we have a wonderful and daunting challenge to do our best to "defend a giant."

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Q: There are several Legal Nurse Consultant (LNC) certifications currently available. What are the differences among them and why should I consider LNC certification if it is not a requirement to practice as an LNC?

Molly Feliciano, MSN BSN LNCC

A: Licensure as a registered nurse is the basic entry-level requirement for the profession of nursing, as well as for the practice of legal nurse consulting. Regulated by state statute, licensure ensures that an individual has acquired entry-level knowledge and skills to function as a registered nurse, but does not indicate expertise in a particular area. Licensure also allows the registered nurse to use the credential "RN." Credentials are marks, or "stamps," that indicate an expected level of quality and achievement (Smolenski, 2005).

As health care has become more complex and specialized, nurses have had to acquire advanced knowledge and skills to meet expanding health care needs. Correspondingly, a mechanism for identifying these specialized nurses was also needed. Certification has emerged as the recognized and accepted method for identifying those who have attained advanced knowledge, experience, and expertise in a specialty area (Scherubel, 2005).

Certification is conferred by nongovernmental agencies or associations to acknowledge that an individual has met certain predetermined criteria established by that particular agency or association. Typically, these agencies or associations are accredited, professional nursing specialty organizations that have met rigorous accreditation criteria.

Since there are no defined regulatory statutes for certification of nurses, however, programs of certification can differ markedly because any professional organization can develop a program of certification for its members (Flarey, 2000). Just as nursing certification programs can have very different standards, the value of their respective certifications also differs significantly. Only by identifying the standards and understanding the quality criteria utilized by each certifying organization and its respective certification program, can the true value of its corresponding certification be established.

Historical Background of Nursing Certification

The first nursing certification examination was offered for nurse anesthetists in 1945. In 1973, the American Nurses Association (ANA) established the ANA Certification Program. In 1991, the American Nurses Credentialing Center (ANCC), a subsidiary of ANA, was formed in an effort to provide a central nursing certifying organization (Scherubel, 2005). At this time, however, other professional nursing specialty organizations continued to offer certification.

In 1991, the American Board of Nursing Specialties (ABNS) was incorporated with the original goals of creating uniformity in nursing certification and increasing public awareness of the value of certification. Since then, it has evolved into "an advocate for consumer protection by establishing and maintaining standards for professional specialty nursing certification" (Stromborg, et al., 2005). ABNS recognized that achieving certification in a nursing specialty was of no value if the organizations and associations that certified nurses did not adhere to rigorous and consistent principles and practices that exemplified quality certification (Bernreuter, 2001).

Today, ABNS is the only accrediting body specifically dedicated to nursing certification (American Board of Nursing Specialties, 2005). It has 19 standards that must be met for a certification program to be recognized by ABNS. Currently, ABNS has accredited the certification programs of 12 professional nursing certifying organizations (Table 1). Individuals who successfully complete professional certification examinations offered by these ABNS-recognized organizations are considered "board certified" (Bednash, Honig, and Gibbs, 2005).

Table 1: ABNS Accredited Certification Programs.

American Board of Perianesthesia Nursing Certification, Inc. (ABPANC)
American Board for Occupational Health Nurses, Inc. (ABOHN)
American Board of Neuroscience Nursing (ABNN)
American Legal Nurse Consultant Certification Board (ALNCCB)
American Nurses Credentialing Center (ANCC)
Board of Certification for Emergency Nursing (BCEN)
Certification Board Perioperative Nursing [Competency & Credentialing Institute] (CCI)
Council on Certification of Nurse Anesthetists (CCNA)
National Board of Certification for Hospice and Palliative Nurses (NBCHPN)
Nephrology Nursing Certification Commission (NNCC)
Oncology Nursing Certification Corporation (ONCC)
Rehabilitation Nursing Certification Board (RNCB)

The other nationally recognized accreditation board serving the certification programs of professional nursing organizations is the National Commission for Certifying Agencies of the National Organization for Competency Assurance (NCCA). Only eight nursing organizations have met the 21 accreditation standards established by NCCA (Table 2).

Table 2: National Commission for Certifying Agencies.
American Academy of Nurse Practitioners
American Association of Critical Care Nurses Certification Corporation
American Nurses Credentialing Center Commission on Certification
ACNM Certification Council
Council on Certification of Nurse Anesthetists
Pediatric Nursing Certification Board
National Certification Corporation for the Obstetric, Gynecologic, and Neonatal Nursing Specialties
Oncology Nursing Certification Corporation

Evolution of Legal Nurse Consultant Certified (LNCC) Certification

The American Association of Legal Nurse Consultants (AALNC), founded in 1989, is the national professional nursing organization for legal nurse consultants, which offers membership to any licensed registered nurse in the United States and its territories. In holding to its strong commitment to and association with professional nursing, AALNC's Scope of Practice for the Legal Nurse Consultant, Standards of Legal Nurse Consulting Practice, and Standards of Professional Performance are based upon the standards of practice framework supported by the ANA.

When AALNC began its process of developing a certification program to recognize advanced knowledge and practice in the field of legal nurse consulting, it again sought expert advice and pursued accreditation through ABNS, the most credible and widely recognized nursing accreditation body. In 1997, the American Legal Nurse Consultant Certification Board (ALNCCB) was established according to the guidelines of ABNS and, in conjunction with AALNC, began the process of developing a certification program to meet ABNS' rigorous list of accreditation standards. Among those were a definition and scope of the nursing specialty, evidence of a research based body of knowledge, organizational autonomy of a certification board, public representation, eligibility criteria for test candidates, psychometrically sound test development (which addresses test validity, reliability, test security, and confidentiality), a mechanism for disciplinary action, and practice analysis (Webster and Garbin, 2003).

In its effort to meet ABNS' specific and strict standard for maintaining the statistical validity, reliability, and security of the examination, ALNCCB turned to an expert in the field of testing. It chose the highly regarded Center for Nursing Education and Testing (C-Net) to develop its certification examination. The first Legal Nurse Consultant Certification Examination was administered in October 1998. Those who successfully met the eligibility requirements and passed the examination were awarded the credential of Legal Nurse Consultant Certified (LNCC).

In September 1999, the ALNCCB Legal Nurse Consultant Certification program satisfactorily met all ABNS standards and was awarded accreditation by ABNS. The LNCC credential became the official designation of certification recognized by AALNC and ABNS. The LNCC credential is a registered trademark of AALNC and can only be used by legal nurse consultants who have successfully completed the ALNCCB certification examination accreditation process.

Current eligibility criteria for LNCC certification require an active RN license in the United States or its territories with a full and unrestricted license, a minimum of 5 years of practice as an RN, evidence of 2,000 hours of legal nurse consulting experience within the last 3 years, completion of the application form, payment of all fees, and achieving a passing score on the certification examination (AALNC, 2005). No specific LNC coursework or formal educational program is required. Recertification is required every 5 years by documenting an active, unrestricted RN license, evidence of 2,000 hours of legal nurse consulting practice within the past 5 years, and evidence of 60 contact hours of continuing education that meet published criteria, or retaking and successfully passing the ALNCCB certification examination (AALNC, 2005).

Other LNC Certifications

Other LNC certifications are currently available; however, none meet the criteria of, or are accredited by, ABNS or NCCA. To adequately assess the value of another LNC certification and the corresponding credential it may award, therefore, it is necessary to compare these other programs to some standardized certification criteria. Since these other programs do not meet the standards of ABNS or NCCA, another method of comparison must be utilized. Flarey (2000) has proposed that nursing certification programs should at least include the following criteria:

1. A certification program that is sponsored by a professional organization dedicated to the ongoing development of reputable standards for the practice specialty;
2. A certifying organization that is committed to ongoing research and the study of emerging trends and changing standards of care and practice within the practice specialty:
3. A certifying organization with an advisory board of specialists currently practicing in the specialty who advise the organization regarding changes in standards of practice and emerging trends, and which has personnel

who collectively review and approve the requirements and processes for granting certification to candidates;
4. Defined organizational requirements for the granting of certification that clearly provide for the need to demonstrate the attainment of skill, knowledge, and practice experience in the area of specialty practice;
5. A clear definition, understandable to members and the public, of the meaning of certification and the support that the organization provides to its members;
6. A means to verify the candidates' attainment of skill, knowledge, and practice experience in the specialty. This must include authentication of test validity and reliability, as well as verification of candidates' practical experience in the specialty;
7. The development and publishing of a code of ethics specific to the specialty, and adherence to which is a requirement of all certified members of the specialty;
8. A process of regular recertification based upon evidence of continued knowledge, skill attainment, and practice experience in the specialty;
9. A means for certified members to acknowledge their certification status in the specialty practice, i.e. a title or use of standardized initials;
10. A program of quality assurance to monitor certification processes and evaluate the effectiveness of the organization's ability to ensure that candidates have met the requirements of certification;
11. Clear information available to employers and health care agencies, explaining the certification program, the intent of the certification, and the scope of practice conveyed by the certification.

These 11 criteria offer only a basic starting point for evaluating all LNC certification programs. ABNS- and NCCA-accredited programs, well-respected and accepted throughout professional nursing organizations, exceed these criteria. If other LNC certification programs are to be considered comparable, therefore, they must at least meet these basic criteria. An informed comparison of the other currently available LNC certification programs reveals that they do not meet these basic criteria. They are not comparable to LNCC certification. Following are some of the areas in which the other LNC certification programs are deficient:

- Not all the other certification programs are sponsored by a professional organization specifically dedicated to the development of reputable standards of practice. Unlike AALNC, the other LNC certification organizations do not have a readily accessible published scope of practice for the LNC, standards of legal nurse consulting practice, standards of professional performance, or code of ethics. Some have no certifying organization, let alone one dedicated to ongoing research. Additionally, some are sponsored by private, for-profit companies.
- The other LNC certifications currently available advise, but do not require, experience as an RN prior to becoming certified as an LNC. Similarly, they do not require any practice experience as an LNC as a prerequisite to LNC certification. This differs significantly from LNCC certification, which requires 5 years of RN experience and 2,000 hours of LNC experience within 3 years of taking the ALNCCB certification examination. It is clear that the initial certifications offered by these other programs are entry-level certifications verifying the attainment of didactic knowledge rather than a validation of expertise and experience.
- Although the other LNC certification entities do require that candidates pass an examination, these other examinations were not developed or established as reliable and valid by a testing center as reputably recognized within the professional nursing community as C-Net. One of the other entities utilizes Prometric Testing Centers (formerly Sylvan Technology Centers)—which also serves IT, government, academics, and professional groups—to develop and offer its LNC certification exam (Vickie Milazzo Institute, 2005). Another private LNC certification entity does not identify which testing service, if any, it used in developing and validating its examination.
- These other LNC certification programs require mandatory course work. The mandatory course work material and all related publications are only available through the respective private company. Certification (and recertification) and the related conferring of registered trademark initials, are accomplished through successful completion of the respective programs offered by these private companies. This differs significantly from the LNCC certification, which does not require any formal course work, offers but does not require educational and relevant study material, and is not affiliated with any for-profit company.
- Membership in the organizations offering LNC certification also differs. AALNC membership is open to all RNs in the United States and its territories. Although there are different levels of membership, one does not have to be an LNCC to be a member of the national organization. Membership in the other entities offering LNC certification is only attainable through successful completion of their respective courses. Continued membership requires successful recertification through the respective private company.

Careful and thorough analyses of the basic criteria for LNC certification and comparison with ABNS or NCCA criteria enable a candidate to easily distinguish the significant differences among the currently available LNC certification programs. While private company certifications attest to entry-level knowledge established as acceptable performance by the respective company, ALNCCB certification validates knowledge, experience, and expertise as defined by the rigorous standards of ABNS. Understanding of, and familiarity with,

the different certifications provide the practicing or aspiring LNC with the information needed to make an informed decision.

Why Certify?

The question of why an LNC should become certified is a separate and often personal issue. Given that certification is not required to practice as an LNC, the choice to become certified is an individual one. Research has identified two motivators for acquiring certification: intrinsic rewards and extrinsic rewards. Intrinsic rewards are identified as motivators internal to the individual, such as personal development, sense of accomplishment, professional growth, demonstration of competence, and professional commitment. Extrinsic rewards are external to the individual and include credibility, marketability, recognition from other health professionals, consumer confidence, and consumer protection (Byrne, Valentine, and Carter, 2005).

From the above analysis of the criteria for LNC certification programs, it is clear that attainment of LNCC certification addresses all the intrinsic motivators and serves to assure the client/patient population, attorneys, other health professionals, and the general public of the LNC's advanced knowledge, skills, and practice experience. Entry-level certifications offered by private companies also meet several of the intrinsic rewards—but with the lack of validation of experience and expertise, the attainment of the extrinsic rewards is more ambiguous.

As in all areas of nursing practice, efforts need to be focused on establishing the relationship between nursing certification and improved outcomes for the client/patient population served. Only by establishing empirical evidence of a statistically significant relationship between LNCC certification and positive practice outcomes will the true value of LNCC certification be recognized, appreciated and rewarded.

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Legal and Ethical Issues in Nursing, Fourth Edition

Reviewed by Eileen Croke, EdD MSN RN ANP GNP LNC-C

Legal and Ethical Issues in Nursing, Fourth Edition

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Publisher: Pearson/Prentice Hall, Upper Saddle River, New Jersey
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Due to the ever-changing health care delivery system, nurses are facing a plethora of ethical and legal dilemmas that increase their risk of becoming named in a malpractice litigation process. To help reduce this risk, nurses need a knowledge base in the fields of ethics and law, as well as an understanding of how to incorporate these fields into their daily nursing practice. The author of *Legal and Ethical Issues in Nursing*, Ginny Wacker Guido, clearly provides the "how to" to meet this need in the updated 4th edition of this text.

The text is sequenced into five parts:

1. Ethics;
2. Introduction to the Law and Judicial Process;
3. Liability Issues;
4. Impact of the Law on the Professional Practice of Nursing; and
5. Impact of the Law on Nursing in Selected Practice Care Settings.

Each chapter begins with a preview of the chapter content, learning objectives, and a list of key concepts to be explored. Within each chapter, there are several critical thinking exercises that challenge the reader to apply chapter content to actual clinical nursing malpractice case scenarios.

These scenarios are valuable exercises for legal nurse consultants (LNCs) to review and apply their own state laws. Chapters conclude with two additional exercises, which are valuable tools for enhancing the LNC's application of ethical and legal knowledge to the professional practice of nursing. The first exercise, "Apply Your Legal Knowledge," includes critical thinking questions based on the chapter content. The second exercise, "You Be the Judge," provides an in-depth case study based upon the legal issues presented in the chapter.

By beginning the text with a section on Ethics, the author is able to provide a knowledge base of how the field of ethics plays a vital role in professional nursing practice. Ethics is then threaded throughout the remaining chapters.

This fourth edition is rich with updated case law and court decisions. Relevant content related to professional nursing practice is covered in-depth throughout each chapter. Topics such as the Health Insurance Portability and Accountability Act (HIPAA), multi-state licensure, standards of care, delegation and supervision, risk management, managed care, telenursing, patient education, and discharge planning are only a few of the topics covered in detail. The table of contents and a clearly detailed cross-referenced index make this text an easy-to-use reference.

This book is a definitive resource for all nurses practicing (or learning to practice) in today's health care delivery system. It serves as a valuable reference for all LNCs.

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The Journal of Legal Nurse Consulting (JLNC), a refereed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). The journal's purposes are to promote legal nurse consulting within the medical-legal community; to provide both the novice and the experienced legal nurse consultant (LNC) with a high-quality professional publication; and to teach and inform the LNC about clinical practice, current national legal issues, and professional development.

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