

Volume 29

Number 1

Spring 2018

THE JOURNAL OF  
**Legal Nurse**  
*Consulting*



FDA AND PRODUCT LIABILITY

AALNC

AMERICAN ASSOCIATION OF  
LEGAL NURSE CONSULTANTS

FIGeducation.com

# Grow your career with **FIG**



## Learning & Mentorship

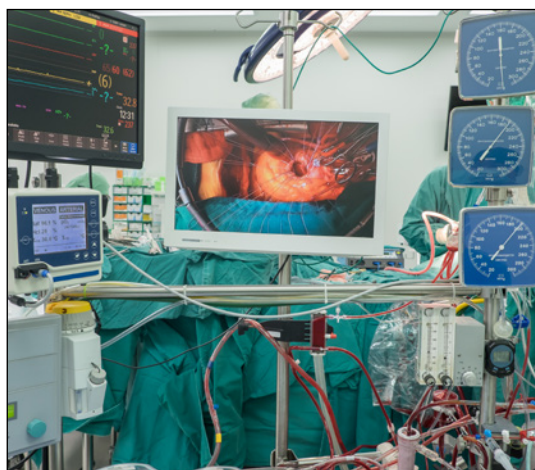
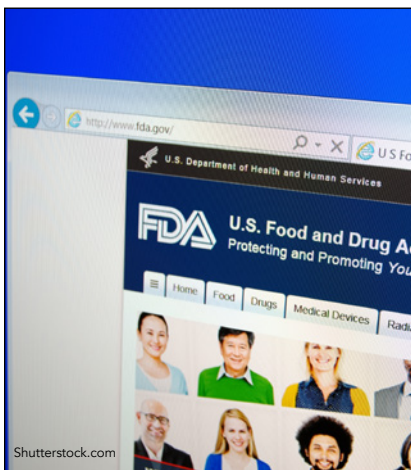
- Life Care Planning
- Medicare Set-Asides
- Medical Cost Projections



Shelene Giles, FIG Founder  
MS, BSN, BA, RN, CRC, CNLCP, CLCP, MSCC, LNCC

©2016, Shelene Giles

**FIGeducation.com**



## 08 FDA HISTORY, MEDICAL DEVICES, AND SEARCHING THE MEDICAL DEVICE DATABASE

Joanne Walker, BSEd, RN

## 14 LITIGATION INVOLVING CONTAMINATED HEATER-COOLER DEVICES USED IN OPEN-HEART SURGERY

Jane E. Barone, BS, RN, LNCC

## 18 THE LEGAL NURSE CONSULTANT'S PRIMER ON PRODUCT LIABILITY

Cynthia Mascaranhas, RN, LNCC

## 22 WHEN IS A DAUBERT "EXPERT" NOT A DAUBERT "EXPERT"?

James Hanus, RN, BSN, OCN, MHA

## 24 THE FAILED EXPERIMENT WITH THE NEW GENERATION OF METAL ON METAL HIP IMPLANTS

Hadley L. Matarazzo, J.D.

## 30 SUPPORT SURFACE TECHNOLOGY: AN ESSENTIAL COMPONENT OF PRESSURE INJURY PREVENTION

Paula Gruccio, MSN, RN, CWOCN, CPPS, Kathleen C. Ashton, PhD, RN, ACNS-BC

## 36 THE PATHOLOGICAL DIAGNOSIS OF MALIGNANT MESOTHELIOMA

Rhonda A. Fritz, BS, RN



- 02 Manuscript Review Process
- 03 Article Submission Guidelines
- 04 From the President
- 05 From the Editor
- 07 Test Your Screening Skills



AMERICAN ASSOCIATION OF  
LEGAL NURSE CONSULTANTS

### American Association of Legal Nurse Consultants

330 North Wabash Ave.  
Suite 2000  
Chicago, IL 60611  
877/402-2562  
312/321-5177  
Fax: 312/673-6655  
E-mail: [info@aalnc.org](mailto:info@aalnc.org)  
Web site: [www.aalnc.org](http://www.aalnc.org)

#### BOARD OF DIRECTORS

##### President

Debbie Pritts RN LNCC

##### President-Elect

Kimberly Beladi NS RN LNCC

##### Past President

Susan Carleo RN, CAPA, LNCC

##### Secretary/Treasurer

Laura Nissim MS RN CNS LNCC

##### Directors at Large

Elizabeth Murray BSN RN LNCC  
Erin Gologly BSN RN  
Mary Flanagan

#### THE JOURNAL OF LEGAL NURSE CONSULTING

##### Editor

Wendie A. Howland, MN, RN-BC,  
CRRN, CCM, CNLCP, LNCP-C, LNCC

##### Editorial Committee For This Issue:

Britney Anderson, DNP, RN, CPNP  
Kathleen Ashton, PhD, RN, ACNS-BC  
Judith Bulau, MSN, RN  
Randall Clarke, BSN, RN  
Rebecca E Czarnik, MS, RN, CLNC,  
LNCP-C  
Stormy Green Wan, RN, BSHS, RNFA,  
CLNC  
James Hanus, BSN, RN, OCN, MHA  
Elizabeth Hill, RN, PhD  
Wendie Howland, MN RN-BC CRRN  
CCM CNLCP  
Regina Jackson, RN, BS, CCM, LNCC  
Mindy Lockertz, BSN, RN  
Cynthia Mascarenhas, RN, LNCC  
Elizabeth Murray, BSN, RN, LNCC  
Ann Peterson, EdD, MSN, RN, FNP-  
BC, LNCC  
Joanne Walker, BSEd, RN  
Elizabeth Zorn, BSN, RN, LNCC

#### STAFF

##### Executive Director

Kristin Dee

## PURPOSE

The purpose of The Journal is to promote legal nurse consulting within the medicallegal community; to provide 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](mailto:JLNC@aalnc.org). Please see the next page for Information for Authors before submitting.

## MANUSCRIPT REVIEW PROCESS

We send all submissions blinded to peer reviewers and return their blinded suggestions to the author. The final version may have minor editing for form and authors will have final approval before publication. Acceptance is based on the quality of the material and its importance to the audience.

The *Journal of Legal Nurse Consulting* is the official publication of the American Association of Legal Nurse Consultants (AALNC) and is a refereed journal. Journal articles express the authors' views only and are not necessarily the official policy of AALNC or the editors of the journal. The association reserves the right to accept, reject or alter all editorial and advertising material submitted for publication.

The content of this publication is for informational purposes only. Neither the Publisher nor AALNC assumes any responsibility for any injury and/or damage to persons or property arising out of any claim, including but not limited to product liability and/or negligence, arising out of the use, performance or operation of any methods, products, instructions, or ideas contained in the material herein. The reader shall assume all risks in connection with his/her use of any of the information contained in this journal. Neither the Publisher nor AALNC shall be held responsible for errors, omissions in medical information given nor liable for any special, consequential, or exemplary damages resulting, in whole or in part, from any reader's use of or reliance on this material.

The appearance of advertising in the *The Journal of Legal Nurse Consulting* does not constitute a guarantee or endorsement of the quality or value of such product or of the claims made for it by its manufacturer. The fact that a product, service, or company is advertised in *The Journal of Legal Nurse Consulting* shall not be referred to by the manufacturer in collateral advertising. For advertising information, contact [JLNC@aalnc.org](mailto:JLNC@aalnc.org) or call 877/402-2562.

Copyright ©2018 by the American Association of Legal Nurse Consultants. All rights reserved. For permission to reprint articles or charts from this journal, please send a written request noting the title of the article, the year of publication, the volume number, and the page number to Permissions, *Journal of Legal Nurse Consulting*, 330 North Wabash Ave., Suite 2000, Chicago, IL 60611; [JLNC@aalnc.org](mailto:JLNC@aalnc.org). Permission to reprint will not be unreasonably withheld.

*Journal of Legal Nurse Consulting* (ISSN 2470-6248) is published digitally by the American Association of Legal Nurse Consultants, 330 North Wabash Ave., Suite 2000, Chicago, IL 60611, 877/402-2562. Members of the American Association of Legal Nurse Consultants receive a subscription to *Journal of Legal Nurse Consulting* as a benefit of membership. Subscriptions are available to non-members for \$165 per year. Back issues are available for free download for members at the Association website and \$40 per copy for non-members subject to availability; prices are subject to change without notice. Back issues more than a year old can be obtained through the Cumulative Index to Nursing & Allied Health Literature (CINAHL). CINAHL's customer service number is 818/409-8005. Address all subscriptions correspondence to Circulation Department, *Journal of Legal Nurse Consulting*, 330 North Wabash Ave., Suite 2000, Chicago, IL 60611. Include the old and new address on change requests and allow 6 weeks for the change.

## ARTICLE SUBMISSION

*The Journal of Legal Nurse Consulting* (JLNC), a refereed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). We invite interested nurses and allied professionals to submit article queries or manuscripts that educate and inform our readership about current practice methods, professional development, and the promotion of legal nurse consulting within the medical-legal community. Manuscript submissions are peer-reviewed by professional LNCs with diverse professional backgrounds. The JLNC follows the ethical guidelines of COPE, the Committee on Publication Ethics, which may be reviewed at: <http://publicationethics.org/resources/code-conduct>.

We particularly encourage first-time authors to submit manuscripts. The editor will provide writing and conceptual assistance as needed. Please follow this checklist for articles submitted for consideration.

## INSTRUCTIONS FOR TEXT

- Manuscript length: 1500 – 4000 words
- Use Word® format only (.doc or .docx)
- Submit only original manuscript not under consideration by other publications
- Put title and page number in a header on each page (using the Header feature in Word)
- Place author name, contact information, and article title on a separate title page, so author name can be blinded for peer review
- Text: Use APA style (Publication Manual of the American Psychological Association, 6th edition) (<https://owl.english.purdue.edu/owl/resource/560/01/>)
- Legal citations: Use The Bluebook: A Uniform System of Citation (15th ed.), Cambridge, MA: The Harvard Law Review Association
- Live links are encouraged. Please include the full URL for each. Be careful that any automatic formatting does not break links and that they are all fully functional.
- Note current retrieval date for all online references.
- Include a 100-word abstract and keywords on the first page
- Submit your article as an email attachment, with document title articlename.doc, e.g., wheelchairs.doc

## INSTRUCTIONS FOR ART, FIGURES, TABLES, LINKS

- All photos, figures, and artwork should be in JPG or PDF format (JPG preferred for photos). Line art should have a minimum resolution of 1000 dpi, halftone art (photos) a minimum of 300 dpi, and combination art (line/tone) a minimum of 500 dpi.
- Each table, figure, photo, or art should be submitted as a separate file attachment, labeled to match its reference in text, with credits if needed (e.g., Table 1, Common nursing diagnoses in SCI; Figure 3, Time to endpoints by intervention, American Cancer Society, 2003)

## INSTRUCTIONS FOR PERMISSIONS

The author must accompany the submission with written release from:

- Any recognizable identified facility or patient/client, for the use of their name or image
- Any recognizable person in a photograph, for unrestricted use of the image
- Any copyright holder, for copyrighted materials including illustrations, photographs, tables, etc.
- All authors must disclose any relationship with facilities, institutions, organizations, or companies mentioned

## GENERAL INFORMATION

Acceptance will be based on the importance of the material for the audience and the quality of the material, and cannot be guaranteed. All accepted manuscripts are subject to editing, which may involve only minor changes of grammar, punctuation, paragraphing, etc. However, some editing may involve condensing or restructuring the narrative. Authors will be notified of extensive editing. Authors will approve the final revision for submission.

The author, not the Journal, is responsible for the views and conclusions of a published manuscript. The author will assign copyright to JLNC upon acceptance of the article. Permission for reprints or reproduction must be obtained from AALNC and will not be unreasonably withheld.



**Debbie Pritts**  
RN LNCC

President, AALNC

## President's update

**M**any of you reading this issue have survived some of the coldest weather we have had for a long time. Now spring is coming! We will have lighter nights, warmer weather, and easier arising in the mornings with fresh air and birds chirping! Are you following through with your New Year's resolutions for personal and professional improvement?

To those who took advantage of your many AALNC benefits this past year, congratulations! I know you've seen success by your membership involvement. However, have some of you let yet another year slip by without making even a first move down your path to LNC success? If you haven't taken that first step to expand your knowledge, it's never too late to become an active member. Now's the time to start! Become more involved by serving on a committee, taskforce, presenting a webinar, or volunteering for our journal – investing a little time in any of these will make you a more successful LNC.

I would like to acknowledge and celebrate some of our accomplishments over the past year:

- Publishing the new **Scopes and Standards**
- Starting the **Principles and Practice 4th edition** revision
- Planning a **new eBook series** launch
- First ever **mock trial in Chicago**, in partnership with John Marshall Law School, in September 2017, providing excellent educational benefits and networking opportunities
- First series of **Online Learning Modules**: quality review and final edits
- Official launch of the revised **AALNC Legal Nurse Consulting Professional Course: Building Skills. Building Careers**, with 59 continuing education contact hours in 17 online modules.
- Investment in a new **AALNC Professional Development Center** to provide members:
  - Enhanced user experience
  - More content in various learning formats
  - Storage for all your CE documentation
- Rekindling the **Educational, Institution, and Business Entities taskforce** to explore the benefits of collaboration
- Creating and improving project plans for ongoing committee projects to increase committee and staff efficiency and contributions
- Increasing AALNC's **social media visibility**
- Continuing to **improve the overall Forum experience** with timely educational sessions: best-ever network opportunities and our first oceanfront venue!

As my term as president comes to an end, I will be forever thankful to all of you for entrusting me with leading our wonderful Association. While requiring some long hours and a lot of hard work on many important tough decisions, this year provided me such incredible opportunities and rewards. I have grown professionally and personally; I have met so many new and experienced LNCs, attorneys, and business associates. What an amazing gift! From here, I will stay involved to continue paying back – and paying forward. I challenge all of you to do the same: Make yourself better and make our Association better!

*The difference between who you are and who you want to be is what you do.* (various attribution)

Start doing!

Best,

*Debbie Pritts RN, LNCC*

Debbie Pritts, RN LNCC

# What LNCs need to know about predatory journals

**W**elcome to the first JLNC of 2018! We're looking at product liability and FDA issues this time. You'll find very useful information and resources here. We actually had more than we could pack into this issue! An embarrassment of riches is a nice problem to have.

Speaking of resources, I've gotten some interesting emails from an active online community of nurse editors, the International Academy of Nurse Editors. It's a pucky group, as partly indicated by its acronym, INANE, but the discussions are anything but. Recently we've been discussing predatory publishing, a term coined by Beall in 2012. What's that? Read on.

A predatory journal looks good. Its title, like these, sounds plausible: "ARC Journal of Forensic Science," "International Journal of Pregnancy and Childbirth," or "American Journal of Advances in Medical Science." It says it's peer-reviewed and has a big impact factor. (Beall's List, 2018)

Its publisher sounds good too, like "American Research Journals," "American Society of Registered Nurses," "Academicians Research Center," or "Fundamental Research and Development International." It may offer a long list of publications. (Beall's List, 2018)

Its solicitation touts "open access" for your paper, an opportunity to get published and indexed to build your resume and gain status. It's understandably attractive. Accept, and you might be offered "prestigious Guest Editor" status and a request to invite colleagues to publish in your issue. Some will even offer to have you speak at an online conference from the comfort of your desk.

Alas, though, the way you and your colleagues get to do this is to pay several thousand dollars, up front, allegedly for "peer review" and "editorial services." These are likely to be nonexistent. That "conference" is likely among hundreds held annually in the same building, in an empty room in a sketchy office, with remote attendees (if any) also paying dearly for the privilege.

There are also memberships offered – how does \$2500/year for an individual sound to you?

Oerman et al. (2017) recently reviewed 358 randomly-selected articles from some of these "journals" in nursing and found that

*Two-thirds (67.4%) of the articles were published between 2014 and 2016, demonstrating the acceleration of publications in predatory nursing journals. The majority (75.9%) of the articles were research reports. Most followed the IMRAD (Introduction-Method-Results-and-Discussion) presentation of a research report but contained errors, or the study was not pertinent to the nursing discipline.*

They concluded that, "Nursing research published in predatory journals may appear legitimate by conforming to an expected structure. However, a lack of quality is apparent, representing inadequate peer review and editorial processes." This phenomenon is pervasive; it isn't limited to nursing publishing.

## WHY SHOULD LNCS CARE ABOUT THIS?

Do you rely on published works in any field to support your research and opinions for your clients? Do you look at experts' publications when you vet them? I thought so. If you're evaluating a journal or citation for content or submission, ask (Etkin & Fullerton, 2017):

- ✦ Do you or your colleagues know the journal?
- ✦ Have you read any articles in the journal before?



**Wendie Howland**  
MN, RN-BC, CRRN,  
CNLCP, LNCC

Editor, JLNC

## SAMPLE, ERRORS INCLUDED:

"... ARC always tries to welcome papers in every one of the subjects for distributed in its worldwide Journals in the wake of fitting examination and compelling review. ARC Publications appropriates the progression and development in all subjects of the insightful world. ARC Publications also is the worldwide stage for conferences and seminars, symposia and workshops for specialists and learners on one hand and Academicians and smart characters of overall refinement and brightness on the other."

(<https://Arcjournals.org>)

- Is it easy to discover the latest papers in the journal?
- Can you easily identify and contact the publisher?
- Can you contact the publisher by telephone, email, and post?
- Is the journal clear about the type of peer review it uses?
- Are articles indexed in services you use?\*
- Do they belong to the Committee on Publication Ethics (COPE)?

\*Note that appearance in an indexing service, such as Google Scholar, PubMed, or EBS-CO, is not a guarantee that a publication is legitimate. These publishers often report doi and ISSN numbers, and impact factors, many of which are fictitious and in any case are no mark of quality.

Know of this threat to academic integrity— and check the citations that come across your desk, whether you're plaintiff or defense, to avoid an unpleasant surprise.

A frequently-updated (Jan. 2018) list of both standalone journals and publishers who promulgate these journals is available at <https://beallslist.weebly.com/> Bookmark it.

## REFERENCES

AuthorAid (2017) What are predatory conferences and how can I avoid them? The Think.Check. Submit program. <http://www.authoraid.info/en/news/details/1156/> Retrieved 2/1/2018

Beall J (2012) Predatory publishers are corrupting open access. *Nature* 489:179

Beall J (2015) Criteria on determining predatory open-access publishers, 3rd ed. <https://beallslist.weebly.com/uploads/3/0/9/5/30958339/criteria-2015.pdf> Accessed 1/26/2018

Beall's List of Predatory Journals and Publishers (2018) <https://beallslist.weebly.com/> (Retrieved Jan 31, 2018)

Etkin, A., Fullerton, J. (2017). Predatory Publishing. *International Journal of Childbirth*, 7(3), 114-116. <http://dx.doi.org/10.1891/2156-5287.7.3.114>

Oermann MH, Nicoll LH, Chinn PL, et al. (2017) Quality of articles published in predatory nursing journals. *Nursing Outlook* (in press) <http://dx.doi.org/10.1016/j.outlook.2017.05.005>

## THINGS THAT SOUNDED GOOD AT THE TIME...

<https://www.medpagetoday.com/primarycare/generalprimarycare/69185>

Greg Von Portz, writing in the November 2017 MedPage Today, published a list of medical devices that sounded good at the time, listed by increasing "magnitude of their unintended bad consequences." Some may be familiar.

7. MAST pants (medical anti-shock trousers): Studies revealed that they did not improve survival in shock despite high cost
6. Metal-on-metal hip replacements: (see Mattazaro, page 24)
5. Absorbable vascular scaffold stent: Off the market after increasing reports of thrombosis
4. Morcellator: Breaks up masses, e.g., fibroids, in minimally-invasive GYN surgery, to allow suction removal. If used on unsuspected malignant tissue, promotes spread.
3. Heart sock: Mesh sleeve intended to remold myocardium after heart failure. Heart grew into the mesh, making further procedures difficult or impossible
2. Dalkon Shield IUD: Woven removal string wicked bacteria into the uterus, causing septic abortion and uterine infections.
1. Transvaginal mesh: Found to erode through adjacent tissues causing chronic pain, infection, incontinence, and more.

# Test Your Case Screening Skills

## CASE #1

Patient underwent lap gastric bypass in March of 2008. By May, she was having trouble keeping any food or medications down, although she was trying. She developed dizziness, muscle weakness, visual changes and was seen and released in the ED on 5/17/08. This progressed to inability to walk, short term memory loss and severe metabolic disturbances and she was back in the ED on 5/22/08. She apparently sat in the ED for 2 or 3 days without seeing surgeon or a neurologist. Finally a neurologist saw her and admitted her to the ICU, but the ultimate diagnosis took a few days to arrive at. The cause of her symptoms was severe thiamine deficiency, which, by the time it was recognized and treated, caused severe and permanent cognitive and functional deficits. She is in her 30's and is confined to a nursing home, unable to walk, with severely diminished vision and a short term memory loss which appears to be permanent.

## CASE #2

Melony called re her daughter Tayler. Tayler was a full-term baby. When she was born she stopped breathing and had brain damage. Her ob-gyn was Dr. Bridgette Jones. Tayler was born at Mercy Hospital. She is fed thru a g-tube. When she was about one year old, the g-tube fell out and it was replaced at Mercy with a temporary one. Two days later Tayler had a bad infection and it was discovered that the food was not going into the right place. She almost died. The g-tube caused a hole inside and surgery was needed. They patched up the hole, cleaned her out and removed her appendix. She is unable to swallow. She has cerebral palsy along with a number of other diagnoses. She receives therapy at home and is on Medicaid. Her mother would like someone to investigate what happened at the birth and also the problem with the g-tube. She was referred by a friend's accountant.

Check your answers on [page 21](#).

## Test Your Case Screening Skills

You decide: reject, or investigate?



# FDA History, Medical Devices, and Searching the Medical Device Database

Joanne Walker BSEd, RN

*The Food and Drug Administration is the oldest comprehensive consumer protection agency in the U. S. federal government, having been around in some form since 1848. However, the regulation of medical devices by the FDA did not commence until more recent times. Understanding the term "medical device" and its classifications are essential to the practice of Legal Nurse Consulting when reviewing cases of alleged device failure or misuse. Researching the FDA MAUDE database to find the information necessary to either prove or disprove this allegation is one focus of this article.*

The Food and Drug Administration is the oldest comprehensive consumer protection agency in the U. S. federal government. Its origins can be traced back to the appointment of Lewis Caleb Beck in the Patent Office around 1848 to carry out chemical analyses of agricultural products, a function that the newly created Department of Agriculture inherited in 1862. Although it was not known by its present name until 1930, FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act.

The FDA and its responsibilities have undergone a metamorphosis since 1906.

Yet the core public health mission of the agency remains now as it did then. <https://www.fda.gov/AboutFDA/WhatWeDo/History/>

Each day when people put in their contact lenses, test their blood sugar levels, turn on their TVs, cook their meals, or punch a button on their cell phones, they are using products regulated by the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). The CDRH protects Americans with safeguards that enable them to go about their daily lives knowing that these medical devices and radiological

products are reasonably safe to use and that they work as intended.

Medical devices are classified and regulated according to their complexity and degree of risk to the public. For example, devices that are life-supporting, life-sustaining, or implanted, such as pacemakers, must receive FDA approval before they can be marketed. But medical devices haven't always come under such scrutiny. In fact, it wasn't until the late 1970s that the FDA actually gained authority to pre-approve medical devices under the 1976 Medical Device Amendments. Additional laws have, over time,



Dalkon Shield

mandated the reporting of adverse reactions to medical devices, post-market monitoring of implants and other devices that pose a serious health risk, recall of dangerous medical devices, and certification and annual inspection of mammography facilities.

Some of the earliest fraudulent medical devices were:

- ✦ Dr. Elisha Perkins' patent tractors in the late 1700s, two rods of brass and iron about three inches long. Dr Perkins claimed they eliminated disease from the body.
- ✦ nose straighteners, height-stretching machines, and heated rubber applicators advertised as a cure for prostate gland disorders.
- ✦ a radium belt, which carried a disc alleged to contain the element. According to proponents, someone wearing the belt would never have appendicitis or gallbladder disease, or perhaps, any other ailment.

Originally, medical devices were officially defined as drugs. The contentious Senate debate that led up to enactment of the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 had much to do with the definition of a medical device being added to the



Dr. Perkins' patent tractors

law. From 1938 until the early 1960s, devices were subject only to policing by the FDA. The agency determined whether a device was safe and effective. If not, the agency could bring charges in the courts only against products or materials that were found to be defective, unsafe, filthy, or produced in unsanitary conditions (adulterated), or against statements, designs, or labeling that was false or misleading (misbranded). There was, however, no requirement for pre-market testing, review, or approval.

In 1962, President John F. Kennedy proposed changes to the way medical devices entered the market. A few months later, however, news came that thousands of European women who took the sedative thalidomide in the first trimester for morning sickness gave birth to babies with phocomelia, deformities or absence of limbs. The issue of medical devices was then set aside so that health officials could focus on the tragedy.

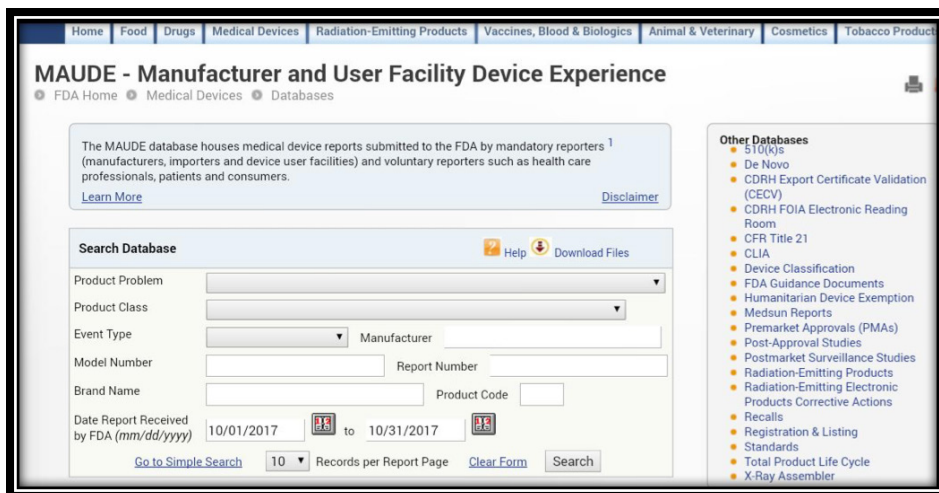
The Cooper Committee, chaired by Theodore Cooper, M.D., then director of the National Heart and Lung Institute, was organized in 1970 specifically to study medical devices. The committee recommended that any



Baby with phocomelia

new legislation be specifically targeted to the device industry, because devices presented entirely different issues from drugs. It also suggested that different classifications for medical devices be created, which would tailor the regulatory controls to the risks involved.

While the Cooper Committee recommendations were being debated in Congress during 1972 and 1973, pacemaker failures were reported. In 1975, hearings took place on problems that had been reported with the Dalkon Shield intrauterine device, which caused thousands of reported injuries. Those two incidents helped underscore the need for the Medical Device Amendments, enacted in 1976. These called for all devices to be divided into classes, with varying amounts of control required in each one. Medical devices were classified in 3 categories:



MAUDE Websearch Feature

Class I (e.g. tongue depressors), Class II (devices requiring performance standards to ensure product safety and effectiveness, e.g. wheelchairs), and Class III (devices requiring pre-market approval, e.g. artificial hearts). Good Manufacturing Practice (GMP) regulations also were authorized at that time. These are a set of procedures to ensure that devices are manufactured to be safe and effective through quality design, manufacture, labeling, testing, storage, and distribution.

According to Mark Barnett, the CDRH's assistant director for education and communications since its inception in 1982, "The safety of most medical devices depends to a large degree on their being used properly. And so, with devices, an important

part of our job is to educate health care practitioners and patients about safe use."

The Medical Device Amendments also gave the FDA authority to deal with the notification, repair, replacement, and refund of defective devices, and the agency was authorized to ban any device that presents a substantial deception or substantial unreasonable risk of injury or illness.

More medical device milestones were:

- ✦ the Safe Medical Devices Act (SMDA), 1990 requiring health care facilities that use medical devices to report to the FDA incidents suggesting that a medical device probably caused or contributed to

a patient's death, serious illness, or serious injury;

- ✦ the Mammography Quality Standards Act (MQSA), 1992 requiring all mammography facilities in the United States to be accredited and certified as meeting quality standards as of Oct. 1, 1994;
- ✦ the Medical Device User Fee and Modernization Act, 2002 (amended in 2005) allowing the FDA to charge a fee for medical device product reviews. The agency uses these funds to hire staff and develop better systems to support effective and timely product reviews, to enact needed regulatory reforms, and to ensure that reprocessed devices are as safe and effective as the original devices. The aim of the legislation is to bring safe and effective devices to the public sooner.

Reference: Rados, Carol. **Medical Device and Radiological Health Regulations Come of Age.** *FDA Consumer magazine*; The Centennial Edition / January-February 2006

## SEARCHING THE MAUDE DATABASE

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. Although

*The Good Manufacturing Practices Act provides for a set of procedures to ensure that devices are manufactured to be safe and effective through quality design, manufacture, labeling, testing, storage, and distribution.*

*Although medical device reports (MDRs) are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data.*

medical device reports (MDRs) are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.

- Please note that the MAUDE web search feature is limited to adverse event reports within the past 10 years.
- MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
- Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
- MAUDE data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.
- Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.
- Submission of a medical device report and the FDA's release of that information is not necessarily an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.
- Certain types of report information are protected from public disclosure under the Freedom of Information Act (FOIA). If a report contains trade secret or confidential business information, that text is replaced by "(b)(4)". If a report contains personnel or medical files information, that text is replaced by "(b)(6)". The designations "(b)(4)" and "(b)(6)" refer to the exemptions in the FOIA. For example, "(b)(4)" may be found in place of the product's composition and "(b)(6)" may be found in place of a patient's age.
- MAUDE is updated monthly and the search page reflects the date of the most recent update. The FDA seeks to include all reports received prior to the update but the inclusion of some reports may be delayed.

Source: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

Forms for reporting adverse events are Form FDA 3500 (voluntary), Form FDA 3500B (consumer-friendly), and FDA 3500A (mandatory). Links to forms and instructions about completing them can be found online at <https://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>

The FDA is building the National Evaluation System for health Technology (NEST) to more efficiently generate better evidence for medical device evaluation and regulatory decision-making. NEST will generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence and applying advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices.

The collaborative national evaluation system will link and synthesize data from different sources across the medical device landscape, including clinical registries, electronic health records and medical billing claims. A national evaluation system will help improve the quality of real-world evidence that health care providers and patients can use to make better

*Although this article has focused on the FDA and its regulation of medical devices, there are other registries that LNCs may consider consulting when researching a case.*

informed treatment decisions and strike the right balance between assuring safety and fostering device innovation and patient access. <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm301912.htm>

## FAERS AND MEDWATCH

The **FDA Adverse Event Reporting System (FAERS)** is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The ultimate goal of FAERS is to improve the public health by providing the best available tools for storing and analyzing safety reports. The reports in FAERS are evaluated by multidisciplinary staff safety evaluators, epidemiologists and other scientists in the Center for Drug Evaluation and Research's (CDER) Office of Surveillance and Epidemiology to detect safety signals and to monitor drug safety. As a result, the FDA may take regulatory actions to improve product safety and protect the public health, such as updating a product's labeling information, sending out a "Dear Health Care Professional" letter, or re-evaluating an approval decision. <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm090385.htm>

**MedWatch** The FDA Safety Information and Adverse Event Reporting Program is "Your FDA gateway for clinically important safety information and reporting serious problems with human medical products." <https://www.fda.gov/Safety/MedWatch/default.htm>

To subscribe to MedWatch Safety Alerts, go to <https://www.fda.gov/Safety/MedWatch/ucm228488.htm>

Although this article has focused on the FDA and its regulation of medical devices, there are other registries that LNCs may consider consulting when researching a case. This link to Chapter 23, Registries for Medical Devices in the textbook *Registries for Evaluating Patient Outcomes: A User's Guide* [Internet]. 3rd edition; Agency for Healthcare Research and Quality may have useful information for the LNC <https://www.ncbi.nlm.nih.gov/books/NBK208640/>

## CONCLUSION

The FDA's MAUDE Database is the tool most often used for finding information on medical devices and their history of reported issues. However, the LNC should be aware of the limitations of the database, which may have incomplete information due to the subjective nature of its reports and the complex mandatory reporting form (NB: forms are under review for renewal by the US Office of Management and Budget by the end of September 2018). MAUDE

remains the most updated repository of information when researching cases involving complaints about medical devices.

*The information in this article was compiled by Joanne Walker, BSEd, RN and was taken mostly verbatim from the FDA website sections cited above.*



**Joanne Walker, BSEd, RN** attained a Bachelor of Science in Early Childhood Education at Towson University in Maryland before moving

to England, where she trained as a nurse. She has over 30 years of perioperative experience in general, cardiothoracic, urology, retinal, ENT, plastics, orthopedic, and neuro surgery. She has been a manager in OR, PACU, GI, and ASC. Joanne returned to the US in 2003, studied legal nurse consulting and founded Clarity Medical Legal Consulting. She has done both behind-the-scenes case reviews for merit and testified as an expert witness. She has participated in a joint webinar for AALNC and ABA, using her knowledge of GI standards of care; and has presented webinars on research for AALNC and the WVUOV virtual chapter of AALNC. She is the 2018 Education Chair for the virtual chapter, and is a member of the Editorial Committee of JLNC and an Associate Editor of *Legal Nurse Consulting: Principles and Practices*, 4th Edition. Joanne can be contacted at [jwalkLNC@yahoo.com](mailto:jwalkLNC@yahoo.com)

# GET PAID WHAT YOU ARE WORTH



**KELYNCO**  
Life Changing, Life Care Planning

Whether you are in business for yourself or working for a company, **Nurse Life Care Planning** offers you the opportunity to enter the ranks of the highest paid nurses in the country!

Enroll now in the courses that will change your life while you continue to do what you love. KelyncO's **Setting the Standards in Nurse Life Care Planning® Course** will prepare you for certification in your new career. All courses are taught by the founder of the American Association of Nurse Life Care Planning, Kelly Lance, MSN, APRN, FNP-C.

- Courses are approved by ANCC for 120 contact hours
- KelyncO is the only program taught using the nursing process at its core
- Totally Online and Totally Convenient!
- 4 Live Webinars are added to the the course to help you with your studies

### **KelyncO courses offer career options:**

- Nurse Life Care Planning
- Medicare Set-Asides

**Mention this ad and receive the Medicare Set-Aside Course FREE with your course registration of Life Care Planning!**

[www.kelyncO.com](http://www.kelyncO.com)



**DETERMINATION OF**  
Economic Loss, Lost Income, Loss of Earning Capacity  
of present & future value of damages



### **41 Years Experience**

- Life Care Planner (Assessment of Future Medical)
- Vocational Expert
- Forensic Economist
- Functional Capacity Evaluator
- Medical Projections
- Expert Testimony

## **Ronald T. Smolarski**

MA, CLCP, CRC, CDEII, ABVE, ABMPP, CVE, CRV, CCM

**1-800-821-8463**

Email: [ron@beaconrehab.com](mailto:ron@beaconrehab.com)  
[www.beaconrehab.com](http://www.beaconrehab.com)

Keep your business at your fingertips.

↳ **Business Assets** ↳ **Continuity of Services**  
↳ **Engagement Management**



 **SUCCESS(ION)  
SOLUTIONS, INC.**  
*The Consultants the Consultants Call*

Mila Carlson  
Phone: (815) 339-0390  
[mila@successionsolutions.us](mailto:mila@successionsolutions.us)

**Order Your Guidebook Today!**  
[successionsolutions.us](http://successionsolutions.us)



# Litigation Involving Contaminated Heater-Cooler Devices Used in Open-Heart Surgery

Jane E. Barone BS RN LNCC

Key Words: device, open-heart, NTM, non-tuberculin M. chimaera, Mycobacterium chimaera, heater-cooler system, cardio-pulmonary bypass

*Non-tuberculin Mycobacterium (NTB) or Mycobacterium chimaera (M. chimaera) infections caused by heater-cooler devices used during open heart surgery are a rapidly growing area of product liability litigation. This article makes the legal nurse consultant aware of the background of this litigation to assist plaintiff and defense attorneys determine causation, liability, and damages.*

## INTRODUCTION

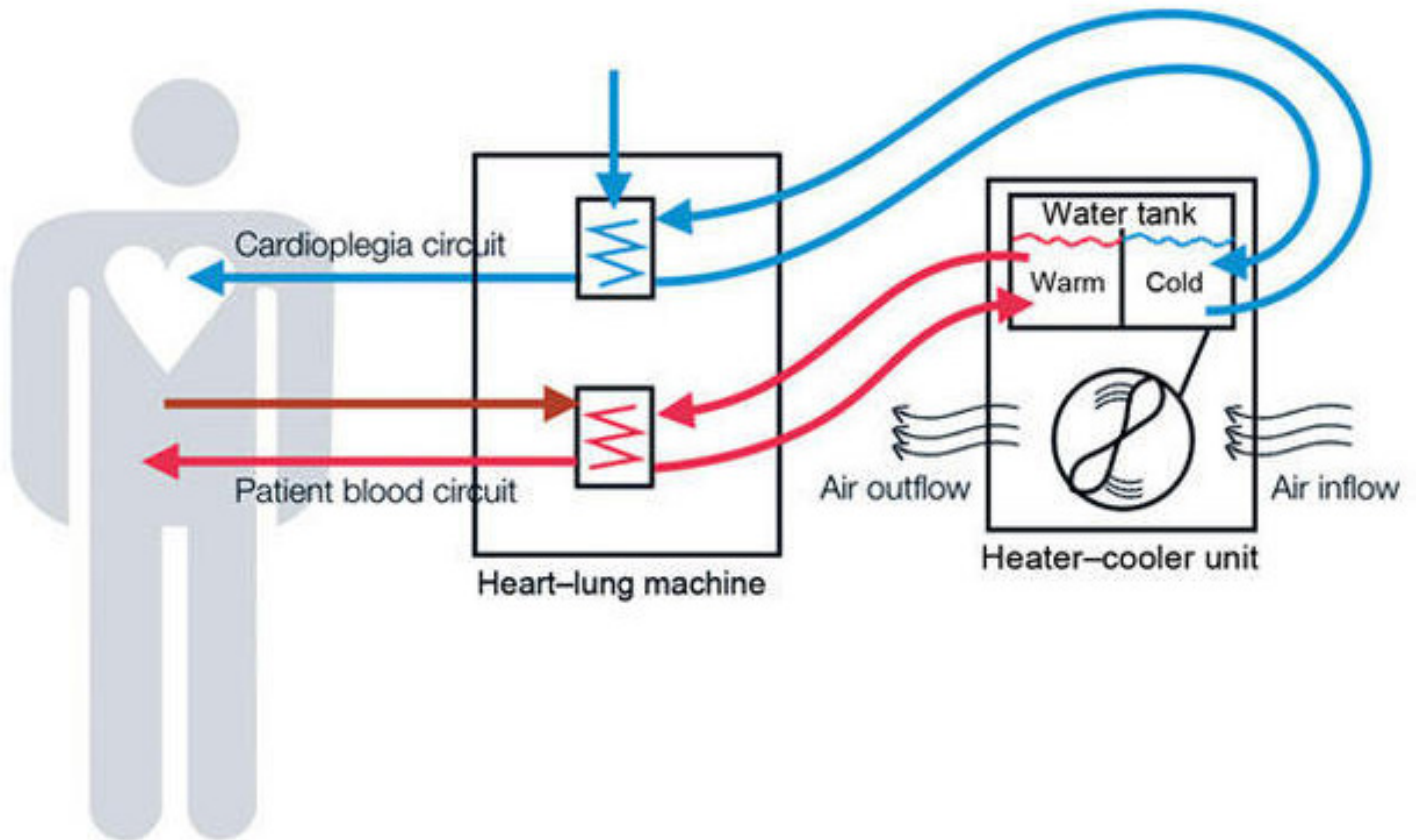
Imagine: you must have open-heart surgery. You probably research your illness, your doctor, the medical facility where you are undergoing the procedure and the procedure itself. You have it; you recover and think all is well. But several weeks to several years later, you do not feel well. You may just think that you

have the flu, or perhaps it's something more: your incision opens. Time passes because your symptoms are vague; fever, pain, night sweats, joint pain, muscle pain and fatigue, persistent cough, weight loss, nausea and vomiting or redness, or heat or pus around the surgical incision. You are found to have Mycobacterium chimaera (M. chimaera), a non-

tuberculin Mycobacterium (NTM). The source was the contaminated heater-cooler device used in your surgery.

## THE HEATER-COOLER DEVICE

A heater-cooler device has tanks of temperature-controlled water used



Schematic of cardiopulmonary bypass circuit.

to regulate blood temperature during cardiopulmonary bypass. The CDC learned that Stockert 3T Heater-Coolers, made in Germany, “might have been contaminated during manufacturing which could put patients at risk for life-threatening infections” (Mundy 2017) by releasing contaminated aerosols into operating rooms. This is not the only heater-cooler system in use, but about 60% of the 250,000 heart bypass procedures performed each year in the US involve use 3T Heater-Cooler systems (Perkins 2016).

## THE INFECTION

*M. chimaera* is a slow-growing bacterium commonly found in soil and water but not generally associated with infections. It can take from two weeks to four years for pulmonary and cardiovascular symptoms to appear; median time is 18

months after surgery (Antonation et al., 2017). Clinicians rarely screen for it, so diagnosis may be delayed. Roughly half of the people who contract it die.

This organism can cause:

- Prosthetic valve endocarditis
- Prosthetic vascular graft infection
- Paravalvular abscess
- Pseudo aneurysm
- Mycotic aneurysms
- Osteomyelitis
- Ocular mycotic emboli
- Immunologic manifestations
- Splenomegaly. (Antonation 2017)

Blood and tissue cultures are used to confirm the diagnosis.

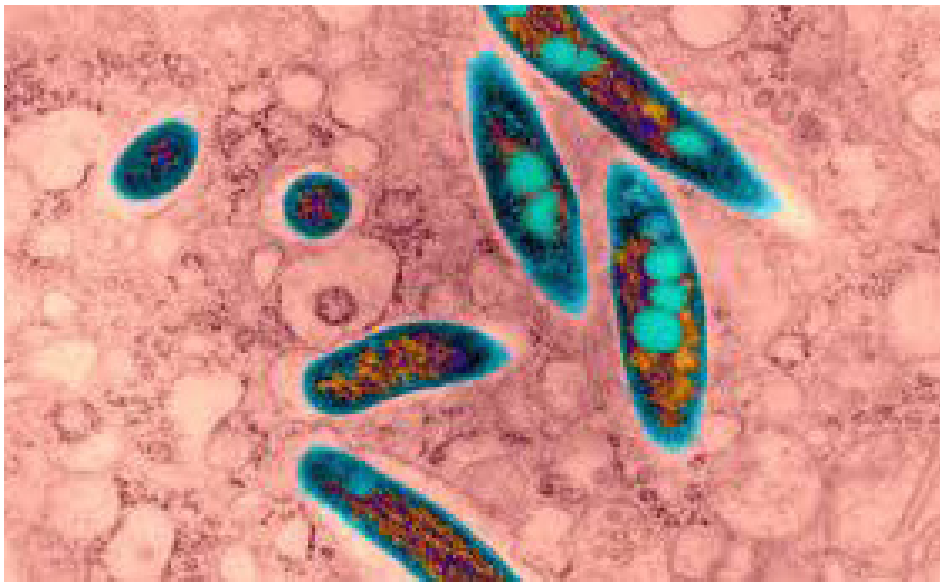
Treatment includes maximum-strength multiple antibiotics over months to years. Early diagnosis and treatment may lead to a successful recovery. However,

there is a significant risk of death with late diagnosis and immunocompromise. Additional surgery may be necessary to remove a contaminated implant.

## WARNINGS

Although The University Hospital of Zurich initially traced infections to this company with cases as far back as 2006, this information was not made public until March 2015. The European Society of Cardiology reported 10 open heart cases with *M. chimaera* infections at three European hospitals. Public Health England and Medicine and Health Care Products Regulatory Agency issued guidance to surgical centers and infection risk was identified (Mundy 2017).

The US Center for Disease Control and Prevention (CDC) issued a Health Alert Network Advisory warning of possible contamination in devices



Mycobacterium chimaera



manufactured before September 2014 (Perkins 2016).

The FDA first issued warnings about the heater-cooler infection risk in October 2015 after receiving at least 34 adverse event reports between 2010 and August 2015 (CDC 2015). They issued an updated Safety Communication on June 1, 2016 indicating that the Stockert 3T Heater-Cooler System used in cardiothoracic surgeries had been associated with *M. chimaera* infections, based on a European gene study linking them to the 3T. (FDA 2017)

The FDA recommended that medical facilities inform their patients of the risk of contracting the infection. They also recommended establishing a surveillance procedure of patients whose cardiopulmonary bypass used the 3T.

On October 13, 2016 another FDA Safety Communication was announced to prevent spread of NTM infections. It recommended (FDA 2017) that:

- accessories, tubing, and connectors be changed to prevent recontamination

- the heater-cooler exhaust be directed away from the patient into an exhaust vent
- use only sterile water to rinse and fill water tanks
- regular cleaning, disinfection, and maintenance schedules
- all 3T units that tested positive for the infection be removed from service

### THE LITIGATION

Litigation alleging exposure to *M. chimaera* or *M. abscessus* is proceeding against the manufacturer, Liva Nova/Sorin Company, in individual suits in Florida, Pennsylvania, Illinois, Washington D.C., South Carolina, South Dakota, Tennessee, Iowa, and North Carolina and a class action in Iowa. Genetic testing confirmed the source of infection is most likely the manufacturing plant.

The suits ask the court to declare that the heater-cooler units are defective and unsafe for their intended use. Some seek medical monitoring of patients who may be at risk for NTM. (Luhana 2017) In March 2017 the US Judicial Panel on Multidistrict Litigation heard

arguments to transfer cases to one judge for coordinated discovery and pretrial proceedings, but manufacturers won opposition to this motion. (About Law 2017)

Because the number of these cases has tripled, on November 6, 2017, defendants moved to ask for consolidation of all federal cases involving 3T Systems and transfer for cases to the US District Court for the District of South Carolina. As of this writing the decision is pending.

Infections in Switzerland, Germany, the Netherlands, UK, Australia, New Zealand and Canada have prompted suits against LivaNova PLC, Sorin Group Deutschland GMBH, and Sorin Group USA Inc. for taking insufficient measures to prevent injuries, negligence, product liability, and violation of federal law. LivaNova has a remediation plan with a design modification to include internal sealing and adding a vacuum system to new and existing devices to reduce risk of aerosol dispersion into operating rooms. The company also made a global announcement for plans for a no-charge deep disinfection service. (BusinessWire March 1, 2017)

Many hospitals have ordered new machines, but there is a backlog of orders. Some have sent letters to patients who have had open heart surgery at their facility warning them of NTM symptoms; others have not. Potentially 250,000 patients in the US who undergo procedures using cardiopulmonary bypass per year could be affected. (Perkins 2016)

## CONCLUSION

Watch this increasing litigation closely. Legal nurse consultants will be of value in these product liability cases by assisting in determining causation, liability, and damages for both plaintiff and defense attorneys.

## REFERENCES

AboutLawSuits.com (2017). Com 3T heater-cooler infection lawsuits to proceed as individual claims: JPML April 18, 2017 Available at: <https://www.aboutlawsuits.com/3t-heater-cooler-mdl-denied-125003/> Retrieved January 29, 2018

Antonation K, Patel S, et al. (2017) Interim laboratory testing guidelines for the detection of non-tuberculous Mycobacterium (NTM) infections in post-operative patients exposed to heater-cooler units. *CCDR* 2017 Jan 5; 43(1), 25-27

Business Wire (2017) LivaNova Pic-Product remediation plan related to 3T heater cooler device. March 1, 2017 Available at: [file:///C:/Users/jbaro/Downloads/Release7d0f441-a6cb-4b9e-809a-ebfd57c5a0f\\_2250486%20\(1\).pdf](file:///C:/Users/jbaro/Downloads/Release7d0f441-a6cb-4b9e-809a-ebfd57c5a0f_2250486%20(1).pdf) Retrieved January 29, 2018

Center for Disease Control and Prevention (CDC) (2015) Non-tuberculous Mycobacterium (NTM) infections and heater-cooler devices interim practical guideline: update October 27, 2015 Available at: <https://www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf> Retrieved January 29, 2018

CDC (2016) Interim guide for the identification of possible cases of nontuberculous Mycobacterium infections associated with exposure to heater-cooler units. May 13, 2016 Available at: <https://www.cdc.gov/hai/pdfs/outbreaks/Guide->

*It can take from two weeks to four years for symptoms to appear. Diagnosis may be delayed. Roughly half of all the people who contract it die.*

for-Case-Finding.pdf Retrieved January 29, 2018

FDA (2016) UPDATE: Mycobacterium chimaera infections associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T HeaterCooler System: FDA Safety Communication October 13, 2016. <http://www.fda.gov/Medical/Devices/Safety/AlertsandNotices/UCM520191.htm> Retrieved December 15, 2016

Federal Drug Administration (FDA) (2017) FDA's Ongoing Investigation of Nontuberculous Mycobacteria Infections Associated with Heater-Cooler Devices (2017) Updated Dec 4, 2017 Available at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492590.htm> Retrieved January 29, 2018

FDA (2017) Heater-cooler devices: information for patients (2017) Available at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492585.htm> Retrieved January 29, 2018

Luhana R (2017) New class action lawsuit filed in Iowa over contaminated heater-cooler units *The Legal Examiner*, August 8, 2017. Available at: <http://newyork.legalexaminer.com> Retrieved August 9, 2017

Lyman M, Grigg C, et al. (2017) Invasive nontuberculous Mycobacterial infections among cardiothoracic surgical patients exposed to heater-cooler devices, *Emerging Infectious Disease*, (2017) May; 23(5) Center for Disease Control and Prevention [https://wwwnc.cdc.gov/eid/article/23/5/16-1899\\_article](https://wwwnc.cdc.gov/eid/article/23/5/16-1899_article) Retrieved January 30, 2018

Mundy J. (2017) Stockert 3T Not the only heater-cooler unit associated with infection discovered years ago: May 2, 20017 Available at <https://www.lawyersandsettlements.com/articles/Stockert-3T-Heater-Cooler-System/>

<heart-surgery-infection-lawsuit-stockert-3t-8-22251.html> January 29, 2018

Perkins K, Laws M (2016) Notes from the field: Mycobacterium chimaera contamination of heater-cooler devices used in cardiac surgery-United States *MMWR* October 14, 2016 65(40) 1117-1118 Available at [https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s\\_cid=mm6540a6\\_w](https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w) Retrieved January 29, 2018

Stobbe M (2016) Contaminated machines linked to heart surgery infections. *The Washington Post* October 13, 2016 Available at: <http://www.modernhealthcare.com/article/20161013/NEWS/310139998> Retrieved January 29, 2018

Sun L (2016) More than half a million heart surgery patients at risk for deadly infection, *The Washington Post* October 13, 2016 Available at: <https://www.washingtonpost.com/news/to-your-health/wp/2016/10/13/more-than-half-a-million-heart-surgery-patients-at-risk-of-a-dangerous-infection/> Retrieved January 29, 2018



### Jane Barone BS RN LNCC

began her career 30 years ago. In 2003, she founded Medi-Law Solutions, a full-service legal nurse consulting firm for medical malpractice, personal injury, toxic tort and pharmaceutical cases for plaintiff and defense. She is a past president and current board member of the New Jersey Chapter of the American Association of Legal Nurse Consultants and published author of a chapter in *Legal Nurse Consulting Principles*, 3rd ed. Her clinical nursing background includes cardiac-telemetry, same day surgery, burn step-down, and plastic surgery. Contact her at [j.barone@medilawsolutions.com](mailto:j.barone@medilawsolutions.com).



# The Legal Nurse Consultant's Primer on Product Liability

Cynthia Mascaranhas, RN, LNCC

Keywords: product liability, privity of contract, statute of limitations, statute of repose, learned intermediaries

## INTRODUCTION

The term product liability conjures up images of a 1-800 telephone number flashing across our television screens. There is, however, a far greater connotation to that term best understood in context. Historically, a contractual relationship known as privity of contract had to exist for a product liability claim to be filed. This meant that the claimant had to have purchased a product directly from the manufacturer to sue the manufacturer for injury caused by the product.

By the 1950s and 1960s the courts moved away from privity of contract because manufacturers were relying more on wholesalers and retailers to sell their products to the consumer. This made it difficult for the consumer to sue the manufacturer for injury caused by a defective product. In 1963, California became the first state to adopt strict product liability, a concept we will further discuss. (Santa Clara Law, 1984). In 1986, after many other states followed California's lead, the U. S. Supreme Court incorporated product liability into admiralty law or maritime law. (476 U.S. 858, 1986).

*(Editor's note: We sincerely regret that we were unable to get reproduction rights to some excellent cartoons the author used to illustrate key concepts. Use your imagination where indicated.)*

## PRODUCT LIABILITY

Product liability is the area of law in which manufacturers, distributors, suppliers, retailers, and others who provide products to the public are held responsible for the injuries those products cause. It means that any party along the chain of manufacture of any product can be held liable for damage

caused by that product. This includes the manufacturer of components, an assembling manufacturer, the wholesaler, and the retail store owner. (Legal Information Institute, n.d.)

Product liability is a subfield of tort law. Torts are civil wrongs that result in injury or harm and their primary aim is to provide relief for damages incurred while serving as a deterrent to others. (Legal Information Institute, n.d.)

Product liability claims can be based on these 3 elements depending on the claim jurisdiction. (Legal Information Institute, n.d.)

(a) Negligence is causing harm by failure to follow the rules; the focus is on the conduct of the defendant and it could be intentional or unintentional.

(b) Breach of warranty of fitness concerns the product not living up to its promise.

(c) Strict liability imposes liability for making and selling defective products without factoring in care exercised by the manufacturer. It is the primary type of product liability lawsuit and is brought under the premise of no-fault.

Degree of carefulness is irrelevant. This motivates the manufacturer to make safer products and shifts the cost of the product-related injuries towards manufacturers and away from consumers.

Product liability lawsuits can be brought individually or as a class action, which is a situation in which multiple claimants have similar allegations against the same defendant. These claims can be consolidated and treated as one lawsuit. If they do not get certified as a class, they could be called a mass tort lawsuit. The basic difference lies in procedural handling. Mass tort cases are handled as a group for pre-trial and then are sent to the jurisdiction in which they are filed for trial.

There is no federal product liability law. Product liability is governed by

*Product liability lawsuits can be brought individually or as a class action, which is a situation in which multiple claimants have similar allegations against the same defendant.*

state law. Regardless of jurisdiction, one must prove that the product is defective. Sometimes, that defect is obvious.

*(Imagine here a great cartoon of a defibrillation attempt resulting in a pile of ashes in the bed. Caption: "Call maintenance!")*

Design defects are inherent to the product; they exist before the product is manufactured and all items are flawed. Manufacturing defects occur during production; some items are flawed. Marketing defects include improper instructions and failure to warn of latent dangers.

## WHO CAN SUE?

In most states today, privity of contract no longer exists, and the injured person need not be the purchaser of the product to recover damages. Any person who foreseeably could have been injured by a defective product can recover for injuries once the product was sold. This would include the original purchaser or any other person who used the product. It would also include remote users or 3rd party users such as passengers in a car or pedestrians hit by a car due to a fault in the mechanism of the car. (Privity of Contract, n.d.)

## WHO CAN BE SUED, AND HOW?

Components manufacturers, product manufacturers, persons involved in the assembly or installation of the product,

wholesalers, and retailers can all be sued for injury caused by a product. Remember that statute of limitations (SOL) differ from state to state; in most states, an action must be brought within 2 to 4 years of when the injury is or should have been discovered. Statute of limitations is distinct from statute of repose, which allows for a claim to be brought 10 to 12 years from the date of manufacture.

This difference presents a challenge: one must determine which state would control statute of limitations in a particular claim. If, for example, the manufacturer is from New York (SOL 3 years), the retailer is from Florida (SOL 4 years), and the injury occurred in Hawaii (SOL 2 years), what would be the statute of limitations? This dilemma can ultimately be resolved only when jurisdiction is determined.

Of special importance is the discovery rule, which dictates that statute of limitations commences once injury is discovered. Statute of limitations on a minor, however, runs from the date the injured turns 18 years old. (Statute of Limitations, (n.d.))

The Consumer Product Safety Act (CPSA), section 15(b), also called Section 2064(b), requires manufacturers, importers, distributors, and retailers to notify the Consumer Product Safety Commission immediately if they obtain information that reasonably supports the conclusion that a product distributed in commerce (1) violates a consumer

*In both product and medical malpractice liability, the plaintiff must prove that a duty was owed, and that duty was breached by a failure to meet the standard of care. In product liability, a manufacturer is expected to exercise a standard of care reasonable for experts in manufacturing similar products; if it is not exercised, plaintiff must prove that but for negligence, there would not be an injury AND that the defendant could have foreseen the risk of injury.*

product safety standard, rule regulation, or banning regulation; (2) contains a defect that could create a substantial product hazard to consumers; or (3) creates an unreasonable risk of serious injury or death. (Ross, 2011). In 2011, there was an exponential growth in the number of product safety laws worldwide requiring incident reporting. This resulted in more reports to governments and more product liability lawsuits and class actions being brought.

Product liability lawsuits have a lot in common with medical malpractice lawsuits. In both product and medical malpractice liability, the plaintiff must prove that a duty was owed, and that duty was breached by a failure to meet the standard of care. In product liability, a manufacturer is expected to exercise a standard of care reasonable for experts in manufacturing similar products; if it is not exercised, plaintiff must prove that but for negligence, there would not be an injury AND that the defendant could have foreseen the risk of injury. The difference is that in negligence in medical malpractice is proven by 4 elements of duty: breach of duty, proximate cause / causal connection, and damages; but negligence in product liability lawsuits is proven by 5 elements: duty, breach, actual cause - cause in fact, proximate cause - but for clause, and actual damages.

Damages are the same: economic (actual cost), non-economic (pain and suffering), and punitive (rare but usually a high-ticket award). A plaintiff could elect to sue the healthcare professionals involved in a product liability lawsuit; in that case, he would bring a medical malpractice claim against the defendants.

### PROVING LIABILITY:

There are several challenges to proving liability: the lines can be blurry, you may be dealing with unavoidably unsafe products, manufacturers' duty to warn, and time-lapse issues. Where plaintiff has not sufficiently identified the supplier of a product it is difficult to connect the product with a supplier or manufacturer. In such a scenario, market share liability comes into play; all manufacturers bear the cost depending on their market share in the area where injury occurred. (Princeton, n.d.) Sometimes, it may happen that the product was altered by the consumer after it left the manufacturer's control, or injury may have been caused by misuse of the product. All these issues can be a defense.

*(Imagine another great cartoon here: Dermatologist with a headless patient holds up a tool. Caption: "Hey, can you turn down the power on this laser?")*

Pharmaceutical drugs are frequently at the center of product liability lawsuits. Testing criteria from the U. S. Food and Drug Administration serve as the industry standard for manufacturers. (USFDA, n.d.) They must appropriately test these drugs before releasing them into the market. Just because the manufacturer was properly licensed by the FDA does not mean he is exempt from liability to an injured plaintiff if a product proves to be defective.

*(Cartoon that was going to be here: Two guys looking at a pile of wreckage. "I thought you tested this thing?" "Didn't work then either.")*

The doctor prescribing the drug, the pharmacist who sold it, or the nurse administering it would all be considered learned intermediaries and, thus, held liable for injury caused by the product. An exception to this is over-the-counter drugs.

The learned intermediary argument could also be a defense whereby a learned intermediary would be expected to know and understand more about the use and effects of a certain product than the general population. Certain products are unavoidably unsafe, like chemotherapy drugs; they may have potentially harmful side effects but are also beneficial to the user in the treatment of their illness. In

such cases, the manufacturer must ensure that adequate warnings accompany the drug and these side effects cannot become the basis of suit. Manufacturers have a duty to warn of all side effects of a drug, even if they would be considered obvious; however, they are not held liable for unforeseen side effects. As an expert in the field, the manufacturer must keep the medical community updated on all the potential adverse effects of their product, even those that may be rare.

In some drug-related injury cases, the plaintiff may not be able to confidently identify the manufacturer or supplier of a certain drug because of the time that has elapsed. For example, a pregnant woman may ingest certain drugs assuming they are safe for her unborn child; 9 months later or even later, she may discover that her child has been harmed by the drugs ingested during pregnancy. She may no longer identify the manufacturer or supplier of that drug. In such a case, the liability will be allocated to all potentially liable manufacturers.

I hope that the information in this article whets your appetite for a better understanding of the issues regarding product liability litigation. Regardless of your area of practice, sooner or later your personal life may be touched by either product malfunction or unintended consequences of a product or drug. The effects of product liability can be as far-reaching as that product's usage: ubiquitous. The next time you see a 1-800 number flash across your television screen, you can pat yourself on the back and say, "I know a thing or two about that."

## REFERENCES:

Ross, K. (2011). In-house Defense Quarterly (Fall 2011) International Reporting Requirements – New Safety Laws May Result in Significant New Liability [http://www.productliabilityprevention.com/images/IDQ-Fall\\_2011-Reporting\\_Comparison.pdf](http://www.productliabilityprevention.com/images/IDQ-Fall_2011-Reporting_Comparison.pdf) Retrieved 11/22/2017

Wildman, S.M., Santa Clara Law (1984). Strict Products Liability in California:

An Ideological Overview <http://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1450&context=facpubs> Retrieved 12/26/2017

476 U.S. 858 (1986). East River S.S. Corp. v. Transamerica

<https://supreme.justia.com/cases/federal/us/476/858/case.html>; Retrieved 12/26/2017

Legal Information Institute (n.d.) Product Liability

[https://www.law.cornell.edu/wex/products\\_liability](https://www.law.cornell.edu/wex/products_liability) Retrieved 11/22/2017

Nolo (n.d.) Product Liability Claims Involving Pharmaceutical Drugs

<https://www.nolo.com/legal-encyclopedia/product-liability-claims-pharmaceutical-drugs-30314.html> Retrieved 11/22/2017

Princeton University, Pharmaceutical R&D; Costs, Risks, & Rewards – Product Liability and the Pharmaceutical Industry (n.d.)

<https://www.princeton.edu/~ota/disk1/1993/9336/933609.PDF> Retrieved 11/22/2017

Privity of contract. (n.d.) A Law Dictionary, Adapted to the Constitution and Laws of the United States. By John Bouvier. (1856).

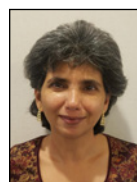
<https://legal-dictionary.thefreedictionary.com/privity+of+contract> Retrieved 1/1/2018

Statute of Limitations. (n.d.) West's Encyclopedia of American Law, edition 2. (2008).

<https://legal-dictionary.thefreedictionary.com/statute+of+limitations> Retrieved 1/1/2018

USFDA (n.d.) Facts About the Current Good Manufacturing Practices (CGMPs)

<https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm>



**Cynthia Mascarenhas, RN, LNCC** is a legal nurse consultant & independent medical cost projection specialist with experience in the areas of product liability and in-house medical malpractice for over 7 years. Her clinical background is in medical-surgical care, home health, cardiovascular stepdown, emergency room, PCU, and skilled nursing.



Check Your Answers

## Test Your Case Screening Skills Page 7

### Case #1: Investigated

\*Favorable expert reviews on liability and causation

\*Very significant damages

\*Multiple defendants worked out apportionment of liability among themselves

**Disposition:** 7 figure settlement

### Case #2: Investigated

\*Teenage mother

\*No merit to issue with G-tube

\*Obtained medical records - very meritorious birth injury case (classic case of birth asphyxia/HIE due to improper management of labor)

**Disposition:** Case settled prior to trial for \$ 3.2 million

# When Is a Daubert “Expert” Not a Daubert “Expert”?

James Hanus, RN, BSN, OCN, MHA<sup>t</sup>

When expert witnesses are retained, be it for Plaintiff or defense, they must be able to pass the “Daubert Test” (1) and the Federal Rules of Evidence Rule 702 (2). However, they must be cautioned as they present their expert opinion during deposition or in court that they must not exceed their Daubert expertise. Presented in this article, the Court found that in the deposition of three medical experts for the Plaintiff, their testimony met the Daubert and Rule 702 “expert” standard regarding the alleged medical malpractice. However these same “experts” then offered their “expert opinion” regarding another aspect, for which the Court found they did not meet the Daubert and Rule 702 standard. The case has not yet gone to trial (one Defendant has settled), so we may never know the impact of the Court’s decision, but every LNC should consider it while identifying and preparing an expert witness.

There is a decision in December 2016 from the Federal District Court for the Eastern District of Kentucky, in *Bentley v. Highlands Hospital, et.al.* (3) where the Plaintiff hired three medical experts. The Court held they all passed the “Daubert Test” and the Federal Rules of Evidence Section 702 test as expert witnesses regarding medical malpractice.

However, in expert reports before deposition, they exceeded their expert scope by opining on an issue unrelated to the alleged malpractice.

In July 2014, Ms. Bentley (whose age or past medical history is not mentioned) had a sore throat. She went to an after hour clinic operated by Highlands Regional Medical Center (HRMC), where a nurse practitioner examined her, found redness and swelling, and made a diagnosis of pharyngitis. Ms. Bentley was sent home with a prescription for an antibiotic.

Several days later, Ms. Bentley returned to HRMC, but now her symptoms included nausea, abdominal and back pain and difficulty urinating. The clinic felt she needed to be seen in the HRMC ER. There she had a CT scan that identified calcified deposits in both kidneys. She was diagnosed with kidney stones and sent home with pain medications. Eleven hours later (1am), she presented to the ER at Paul Hall Regional Medical Center (PBH) with severe pain in both legs along with a tingling and weakening of both legs. The ER physician ordered a CT scan of her spine which was negative and the patient was sent home four hours later with a diagnosis of acute back pain and to see her family practice physician.

Four hours later, Ms. Bentley was at her family practice physician with diminished reflexes and loss of control of her left foot. The physician was concerned and was sending her to another hospital 2 hours away, but before she was transferred, Ms. Bentley has an MRI of her spine at HRMC, which according to the radiologist was negative, but as part of the lawsuit, the Plaintiff claims there was a “shadow” that the radiologist missed.

During the two-hour ambulance ride, Ms. Bentley’s clinical condition continued to deteriorate as she was experiencing shortness of breath and by the time she was examined at the referral hospital, Central Baptist Hospital (CBH), she was paralyzed from the chest down.

At CBH, physicians performed another MRI and found significant swelling of Ms. Bentley’s spinal cord and they immediately started her on IV steroids. After several days of steroid treatment Ms. Bentley’s symptoms stabilized, but she remained paralyzed from the chest down.

One year later, in September 2015, Ms. Bentley sued HRMC, PBH, the emergency room MD at HRMC, the company that provided the ER physician to HRMC, and the radiologist who

misread the MRI at HRMC for medical negligence and violation of the Kentucky Consumer Protection Act (KCPA) and the federal Emergency Treatment and Labor Act (EMTALA). Bentley contended the KCPA and EMTALA claims that HRMC allegedly advertised that the ER provided “competent emergency care” and in her case she alleged that they failed to do so.

The Plaintiff hired three medical experts to testify. The first, Dr. Pardo, was a well-known neurologist and Director of the Transverse Myelitis Center at Johns Hopkins Medical Center. The second expert was Dr. DeLorenzo, an MD and Ph.D. in neuropharmacology and professor of neurology and pharmacology at Virginia Commonwealth University. The third expert was Dr. Betz, an MD, a registered pharmacist, and professor of pharmacology.

Each expert testified at deposition that had any of the three hospitals administered IV steroids before Ms. Bentley lost motor control or sensation in her legs, the steroids would have stopped the progression of her condition, and she would not have been paralyzed from the chest down. According to the Motion Hearing decision of 12/27/16, the Defense conceded at deposition and by motion that these experts were qualified and met both the Rule 702 and Daubert test as expert witnesses regarding the conclusions they came to regarding the steroids. We note that in this decision, HMRC agreed to a settlement as the result of the depositions by the three experts.

These experts also mentioned in their depositions (and the Defense objected to) that Ms. Bentley could not consent to a PBH liability release form before she was transferred to CBH. She has been given gabapentin (anticonvulsant), lamotrigine (CNS depressant) and hydrocodone (opioid), which the

experts stated, caused “mental foginess and fatigue” and as such, Bentley lacked the mental capacity to make an informed decision regarding the form. A Memorandum Opinion and Order dated 12/13/16 (4) stated that Ms. Bentley had no memory of signing the PBH form.

The Courts Memorandum Opinion and Order dated 12/27/16 (3) decided that the experts exceeded both the Daubert test and Rule 702 because they could not testify on what percentage of patients might experience this “mental foginess” for this three-drug combination. In addition, the experts

---

## *Before they present their expert opinions, they must be cautioned not to exceed their Daubert expertise.*

stated to the Court that they could not explain how they determined that Ms. Bentley had foginess so profound as to render her unable to have the mental capacity to exercise the necessary informed judgment to sign the PBH liability release.

Here, Plaintiff, Defense, and the Court, found the three experts were qualified under Daubert and Rule 702 to expertly opine regard to whether or not the use of IV steroids would have had an impact in the unfortunate outcome of this case (Ms. Bentley was still paralyzed from the chest down after discharge from CBH). However, as a caution to LNCs who obtain or prepare an expert witnesses for testimony, expert opinions must have a clinical and/or scientific basis. While the experts had sufficient professional and clinical background to support their opinions regarding the IV steroids, they admitted to the Court that they had

no clinical or scientific basis for their “mental foginess” conclusion.

Based on all sources available to the author, the last activity regarding this case was the Memorandum Opinion and Order dated 12/17/16 (4), and as far as the author can determine there has been no further action regarding this case. Therefore, we may never know if the Court’s decision regarding the expert opinion had a positive or negative impact on the case at trial.

## REFERENCES

Daubert v. Merrell Down Pharmaceuticals, Inc., 509 U.S. 579 (1993)

Federal Rules of Evidence, Rule 702

Bentley v. Highlands Hospital Corp., et.al. U.S. District Court, Eastern District Kentucky, Southern Division, Civil No. 15-97-ART, 12/17/16

Bentley v. Highlands Hospital Corp., et.al. U.S. District Court, Eastern District Kentucky, Southern Division, Civil No. 15-97-ART, 12/13/16



**James Hanus, RN, BSN, OCN, MHA** is the Manager of Clinical Appeals, leading a team that defends medical and radiation oncology clinics against denied

government and commercial insurance claim denials. The team has a success rate of winning on average 91% of its appeals. He has nursing experience in telemetry, radiation and medical oncology, clinical research and safety and risk management. He served in the U.S. Air Force in healthcare management positions and retired as a Lt. Col. He is a member of the Editorial Board of JLNC. He can be contacted at [jhanus11@gmail.com](mailto:jhanus11@gmail.com).



# The Failed Experiment with the New Generation of Metal on Metal Hip Implants

*Hadley L. Matarazzo J.D.*

**T**he first artificial hips with metal on metal articulation were introduced in 1953 in England and remained on the market until the mid-1970s.<sup>1</sup> The first devices were removed from the market because of a high failure rate associated with their use of polyethylene. A second generation was developed in the early 1980s and shortly thereafter a third, similar to

the second. However, the wear rates of the second and third generation devices far exceeded those of metal on polyethylene devices leading to complications associated with blood-borne metal ions and debris. Device makers continued to work to improve the design of these implants, and the current fourth generation was released in the late 1990s. This article focuses on these devices.

## TOTAL HIP REPLACEMENT SURGERY

Hip replacements are among the most common and successful orthopedic surgeries performed in the United States. The average age for a total hip replacement patient is 66 years.<sup>2</sup> According to the National Center for Health Statistics, 326,100 individuals had hip replacement surgery in 2010,

and the demand for hip replacement surgery in patients aged 45 and over more than doubled from 2000 to 2010.<sup>3</sup> Much of the rise in demand can be attributed to a growing percentage of the population over 65 years of age.

Patients who undergo a total hip replacement have their natural hip replaced with a prosthetic hip generally composed of a femoral stem, a femoral head, and a cup fitted into the acetabulum. The components may or may not include a liner or shell. In recent years, patients with arthritis can also undergo hip resurfacing, in which only the natural femoral head and acetabulum are replaced.<sup>4</sup> There are several hip systems available today, including metal on metal, metal on polyethylene, ceramic on polyethylene and ceramic on ceramic.

Figure 1, from a U. S. Food and Drug Administration (FDA) publication, show typical options for hip implants.<sup>5</sup> (see Figure 1)

Common causes of chronic hip pain and disability leading to total hip replacement are osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis, trauma and childhood hip disease.<sup>6</sup>

In the past, orthopedic surgeons primarily limited hip replacement to patients 60 years and older due to limitations on the life of the device.<sup>7</sup> However, with improvements in the technology and the growing demand for replacement in the younger population, surgeons no longer have a threshold age and instead look at a patient's overall health to determine whether the patient will benefit from a replacement.

## THE FDA APPROVAL PROCESS: 510(K) VERSUS PRE-MARKET APPROVAL

The Medical Device Amendments of 1976 (MDA) created three classes of medical devices ranked by their

### Metal-on-Metal Hip Implant Systems

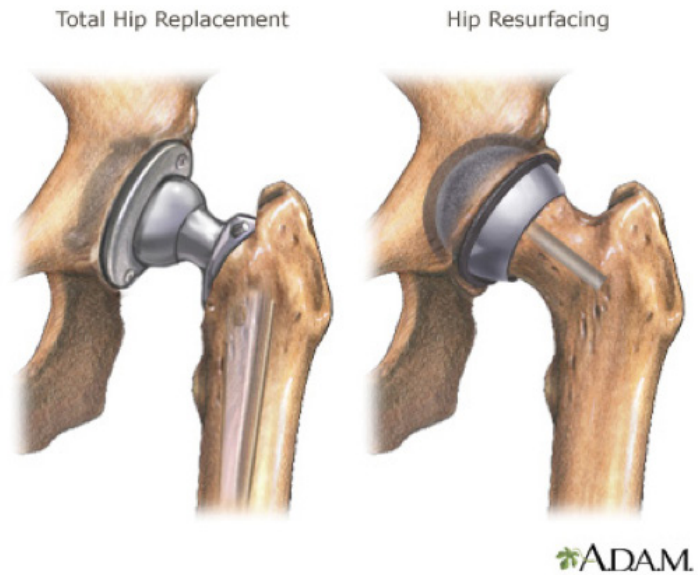


Figure 1. Types of hip implants (USFDA)

potential to cause harm.<sup>8</sup> Hip implant devices are Class III devices, high-risk. Under the MDA, less risky Class I and II devices can go through a process defined by Section 510(k) of the Food, Drug and Cosmetic Act, which requires only showing substantial equivalence to devices already on the market.<sup>9</sup>

Class III devices are supposed to undergo the more rigorous pre-market approval (PMA) process, which requires clinical trials.<sup>10</sup> This is not, however, how the vast majority of hip implants get to market. Instead, due to a loophole in the MDA, Class III devices could temporarily get to market via 510(k). This loophole was supposed to be closed by the FDA over time as it established effective dates for when each Class III medical device would undergo PMA.<sup>11</sup> As of today, the FDA has not closed this loophole and hip implant devices can still get to market under 510(k).

Under the 510(k) process, the manufacturer must show that the device is substantially equivalent to devices marketed through the 510(k) process (known as a predicate device) prior

to May 28, 1976.<sup>12</sup> A substantially equivalent device has the same intended use and technological characteristics, or has different technological characteristics but does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device.<sup>13</sup> An FDA finding of substantial equivalence does not mean that the device is safe and effective.

## FDA'S ACTIVITIES AROUND METAL ON METAL HIP IMPLANTS

Metal on metal hip implant devices were developed to provide an alternative to polyethylene and ceramic devices. Polyethylene wear debris causes an immunological reaction that results in osteolysis, and ceramic implants are prone to fracture. Besides providing an alternative to avoid these problems, metal on metal devices were also supposed to generate less wear debris and decrease the risk of dislocation. The majority of metal on metal hip implants have been cleared through 510(k). It is estimated that more than 500,000 patients in the United States received

metal on metal hip implants between 2003 and 2010.<sup>14</sup>

No hip implant is without risk. A significant risk with metal on metal devices is shedding of metal debris, specifically cobalt and chromium, and release of cobalt and chromium ions into the bloodstream, which can cause painful soft tissue destruction and osteolysis with implant loosening and device failure requiring surgical revision. Although there are not sufficient data to draw conclusions, there is also concern about adverse systemic reactions to the circulating metal ions. Metal on metal hip implants are contraindicated for, among others, patients who have known sensitivity to metal, patients with kidney problems, patients who have suppressed immune systems, and women of childbearing age.<sup>15</sup>

Unfortunately, the promise of these devices has not been fulfilled. Instead, data from other countries' joint registries, such as the Australian and British, has shown that they have a lower survivorship rate than alternative devices. The high revision rate led regulatory agencies in several countries to release

healthcare alerts and medical device makers to recall certain implants, such as DePuy's ASR, with an anticipated failure rate of 49% at six years.<sup>16, 17, 18</sup>

## POSTMARKET SURVEILLANCE AND PERMITTING TIMELINE

On May 6, 2011, the FDA ordered manufacturers to conduct postmarket surveillance<sup>19</sup> to study adverse events and pre- and post-implantation cobalt and chromium blood levels, but the results will not be available for years.

On June 27-28, 2012, the FDA convened the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee "to seek expert scientific and clinical opinion on the benefits and risk of MoM hip implants including: Failure rates and modes; Metal ion testing; Imaging methods; Local and systemic complications; Patient risk factors; and Consideration for follow-up after surgery."<sup>20</sup>

An updated FDA Safety Communication on January 17, 2013 and the January 18, 2013 publication

of a Proposed Rule in the Federal Register required manufacturers to conduct clinical trials if they sought to keep metal on metal hip implants on the market.<sup>21, 22</sup>

On February 18, 2016, the FDA issued a Final Order requiring hip implant manufacturers to submit PMA applications for two types of devices: the hip joint metal/metal semi-constrained with a cemented acetabular component, and the hip joint metal/metal semi-constrained with an uncemented acetabular component.<sup>23</sup>

## IDENTIFYING A FAILED IMPLANT AND PATIENT CONSEQUENCES

The medical literature regarding metal on metal hip implants has exploded since 2010. Articles cover a range of topics, including the clinical significance of cobalt and chromium levels; diagnosing soft tissue damage using imaging studies; determining when to replace an implant; and diagnosing adverse reactions to metal debris (ARMD) or adverse local tissue reaction (ALTR) (commonly described using the non-medical term "metallosis").

1. Griffin, Justin W., et al., Management of failed metal-on-metal total hip arthroplasty. *World J Orthop* 2012; 3(6):70-74.  
 2. Passias, P.G., et al., Total Hip Arthroplasty in the Older Population. *Geriatrics and Aging* 2006; 9(8):535-543.  
 3. <https://www.cdc.gov/nchs/data/data-briefs/db186.pdf> (last visited December 15, 2017)  
 4. <https://orthoinfo.aaos.org/en/treatment/hip-resurfacing> (last visited December 15, 2017).  
 5. <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/metalonmetal-hipimplants/default.htm> (last visited December 15, 2017)  
 6. <https://orthoinfo.aaos.org/en/treatment/total-hip-replacement> (last visited December 15, 2017).

7. <https://www.webmd.com/arthritis/about-hip-replacement#1> (last visited December 15, 2017)  
 8. Ardaugh, B., et al., The 510(k) Ancestry of a Metal-on-Metal Hip Implant. *The N Engl J Med*. 2013; 368(2): 97-100.  
 9. Id.  
 10. <https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/default.htm> (last visited December 15, 2017)  
 11. Id.; Ardaugh, B., et al., The 510(k) Ancestry of a Metal-on-Metal Hip Implant. *N Engl J Med*. 2013; 368(2): 97-100.  
 12. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm2005718.htm> (last visited December 15, 2017)

13. Id.  
 14. Rising, J.P., et al., Delays and Difficulties in Assessing Metal-on-Metal Hip Implants. *N Engl J Med*. 2012; 367:e1.  
 15. <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal-HipImplants/ucm241767.htm> (last visited December 15, 2017)  
 16. <https://www1.imperial.ac.uk/resources/C9446609-2730-415C-B39C-6F2AE7746605/mhraasrdepuyre-callalertmda2010069final.pdf> (last visited December 17, 2015)  
 17. <https://www.gov.uk/drug-device-alerts/all-metal-on-metal-mom-hip-replacements-updated-advice-for-follow-up-of-patients> (last visited December 15, 2017)  
 18. <https://www.britishhipociety.com/>

Orthopedic surgeons continue to wrestle with questions on whether the risk of revision surgery is outweighed by the damage a metal on metal hip implant is causing a patient, and the risk of a poor outcome from the surgery.

The FDA provides guidance for orthopedic surgeons regarding follow up of patients with metal on metal hip implants.<sup>24</sup> The FDA recommends routine long-term follow up of patients every 1 to 2 years for evaluation if they remain asymptomatic.<sup>25</sup> The evaluation should include a physical examination, assessment of organs and systems for systemic adverse events in cardiovascular, nervous, endocrine (especially thyroid) and renal systems.<sup>26</sup> Asymptomatic patients at increased risk of ALTR such as patients with bilateral implants, female patients, and patients with renal insufficiency, or suppressed immune systems should be monitored more closely.<sup>27</sup> For symptomatic patients, the FDA recommends follow up at least every six months; considering cross-sectional imaging to assess soft tissue surrounding the implant; and

*The evaluation should include a physical examination, assessment of organs and systems for systemic adverse events in cardiovascular, nervous, endocrine (especially thyroid) and renal systems.*

metal ion testing if plain radiographs do not provide sufficient information for a treatment plan.<sup>28</sup>

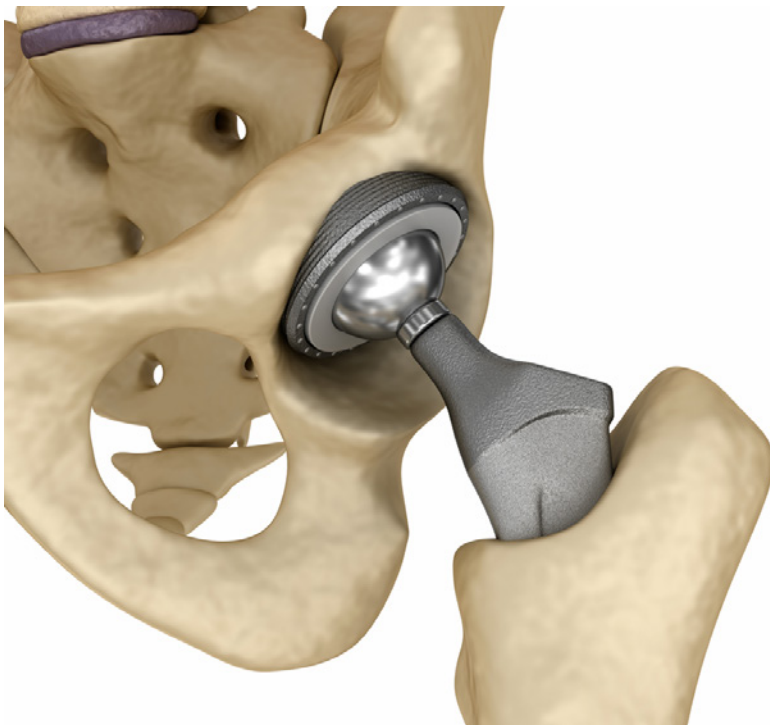
The British Hip Society published an algorithmic approach to diagnosing and managing these implants in 2012.<sup>29</sup> The authors noted that metal debris can be generated by the bearing couple or the taper junction, and even well-functioning implants have a three- to five-fold increase in cobalt and chromium compared with metal on polyethylene devices.<sup>30</sup> This debris can lead to ALTR, which damages the surrounding hip tissue, and can also cause an undesirable

immune response known as a Type IV hypersensitivity reaction with pain, loosening, and osteolysis.<sup>31</sup> On gross tissue examination, the debris appears as grayish-black discoloration.<sup>32</sup> On pathological examination, metal debris can be seen engulfed by histiocytes and macrophages, tissue necrosis,<sup>33</sup> and aseptic lymphocyte predominant vasculitis associated lesion (ALVAL), lymphocytes around small vessels.<sup>34</sup> Some patients develop pseudotumors, fluid filled masses.<sup>35</sup> The authors identify four areas of patient evaluation: (1) clinical condition; (2) radiographs (position and fixation); (3) blood/serum metal ion levels; and (4) cross-sectional imaging.<sup>36</sup> To assess metal ion levels, the authors state that 7 ppb can be considered elevated, but caution against making any determinations based on metal levels alone.<sup>37</sup>

Several other organizations issued guidance documents, but none vary significantly in their recommendations.<sup>38</sup> Ultimately, the decision is made on a case-by-case by the surgeon and the patient.

## **MULTI DISTRICT LITIGATION (MDL)**

The United States Supreme Court in *Riegel v. Medtronic*, 552 U.S. 312 (2008), held that the pre-emption clause of the MDA bars state common-law claims that challenge the safety or effectiveness of a medical device that received premarket approval from the FDA. However, the Riegel court



compared the PMA process to the 510(k) process and also held that under 510(k) there is no formal FDA review of safety and effectiveness. The Court thus allowed state law claims arising from injuries caused by Class III devices marketed via 510(k). *Id.* at 323.

Thousands of cases have been filed around the country. Where litigation is pending in multiple federal districts, either or both parties can move for centralization with the Judicial Panel on Multidistrict Litigation (the “Panel”).<sup>39</sup> The Panel, after hearing argument, will determine whether issues of fact common to actions are pending in different federal districts and it would be appropriate to transfer all the actions to one judge to handle all the pretrial proceedings. If the transfer is deemed appropriate, the Panel creates a Multidistrict Litigation (“MDL”), selects venue and assigns the judge. The purpose of centralization is to avoid duplication of discovery, inconsistent pretrial rulings, and conserve judicial and the parties’ resources. Once pretrial proceedings conclude, the cases that have not terminated in the MDL are

remanded to the originating federal district for trial.

## BELLWETHER CASES

Besides overseeing pretrial proceedings, an MDL judge can also conduct bellwether or test cases subject to the restrictions imposed by the Supreme Court in *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). Under *Lexecon*, the Supreme Court held that an MDL court cannot transfer cases to itself for trial because the statute requires the Panel to remand cases back to the originating district court at the end of the pretrial proceedings. However, in many MDLs, the MDL court will issue an order permitting direct filing of cases into the MDL. In this situation, the MDL court can conduct a bellwether trial of the directly filed actions.

Cases chosen as bellwethers are deemed representative. The hope is that they will enable the parties to gauge the strengths and weaknesses of their claims and defenses to facilitate resolution of the remaining cases in the MDL.<sup>40</sup> In addition, the parties can consent to the application, where feasible, of the

decisions made leading to and during a bellwether trial to all cases in the MDL. For example, motions in limine not specific to the evidence in a particular plaintiff’s case, but instead apply to evidence pertaining to the liability of the defendant or defendants, can bind all cases in the MDL if they go to trial.

Once an MDL is created, the MDL judge sets a schedule for filing applications to the court. Although there is variation, the court generally appoints the positions of plaintiffs’ lead counsel or co-lead counsel, plaintiffs’ liaison counsel, and the members of the plaintiffs’ executive committee and plaintiffs’ steering committee. These individuals acting together as plaintiffs’ leadership are charged with representing the interests of all plaintiffs in the MDL by, among other things, conducting discovery of the defendant or defendants, hiring experts to help establish liability, and otherwise moving the litigation forward. The plaintiffs’ leadership is also charged with negotiating settlement if there is an opportunity to do so. During litigation, the judge usually issues a Common Benefit Order that levies a

uploaded/BHS\_MOM\_THR.pdf (last visited December 15, 2017)

<sup>19</sup> <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal-HipImplants/ucm241769.htm> (last visited December 15, 2017)

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* (last visited December 15, 2017)

<sup>22</sup> <https://www.federalregister.gov/articles/2013/01/18/2013-01006/ef-fective-date-of-requirement-for-pre-market-approval-for-two-class-iii-pre-amendments-devices> (last visited February 20, 2014)

<sup>23</sup> <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal-HipImplants/ucm241769.htm> (last visited December 15, 2017)

<sup>24</sup> <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/Im->

<plantsandProsthetics/MetalonMetal-HipImplants/ucm241667.htm#3> (last visited December 15, 2017)

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> Lombardi, Jr., et al., The Hip Society: Algorithmic Approach to Diagnosis and Management of Metal-on-Metal Arthroplasty, *J Bone Joint Surg Br*, 2012; 94-B, Supple A:14-18.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> Vigorita, V. Orthopedic Pathology (2d ed. 2008).

<sup>33</sup> *Id.*

<sup>34</sup> Willert, et al., Metal-on-Metal Bearings and Hypersensitivity in Patients with Artificial Hip Joints, *J Bone Joint*

*Surg Br* 2005;87-A; 28-36.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

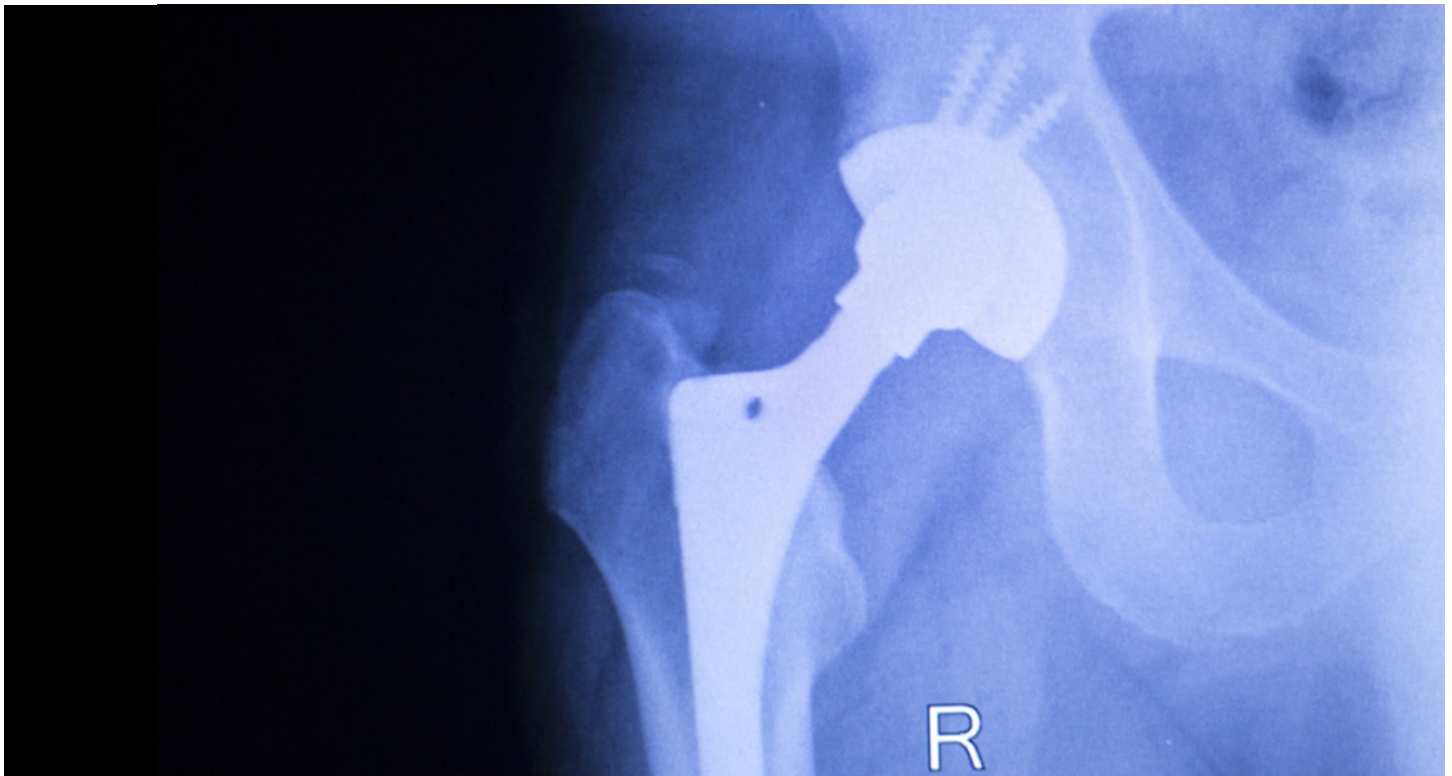
<sup>38</sup> Berber, et al. Management of metal-on-metal hip implants: Who, when and how to revise?, *World J Orthop*, 106 May 18; 7(5):272-279.

<sup>39</sup> <http://www.jpml.uscourts.gov/overview-panel-0> (last visited December 15, 2017)

<sup>40</sup> Manual for Complex Litigation § 22.314.

<sup>41</sup> [http://www.jpml.uscourts.gov/sites/jpml/files/Pending\\_MD\\_L\\_Dockets\\_By\\_District-November-15-2017.pdf](http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MD_L_Dockets_By_District-November-15-2017.pdf) (Last visited December 15, 2017)

<sup>42</sup> [http://www.ca5.uscourts.gov/OralArgRecordings/17/17-10030\\_12-7-2017.mp3](http://www.ca5.uscourts.gov/OralArgRecordings/17/17-10030_12-7-2017.mp3)



cost and an attorneys' fee assessment on every case filed in the MDL. This is then used to compensate the members of the committees for their time and expenses incurred in pretrial proceedings.

## METAL ON METAL HIP IMPLANT LITIGATION

Metal on metal hip implant cases have been consolidated into several MDLs based on manufacturer and model. When this article was written, the following are the pending metal on metal hip implant MDLs and the most recent statistics from the Panel regarding the number of cases filed in each MDL:

- MDL 2158 In re Zimmer Durom Hip Cup (256 filed cases);
- MDL 2197 In re DePuy Orthopaedics, Inc. ASR Hip Implant (1,653 filed cases);
- MDL 2244 In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant (9,226 filed cases) ("Pinnacle MDL");
- MDL 2329 In re Wright Medical Technology, Inc. Conserve Hip Implant (510 filed cases);
- MDL 2391 In re Biomet M2a Magnum Hip Implant (474 filed cases).<sup>41</sup>

Global settlements have occurred in all except for the Pinnacle MDL. While global settlements have been announced that include all cases filed or revised before an agreed date, attorneys continue to file to cases in the metal on metal hip implant MDLs. Understand the parameters of the settlement because they will likely provide the framework for any future settlement extension in those MDLs.

Regarding the Pinnacle MDL, the MDL judge has overseen four bellwether trials. The first, in 2014, involved a single plaintiff and resulted in a defense verdict. Thereafter the judge consolidated multi-plaintiff's cases for trial and each trial resulted in large verdicts for the plaintiffs. Defendants filed several appeals with the Fifth Circuit Court of Appeals related to

the second and third bellwether trials. The appeals related to the second were argued on December 7, 2017 and recording that argument is on the Fifth Circuit Court of Appeal's website.<sup>42</sup>



**Hadley L. Matarazzo**, Partner at Faraci Lange LLP, oversees the firm's defective drug and medical device practice and also litigates cases involving consumer protection, toxic torts, medical malpractice, and catastrophic personal injury. She has extensive experience handling complex litigation, including serving in court appointed leadership positions in multi-district litigation (MDL) in federal court and multi-county litigation (MCL) in New Jersey. Hadley has been litigating claims related to metal-on-metal hip implants for several years. She had the lead trial case in the DePuy ASR MDL and was appointed by the court to the Plaintiffs' Steering Committee in the Biomet hip implant MDL, as well as to the Science Committee in the Stryker Rejuvenate/ABGII hip implant MCL.



# PRESSURE INJURY

## Support surface technology: An essential component of pressure injury prevention

*Paula Gruccio, MSN, RN, CWOCN, CPPS, Kathleen C. Ashton, PhD, RN, ACNS-BC*

Keywords: Pressure injury, pressure ulcer, low air loss, bed surfaces

### PREFACE

The National Pressure Ulcer Advisory Panel (NPUAP) changed the term “pressure ulcer” to “pressure injury” in 2016. Both terms will be found in this document, as past research includes “pressure ulcer.” Many agencies, organizations, and facilities are changing their terminology to reflect the new Pressure Injury Staging definitions. The

legal nurse consultant assisting with pressure-injury cases would benefit by information on the current state of research and therapeutic/preventative measures available.

### INTRODUCTION

Prevention of pressure injuries continues to be a challenge in healthcare. In 2015, the Agency for

Healthcare Research and Quality (AHRQ) stated that 2.5 million people develop a pressure ulcer annually. The estimated cost for an individual’s pressure ulcer care is variously estimated from \$500 to \$20,000 (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance (NPUAP, EPUAP, PPIA),

2014) to \$20,900 to \$151,700 (AHRQ, 2015).

Besides the financial burden that pressure ulcers place on the healthcare system, consider the human costs: pain, effect on quality of life, infection, and possibly death. The AHRQ (2015) estimates that approximately 60,000 deaths each year result from pressure ulcers. A person with a pressure ulcer may face a longer hospital stay and possible need for discharge to a post-acute or long term care facility (Russo, Steiner, & Spector, 2008).

The causes are complex: pressure, shear, tissue deformation, and effects of microclimate, the temperature and humidity between surface and skin (Brienza & Geyer, 2005; NPUAP, EPUAP, PPIA, 2014). Intrinsic risk factors include:

- immobility
- decreased activity
- impaired nutritional status
- advanced age
- co-morbidities
  - problems with ventilation and tissue perfusion
  - spinal cord injury
  - history of previous pressure ulcer (NPUAP and EPUAP, 2009)
  - diabetes (NPUAP, EPUAP, PPIA, 2014)

The prevention section of the 2014 Guideline includes:

- Risk Factors and Risk Assessment
- Skin and Tissue Assessment
- Preventive Skin Care
- Emerging Therapies for Prevention of Pressure Ulcers
- The interventions section includes:
  - Nutrition for Pressure Ulcer Prevention and Treatment
  - Repositioning and Early Mobilization

- Repositioning to Prevent and Treat Heel Pressure Ulcers
- Support Surfaces
- Medical Device Related Pressure Ulcers

The number and scope of these measures underscore pressure injury's multifactorial nature. A successful prevention program requires many components for a comprehensive plan of care (NPUAP, EPUAP, PPIA, 2014).

## SUPPORT SURFACES

Support surfaces assist in minimizing the effects of extrinsic risk factors (Brienza & Geyer, 2005) (See sidebar)

Immersion and/or envelopment increases the amount of tissue in contact with the support surface (Brienza & Geyer, 2005). This redistributes (decreases) pressure (Brienza & Geyer, 2005). Materials are important to function; various materials: surfaces using foam, gel, vinyl, polyurethane, and air, individually and in combinations, are designed to redistribute pressure (Brienza & Geyer, 2005).

**Categories And Features** Features describe particular therapeutic functions, such as low air loss, alternating pressure, air fluidized, and lateral rotation (used primarily for pulmonary purposes).

**Active surfaces** are always powered and have the "capability to change its load distribution properties, with or without applied load" (NPUAP, 2007 p.5).

**Alternating pressure** "provides pressure redistribution via cyclic changes in

## GLOSSARY

*Envelopment: the ability of a support surface to conform, to fit or mold around irregularities on the body" (NPUAP, 2007, p. 2)*

*Immersion: depth of penetration (sinking) into a support surface (NPUAP, 2007, p.2)*

*Support surface: a specialized device for pressure redistribution designed for management of tissue loads, micro-climate and/or other therapeutic function, i.e., mattress, mattress overlay, integrated bed system, seat cushion or seat cushion overlay. (NPUAP, 2007; Posthauer, M. E., Jordan, R. S., Sylvia, C., 2006, p. 487).*

*Pressure redistribution: the ability of a support surface to distribute load over the contact areas of the human body. (Posthauer, M. E., Jordan, R. S., Sylvia, C., 2006, p. 488).*

loading and unloading ... by frequency, duration, amplitude, and rate of change parameters" (NPUAP, 2007, p. 4) to "periodically off-load tissues and restore blood flow mimicking natural movement" (Ward, 2010). The 2014 Guideline recommends alternating therapy for those at high risk for whom repositioning is impossible.

Support surfaces with this feature have material composition and function variations, may be combined with low

*Besides the financial burden that pressure ulcers place on the healthcare system, consider the human costs: pain, effect on quality of life, infection, and possibly death.*

air loss, and some may have additional specialized functions, such as the ability to turn off the alternating feature under specific areas of the body as needed. Nixon, Cranny, and Inglesias (2006) demonstrated there was not a significant difference in using alternating therapy overlays versus alternating therapy replacement mattresses.

**Reactive surfaces** may be powered or non-powered with the “capability to change its load distribution properties only in response to applied load” (NPUAP, 2007 p.5).

**Air-fluidized** technology is “a fluid-like medium created by forcing air through beads (creating) immersion and envelopment” (NPUAP, 2007 p. 4), resulting in pressure redistribution and microclimate management (Lachenbruch, 2010; Reger, Ranganathan, & Sahgal, 2007); it has long been used to unload pressure on post-operative flaps and grafts. Patient hydration may be a concern and additional fluids may be considered (Lachenbruch, 2010).

Other therapies such as low air loss and specialized alternating therapy technology can also be safely used for these patients (Finnegan, M. J., Gazzero, Finnegan, J. O., & Lo, 2007; Fleck, C. A., et al., 2010; Woo, K. Y., 2014).

**Low air loss** uses airflow to help manage skin microclimate (NPUAP,

2007, p. 4). It can be influenced by many factors, such as the person’s own body temperature, amount and type of clothing, numbers of pieces of bed linens, perspiration, wound drainage, and incontinence (Clark, et al., 2010). According to some studies, elevated body temperature increases an individual’s risk for pressure ulcer development [Bergstrom & Braden, 1992; Nixon, Brown, & McElvenny, 2000 (as cited in Clark, et al., 2010)]. Elevated body temperature leads to perspiration (Clark, et al., 2010) and increases metabolism [Fisher, Szymke, Apte, & Kosiak, 1978, (as cited in Clark, et al., 2010)].

Low air loss is less effective with extra layers of linens (Williamson, Lachenbruch, VanGilder, and Sauser, 2013). Impermeable disposable incontinence pads completely block airflow, cancelling the therapeutic effect; air-permeable pads should be used.

**NON-POWERED REACTIVE**

Foam and gel mattresses provide immersion and envelopment. Some manufacturers offer powered options such an air pump for low air loss or alternating therapy.

**CLINICAL APPLICATIONS/ IMPLICATIONS**

Both nursing and facility considerations are important to

determine features for any given individual needs, such as:

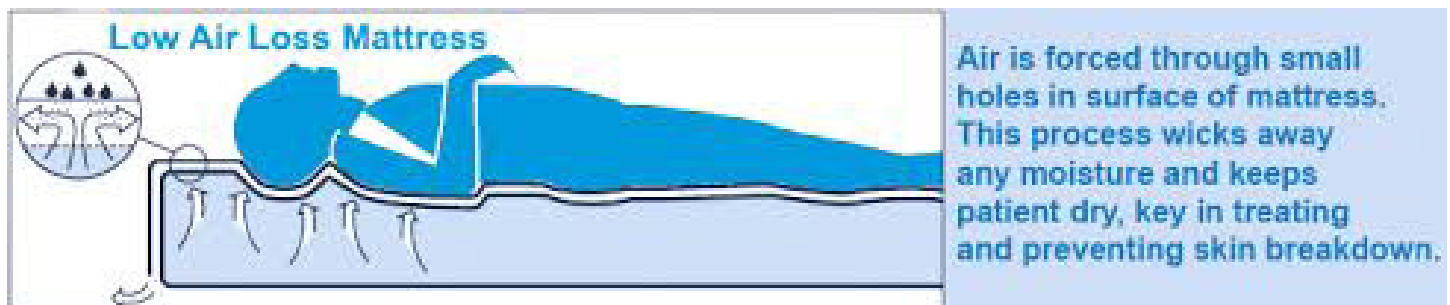
- mobility status
- risk level
- existing pressure injuries, including location and stage
- microclimate for moisture problems (NPUAP, EPUAP, PPPIA, 2014)

Patients with low mobility scores, existing pressure ulcers, and severe moisture issues may benefit from reactive support surfaces providing continuous low pressure, with a low air loss, or alternating air feature (McNichol, et al., 2015).

Height, weight, girth the widest part of the body, not just the abdomen), and preferred position of comfort assessment may dictate a specialized bed frame and support surface if they exceed the manufacturer’s recommended weight limit or if girth makes repositioning not feasible (Kramer-Jackman & Kramer, 2010; Morello, 2016; NPUAP, EPUAP, PPPIA, 2014). Special beds and surfaces are also often indicated for patients with spinal cord injury (NPUAP, EPUAP, PPPIA, 2014; McNichol, et al., 2015) and patients requiring pulmonary therapy from a support surface.

Risk for falls or entrapment (Norton, Coutts, & Sibbald, 2011) and facility physical and financial resources are

Low Air Loss Mattress



also considerations. A wound care professional is called upon to assist with support surface selection, in consultation with other members of the health care team, including physicians, nursing department staff, management, or other clinical specialists. Knowing and following manufacturers' recommendations and any contraindications for use are essential.

In the 2015 WOCN Algorithm for support surface use, McNichol et al. inform us there is insufficient evidence to determine if any one category or feature is more effective than another in treatment or prevention. Existing replicable and validated laboratory performance tests are not intended to grade or rank support surfaces individually, but to serve as a step in determining which patients may benefit from particular features (Stone, et al., 2015).

### FACILITY RESOURCES/ RESPONSIBILITIES

- Facilities should have and adhere to an evidence-based policy and procedure or algorithms, including professional judgment, for support

## Knowing and following manufacturers' recommendations and any contraindications for use are essential.

- surface selection and replacement.
- There are many manufacturers and distributors, but not all healthcare organizations have access to all products due to geography, budget, or group purchasing agreements.
- The facility must ensure that support surfaces are maintained and functioning as intended (McNichol, et al., 2015). This can be accomplished by following manufacturers' maintenance schedules, recommended care, including cleaning, and functional assessment (NPUAP, EPUAP, PPIIA, 2014).

### DOCUMENTATION

Many facilities have some kind of pressure redistribution support surface as their standard of care and may not have specific documentation on use unless a patient requires a different support surface for a specific clinical

indication. This should be noted in the policies and procedures; the care should be documented in the patient record.

### CONCLUSIONS

Although technology offers caregivers many options for pressure redistribution, support surfaces do not completely replace repositioning the patient (McNichol, et al., 2015; NPUAP, EPUAP, PPIIA, 2014). A comprehensive pressure injury prevention and treatment plan is essential to achieve more successful patient outcomes (McNichol, et al., 2015). Interventions include assessment, skin care, nutrition, skin microclimate management, repositioning, and support surfaces in bed and chair. Patient and care giver education (McNichol, et al., 2015) and performance improvement (NPUAP, EPUAP, PPIIA, 2014) are essential and should be documented. A Legal Nurse Consultant should investigate and consider all patient risk factors and care activities to mitigate them.

### REFERENCES

- Agency for Healthcare Research and Quality, Rockville, MD. Preventing Pressure Ulcers in Hospitals. Content last reviewed October 2014. Retrieved from <http://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit/index.html>
- Bergstrom, N. & Braden, B. A. (1992). A prospective study of pressure sore risk among institutionalized elderly. *Journal of the American Geriatric Society* 40 (8), 747-758.
- Brienza, D. M. & Geyer, M. J. (2005). Using support surfaces to manage tissue integrity. *Advances in Skin & Wound Care* 18 (3), 151-157.
- Clark, M., Romanelli, M, Reger, S.I., Ranganathan, V. K., Black, J., & Dealy, C.

## Customized Lateral Rotation



Lateral Rotation Mattress

(2010). Microclimate in context in Pressure Ulcer Prevention: Pressure, shear, friction and microclimate in context, a consensus document. London: *Wounds International*.

Finnegan, M. J., Gazzero, L., Finnegan, J. O., & Lo, P. (2007). Comparing the effectiveness of a specialized alternating air pressure Mattress replacement system and an air-fluidized integrated bed in the management of post-operative flap patients: A randomized controlled pilot study. *Journal of Tissue Viability*, 17 (1), 2-9.

Fleck, C. A., Rapp, L. M., Simman, R., Titterton, F., Conwill, J., Koerner, C., Locke, P., Bechtold, D., Papanonio, C., Gray, D. P., Lawrence, K. (2010). Use of alternatives to air-fluidized support surfaces in the care of complex wounds in postflap and postgraft patients, *Journal of the American College of Certified Wound Specialists*, 2, Issue (1) 4-8. Retrieved from <http://dx.doi.org/10.1016/j.jcws.2010.02.002>

Kramer-Jackman, K. & Kramer, D.W. (2010). Bariatric Hospital Bed Safety and Selection. *Bariatric Nursing and Surgical Patient Care* 5 (1), 1-11. Retrieved from [online.liebertpub.com](http://online.liebertpub.com)

Lachenbruch, C. (2010). A laboratory study comparing skin temperature and fluid loss on air-fluidized therapy, low-air-loss, and foam support surfaces. *Ostomy Wound Management*, 56 (8): 52-60.

McNichol, L., Watts, C., Mackey, D., Beitz, J. M., & Gray, M. (2015). Identifying the right surface for the right patient at the right time: Generation and content validation of an algorithm for support surface selection, *Journal of Wound Ostomy and Continence Nursing*, 42 (1): 19-37.

Morello, S. S. (2016). Skin and wound care for the bariatric population. In D. B. Doughty & L. L. McNichol, *Wound Ostomy and Continence Nurses Society Core Curriculum: Wound Management* (pp. 242-252). Philadelphia, PA: Wolters Kluwer.

National Pressure Ulcer Advisory Panel (2016). National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure

injury. Press Release. April 13, 2016. Retrieved from <http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/>

National Pressure Ulcer Advisory Panel, & European Pressure Ulcer Advisory Panel (Eds.). (2009). *Prevention and treatment of pressure ulcers: Clinical practice guideline*. Washington, DC: NPUAP

National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance, Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.

National Pressure Ulcer Advisory Panel Support Surface Standards Initiative. (2007). Terms and definitions related to support surfaces. Retrieved from [http://www.npuap.org/NPUAP\\_S3I\\_TD.pdf](http://www.npuap.org/NPUAP_S3I_TD.pdf)

Nixon, J., Cranny, G., Iglesias, E., Nelson, A., Hawkins, K., Phillips, A., Torgerson, D., Mason, S., & Collum, N. Randomized, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial: BMJ. doi:10.1136/bmj.38849.478299.7C (published 2006, June 17). Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/16740530>

Norton, L., Coutts, P., & Sibbald, R. G. (2011). Beds: Practical pressure management for surfaces/mattresses. *Advances in Skin & Wound Care*, 24 (7) 324-334.

Posthauer, M. E., Jordan, R. S., Sylvia, C. J. Support surface initiative: terms, definitions and patient care. (2006). *Advances in Skin & Wound Care*, 19 (9) 487-89.

Reger, S. I., Ranganathan, V. K., & Sahgal, V. (2007). Support surface interface pressure, microenvironment, and the prevalence of pressure ulcers: An analysis of the literature.

*Ostomy/Wound Management*, 53 (10) 50-58.

Russo, C. A., Steiner, C. and Spector, W. (2008). Hospitalizations related to pressure ulcers, 2006. HCUP Statistical Brief #64. December 2008. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved from <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf>

Stone, A., Brienza, D., Call, E., Fontaine, R., Goldberg, M., Hong, K. Z., Jordan, R., Lachenbruch, C., LaFleche, P., & Sylvia, C. (2015). Standardizing support surface testing and reporting: A National Pressure Ulcer Advisory Panel Executive Summary. *Journal of Wound Ostomy and Continence Nursing*, 42 (5): 445-449.

Ward, C. (2010). The value of systematic evaluation in determining the effectiveness and practical utility of a pressure-redistributing support surface. *Journal of Tissue Viability*, 19 (1) 22-27. Retrieved from <http://dx.doi.org/10.1016/j.jtv.2009.12.004>

Williamson, R., Lachenbruch, C., VanGilder, C., & Saucer, F. (2013). The effect of multiple layers of linens on surface interface pressure: Results of a laboratory study. *Ostomy Wound Management*, 59 (6) 38-47.

Woo, K. Y. (2014). Support surfaces for skin grafts and flaps: A scoping review. White Papers: [woundsource.com](http://www.woundsource.com), Kestrel Health Information, Inc. Retrieved from [http://www.woundsource.com/sites/default/files/whitepapers/support\\_surfaces\\_for\\_skin\\_grafts\\_and\\_flaps.pdf](http://www.woundsource.com/sites/default/files/whitepapers/support_surfaces_for_skin_grafts_and_flaps.pdf)



**Paula Gruccio, MSN, RN, CWOCN, CPPS** is an experienced nurse who has practiced in acute care nursing, long-term care, consulting, and industry positions. She is a member of the Wound Ostomy and Continence Nurses' Society, the Delaware Valley WOCN, and a former member of the Support Surface Standards Initiative.

*Many facilities have some kind of pressure redistribution support surface as their standard of care and may not have specific documentation on use unless a patient requires a different support surface for a specific clinical indication.*

# Medical Malpractice

## Verdicts, Settlements & Experts

Published Every Month Since 1984

FEDERAL EMPLOYERS' LIABILITY ACT

# FELA *Reporter*



and Railroad Liability Monitor

Since 1989 the Nation's Only Journal of Railroad Safety and Liability

Published Every Month Since 1987

# National

# *Products Liability*

## Database Report

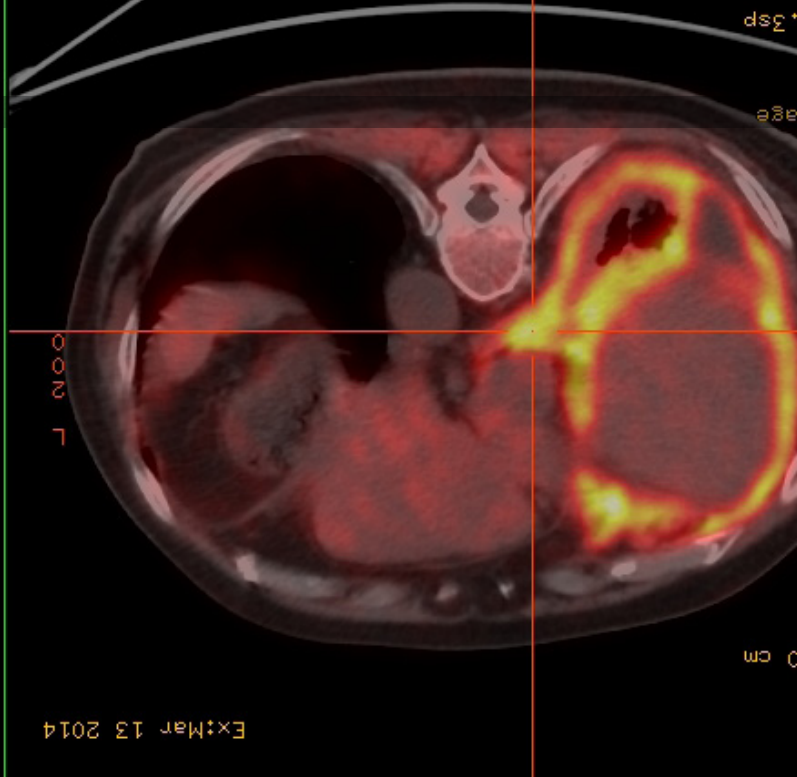
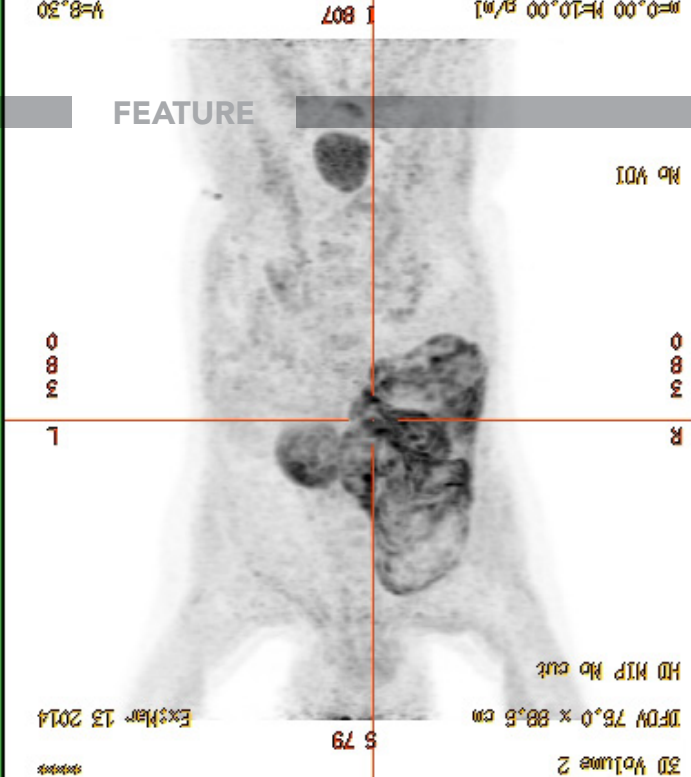
Published Every Month Since 1991

While we may not be older than dirt, we have been around longer than the Internet.

We provide detailed case reports that give you access to the name, specialty and location of the experts you need to craft a winning case.

Stop by the Triple L Publications, LLC exhibit in Clearwater.

Visit us on the web: [www.triplelpublications.com](http://www.triplelpublications.com)



# The Pathological Diagnosis of Malignant Mesothelioma

Rhonda A. Fritz, BS, RN

Keywords: Surgical Pathology; Malignant Mesothelioma; Immunohistochemistry; Differential Diagnosis

*Malignant mesothelioma is a rare serosal membrane cancer with much media and medicolegal attention. Pathologists today use immunohistochemistry, an ancillary method, to diagnose malignant neoplasms. To develop a final diagnosis, pathologists form a decision tree of possible histological entities and review slides with clinical, radiological, and surgical findings. When LNCs review a case for the diagnosis, the pathology report is the primary document to analyze. This article will discuss the parts of the pathology report most important to review. Illustrations can be found in the source materials as noted.*

## INTRODUCTION

Diffuse malignant mesothelioma is a primary tumor of the serosal membranes, i.e., the pleura and the peritoneum. Mesotheliomas do not originate from an underlying organ. Diffuse can mean multiple small nodules, typical in early disease; plaque like masses of tumor; or large confluent sheets that form a rind completely or almost surrounding the lung or abdominal viscera. Encasement by a

rind is a sign of advanced disease, and with time this process may obliterate the pleural or peritoneal cavity. (Churg et al., 2006, Figures 4-4, 4-6, pp. 38-39 of the textbook)

The majority of originate in the pleura, followed by peritoneal primaries. (Churg et al. 2006)

The median age for presentation is around 60 years; mesothelioma is uncommon in men under age 50. Women with peritoneal mesothelioma

have a wide age range, with a much larger proportion seen in young women. (Churg et al., 2006)

## NORMAL GROSS ANATOMY

*The pleura forms a continuous layer over the thoracic structures. The visceral pleura covers the lungs and the interlobar fissures. The parietal pleura lines the thoracic wall, including the thoracic inlet, the lateral aspect of the mediastinum, the thoracic surface*

of the diaphragm, and forms the subpleural membrane.

*The peritoneum forms a continuous layer over the abdominal structures, except for the ostia of the oviducts. The visceral peritoneum covers the intra-abdominal organs and their mesenteries. The parietal peritoneum lines the abdominal wall, the pelvis, the undersurface of the diaphragm, and part of the anterior surfaces of the retroperitoneal viscera. (Churg et al., 2006)*

## **NORMAL MICROSCOPIC ANATOMY**

The serous membranes are lined by a single layer of flattened mesothelial cells that rest on a basal membrane. Mesothelial cells have abundant cytoplasm, centrally placed round nuclei, and a single small nucleolus. The most prominent ultrastructural feature of mesothelial cells is long, slender surface microvilli. Underneath the mesothelial cells lies a thin basal lamina, separating the cells from a connective tissue layer that consists of variable amounts of collagen and elastic fibers, fibroblast like cells, capillaries, and lymphatics. (Churg et al., 2006)

## **NEOPLASTIC DEFINITIONS**

*Anaplastic* cells lack differentiation.

*Differentiation* means how much cancer cells resemble normal cells of the tissue of origin. Well-differentiated cells closely resemble tissue of origin, poorly-differentiated cells are barely recognizable.

*Hematoxylin and eosin (H & E)* is the primary stain for pathologic diagnosis. Hematoxylin stains the cell nucleus from blue to purple; eosin stains the cell cytoplasm from pink to red. (Husain et al., 2013, Figure 10D p. 654)

*Histology* is examination of a specimen under a microscope after sectioning, fixation, and mounting on a slide.

*In mesothelioma cases, the plaintiff usually needs to prove the primary origin. Without proof of diagnosis, the defense will try to dispute the primary tumor, because settlement amount is based on primary tumor.*

*Immunohistochemistry (IHC)* is the science of using antibodies to surface markers to help determine tumor origin site and exclude other primary origin. Tumors of epithelial origin produce *cytokeratins*. Carcinomas and mesotheliomas are epithelial in origin; adenocarcinomas are derived from glandular or ductal epithelium. Mesotheliomas and adenocarcinomas both produce *cytokeratins*. *Sarcomas* are of mesenchymal (connective tissue) origin.

*Morphology* is the science of structure and form.

*Pleomorphism* is the variation in size and shape of neoplastic cells.

*Stroma* refers to connective tissue and blood vessels.

## **REVIEWING A SURGICAL PATHOLOGY REPORT**

### **Procedure**

Refer to the surgeon's operative report and findings for type of procedure performed; the pathologist will note the procedure in the pathology report. The surgeon should document preoperative diagnosis, procedure performed, operative findings, complications, and postoperative findings.

Pay particular attention to the operative findings and complications, how the surgeon describes what was seen during the procedure, and

what specimens were obtained.

Note whether any biopsies were also taken. The surgeon provides a gross description of the tumor site; the pathologist refers to the surgeon's note for clinical findings. The diagnosis of malignant mesothelioma should be found in the pathology report.

## **GROSS/TISSUE SPECIMEN**

The histologic diagnosis of mesothelioma is based on morphology and immunohistochemistry. (Husain et al. 2013)

Check to see that the number of specimens noted by the surgeon (this may include washings) in the operative report matches the number of specimens in the pathology report. Each specimen must have a diagnosis.

Diagnosing malignant mesothelioma presents two problems: determining whether a malignant tumor is mesothelioma or metastatic spread from a nearby organ, e.g., lung or chest wall, and confirming the malignant tumor is a mesothelial proliferation. (Churg et al., 2006)

Diagnosis of mesothelioma requires thoracoscopic/laparoscopic or open surgical biopsies. A large tissue sample is necessary to confirm tissue invasion. If the process is clinically malignant, and the biopsy benign, the biopsy may have missed a diagnostic lesion. (Churg et al., 2006) Large surgical biopsies

Table A. Tumor immunoreactivity in the differential diagnosis of malignant mesothelioma (Fritz, 2018)

TUMOR	ANTIBODIES
Adenocarcinoma <sup>1</sup>	PanCK, CEA, BerEP4, CD15 (LeuM1), B72.3, BG8, MOC31, TTF1 (nuclear, greater than 70% in lung, and thyroid), Vimentin (lung). Negative for CK 5/6, Calretinin rare, Thrombomodulin, WT1, Mesothelin, HBME1.
Epithelioid Hemangioendothelioma, Melanoma, Lymphoma <sup>1</sup>	Negative for CK.
Squamous Cell, Large Cell, Bladder Transitional Cell Carcinoma <sup>1</sup>	CK 5/6
Gastrointestinal Adenocarcinoma <sup>1</sup>	CK 20
Pulmonary Giant Cell, Pulmonary Small Cell, Pulmonary Large Cell Carcinoma <sup>1</sup>	Calretinin
Pulmonary Non-Small Cell Carcinoma <sup>1</sup>	Negative for WT1, CEA, BerEP4, CD15, B72.3, BG8, MOC31.
Ovarian Serous Carcinoma <sup>1</sup>	WT1
Ovarian Non-Mucinous Carcinoma, Pancreatic Adenocarcinoma, Pulmonary Adenocarcinoma (40%) <sup>1</sup>	Mesothelin
Prostatic Adenocarcinoma, Carcinoid Tumors, Renal Cell, Hepatocellular, Thyroid, Adrenal Cortical Carcinoma <sup>1</sup>	Negative for Mesothelin.
Squamous Cell, Pulmonary Small Cell (25%), Pulmonary Large Cell Carcinoma (25%) <sup>1</sup>	Thrombomodulin
Melanoma Spindle Cell variant <sup>1</sup>	S100
Leiomyosarcoma <sup>1</sup>	Actin, Desmin
Primary Serous Papillary Carcinoma <sup>1</sup>	MOC31, B72.3, BerEP4, CA 19-9, CD15, WT1
Vascular Sarcomas <sup>1</sup>	Weakly positive for broad spectrum keratin, but stain for one or more of CD31, CD34, Factor VIII, and Ulex europaeus agglutinin I
Synovial Sarcoma (SS) <sup>1</sup>	Biphasic form epithelial component is keratin, mesothelin positive. Monophasic form focal keratin positivity. Many SS are positive for BerEP4, BCL2, Calretinin.
Thymoma <sup>1</sup>	Keratin, calretinin, CK 5/6 positive. May show CD20 positivity.
Desmoplastic Small Round Cell Tumor (DSRCT) <sup>1</sup>	Epithelial, mesenchymal, neural: Generally, but not always, positive for mesothelin, desmin, vimentin, keratin, EMA, WT1, NSE.
Lymphoma, Primary Effusion (PEL); Lymphoma, Pyothorax Associated (PAL) <sup>1</sup>	PEL: KSHV, HHV8, EBV PAL: EBNA1, LMP1
Lymphoma, Large Cell <sup>2</sup>	CD45, CD20, CD3, CD30
Melanoma <sup>2</sup>	S100, HMB45
Epithelioid Hemangioendothelioma, Angiosarcoma <sup>3</sup>	CD31, CD34, ERG or FLI1
Carcinoma Markers <sup>3</sup>	MOC31, BerEP4, Claudin 4
Squamous Cell Carcinoma <sup>3</sup>	Claudin 4, MOC31, BerEP4, CEA, p40 (p63 less useful, reacts with adenocarcinoma)
Breast Carcinoma <sup>3</sup>	ER, GCDFP15, Mammaglobin, GATA3
Sarcomatoid Lung Carcinoma involving the Pleura <sup>3</sup>	TTF1, NapsinA, and p40/p63
Pulmonary Adenocarcinoma involving the Pleura <sup>3</sup>	Calretinin 5-10% focal, CK 5 or CK 5/6 2-20% focal, WT1 negative, D2-40 up to 15% focal, Claudin 4 (membranous), MOC31 95-100%, CEA 80-100%, B72.3 75-85%, BerEP4 95-100%, BG8 90-100%, TTF1 75-85% (nuclear), NapsinA 80-90% (cytoplasmic)
Pulmonary Squamous Carcinoma involving the Pleura <sup>3</sup>	WT1 negative, Calretinin about 40% focal, D2-40 50%, CK 5 or CK 5/6, p40 or p63 (nuclear), Claudin 4 about 95%, MOC31 97-100%, BG8 about 80%, BerEP4 about 85-100%
Metastatic Renal Cell Carcinoma <sup>3</sup>	Calretinin 4-10% focal, CK 5 or CK 5/6 negative, D2-40 negative, Mesothelin negative, WT1 4%, PAX8 85-100%, PAX2 60-75%, Claudin 4 about 90%, CD15 (LeuM1) about 65%, RCC Ma about 50-70%, NapsinA about 30%, MOC31 about 50%, BerEP4 about 40%, CD10 about 80%, BG8 about 4%
Papillary Serous Carcinoma <sup>3</sup>	Calretinin 0-38%, D2-40 13-65%, CK 5/6 22-35%, WT1 89-93%, Claudin 4 98%, MOC31 98%, PAX8 most Müllerian carcinomas, BG8 73%, BerEP4 83-100%, B72.3 65-100%, CEA 0-45% (average 20%) sensitivity low, ER 60-93%, PR lower sensitivity than ER
Non-Gynecologic Adenocarcinoma <sup>3</sup>	General – MOC31 87%, BG8 89%, CEA 81% Prostatic Adenocarcinoma - PSA Pancreatic Adenocarcinoma – Claudin 4, Calretinin 10%, WT1 negative, D2-40 negative, CK 5/6 38%, B72.3 84%, BerEP4 more than 98%, GI Adenocarcinoma - Colonic (Claudin 4, B72.3 98%, CDX2 90-100%), Small Intestine CDX2 80%, Gastric (Claudin 4, WT1 3%, D2-40 negative, BerEP4 more than 98%, CDX2 70%), Biliary (Claudin 4, B72.3 89%)

<sup>1</sup>Churg et al. 2006; <sup>2</sup>Husain et al. 2013; <sup>3</sup>Husain et al. 2017

are generally, but not always, needed in identification of features of malignancy in desmoplastic mesotheliomas. (Husain et al., 2017)

A history of asbestos exposure should not be considered by the pathologist when diagnosing malignant mesothelioma. (Husain et al., 2013)

## TUMOR SITE/LATERALITY

This specifies location of the tumor - right or left.

## TUMOR EXTENSION (ALSO KNOWN AS INVASION)

The most reliable criterion of malignancy is true invasion of the stroma (Churg et al., 2006).

In the pleural cavity, tumor frequently extends along the fissures between the lobes of the lung and along the interlobular septa, and can enter airspaces or lymphatic vessels. Pleural mesotheliomas may grow into the chest wall, particularly along needle tracts or biopsy incisions, and then manifest as subcutaneous tumor nodules. Extension can occur to the contralateral lung and pleura. Spread

into and through the diaphragm, with superficial involvement of underlying organs such as the liver, is not uncommon. (Churg et al., 2006)

In the peritoneal cavity, tumor encasement of the bowel is seen in advanced disease. Tumor may spread into viscera, particularly into the wall of the bowel, omentum, and less frequently the retroperitoneum. Peritoneal tumors can grow along incisions into the subcutaneous tissue. Rarely, a patient presents with an apparent inflammatory process, such as appendicitis, and then is found to have foci of mesothelioma on microscopic tissue examination. Peritoneal tumors may grow through the diaphragm into the pleural cavity. (Churg et al., 2006)

## HISTOLOGIC SUBTYPES

Most malignant mesotheliomas are strongly suspected on routine H&E staining where they exhibit three subtypes in the updated 2015 World Health Organization classification: epithelioid, sarcomatoid, or biphasic. The major subtype must be given in the final diagnosis. (Husain et al., 2017)

Epithelioid mesotheliomas often appear as numerous large balls of cells with berrylike external contours. Most cells

are larger than the average mesothelial cell which includes enlargement of the cytoplasm, nucleus and nucleolus. (Husain et al., 2013)

Sarcomatoid mesotheliomas are diffuse neoplasms composed of infiltrating, solid sheets of spindle cells with variable cytologic atypia. The presence of necrosis, atypical mitoses, and/or heterologous elements is helpful for diagnosis. (Husain et al., 2017)

Biphasic mesotheliomas combine an epithelioid and sarcomatoid component within the same tumor. (Husain et al., 2013). Definitions of pleural mesothelioma have proposed at least 10% spindled growth for biphasic designation. (Husain et al., 2013)

The morphology of peritoneal mesothelioma is similar to that of pleural mesothelioma. There are epithelioid and sarcomatoid types, although the incidence of biphasic tumors is lower than in pleural disease. Pure sarcomatoid tumors are very rare. (Husain et al., 2013)

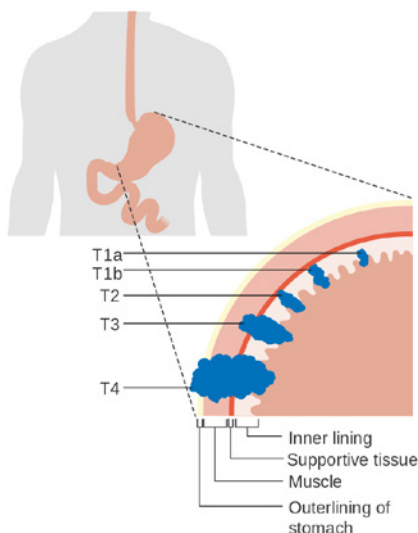
Distinguishing features of malignant mesothelioma include:

- ✦ dense cellularity including cells surrounded by stroma (Churg et al., 2006; Husain et al. 2013)
- ✦ complex papillae: tubules, cellular stratification (Husain et al., 2013)
- ✦ nodular expansion of stroma (Churg et al., 2006; Husain et al., 2013)
- ✦ disorganized growth (Husain et al., 2013)

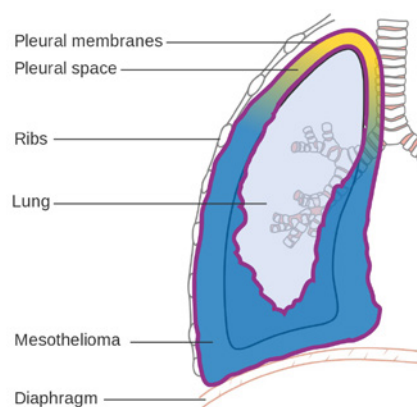
## MICROSCOPIC EXAMINATION/HISTOLOGIC PATTERNS

Most mesotheliomas have several patterns, and a biopsy may not represent the whole tumor. The pattern may be included in the microscopic description. (Husain et al. 2013 pp. 652-653, 655, Husain et al. 2017)

Mesothelioma, gastric



Pleural mesothelioma



A diagnosis of desmoplastic mesothelioma requires the storiform pattern (a matted, irregularly whorled pattern, somewhat resembling that of a straw mat) and one of:

- + stromal invasion;
- + bland necrosis;
- + overtly sarcomatous foci
- + distant metastases (Churg et al., 2006; Husain et al., 2013).

To clarify what the pathologist sees under microscopy, please refer to

- + Husain et al., 2013; Figures 2 - 5, 10 - 18 pp. 649, 651, 654, 658 - 661
- + Husain et al., 2017; Figures 2, 3 - 4, 6, 8 - 15, pp. 3, 5, 10 - 13, 15

## ANCILLARY STUDIES

Immunohistochemistry results support a primary tumor: where did the cancer originate? (See Table A) However, in mesothelioma cases, the plaintiff usually needs to prove the primary origin. Without proof of diagnosis, the defense will try to dispute the primary tumor, because settlement amount is based on primary tumor. If it was epithelial, then other epithelial tumors must be ruled out as the origin to confirm mesothelioma as the primary.

*No single marker is diagnostic of mesothelioma.* Different laboratories may report different results with the same antibodies. Classifying a poorly differentiated tumor based on stains alone is likely to lead to misdiagnosis. Immunohistochemical markers should never substitute for careful

examination of morphology on H & E stained sections, correlation of gross distribution of the tumor as determined by the surgeon at time of surgery, and radiographic studies. (Churg et al. 2006)

Typical workup is done in stages. Many markers to distinguish pleural epithelioid mesothelioma from metastatic carcinoma originating in the lung and distant organs (kidney, breast, ovary, gastrointestinal tract) are available. No markers are 100% specific. The International Mesothelioma Interest Group (IMIG) recommends that at least two mesothelial markers, two carcinoma markers, and a broad spectrum keratin antibody should be sought. Additional antibodies should be selected according to the differential diagnosis. (Husain et al. 2017)

Concordant results can establish the diagnosis. Discordant results may require a second diagnostic stage, expanding the antibody panel. The pattern of staining is important for certain antibodies to support a diagnosis of mesothelioma: Calretinin (cytoplasmic, nuclear), and WT1 (nuclear). There is no standard for the percentage of tumor cells that should be positive, but some have used a 10% cutoff for membranous and cytoplasmic staining. (Husain et al., 2013)

## CLINICAL HISTORY

According to Churg et al. (2006), patients with pleural tumors commonly present with chest pain, shortness of breath, weight loss, cough, or fever.

Patients with peritoneal tumors may present with abdominal pain, gastrointestinal complaints, ascites, and localized abdominal masses including ovarian masses. Bowel obstruction is fairly common in advanced disease.

Look for respiratory and gastrointestinal complaints or related diseases. Symptoms will be in

- + chief complaints
- + indications for radiology tests
- + medication side effects
- + review of systems in physical examinations
- + face sheets
- + emergency room triage notes
- + problem list in electronic health record documentation

Diagnostic testing is important. Look for, at a minimum, chest x-ray, CT of the chest, barium enema, and CT of the abdomen. If another primary is suspected, check results from other body sites, e.g. bronchoscopies and upper and lower endoscopies.

In the pleural cavity, radiological examination shows pleural effusion at time of presentation, and drainage of the effusion reveals a pleural nodules or tumor. The effusion is commonly blood tinged; with disease progression, greater and greater amounts of tumor become radiographically visible, and the thorax becomes contracted. In the peritoneal cavity, radiological examination reveals ascites, omental or mesenteric thickening, and small to large tumor masses. (Churg et al., 2006)

*The median age for presentation is around 60 years; mesothelioma is uncommon in men under age 50. Women with peritoneal mesothelioma have a wide age range, with a much larger proportion seen in young women.*

## DIFFERENTIAL DIAGNOSIS

The pathologist should document the process used to make the final diagnosis. If you have cytology reports of pleural effusion or ascites, check to determine whether or not the specimen is cellular. Cytospins concentrate scarce cells in fluid using a centrifuge, so they can be retrieved for immunocytochemistry.

Any carcinoma can metastasize to the pleura or peritoneum and create a malignant effusion. Sarcomatoid mesothelioma, sarcomatoid carcinoma, sarcomas, and squamous/small cell carcinomas are less likely to exfoliate cells into an effusion. (Churg et al. 2006) Mesothelioma, however, produces a highly cellular sample.

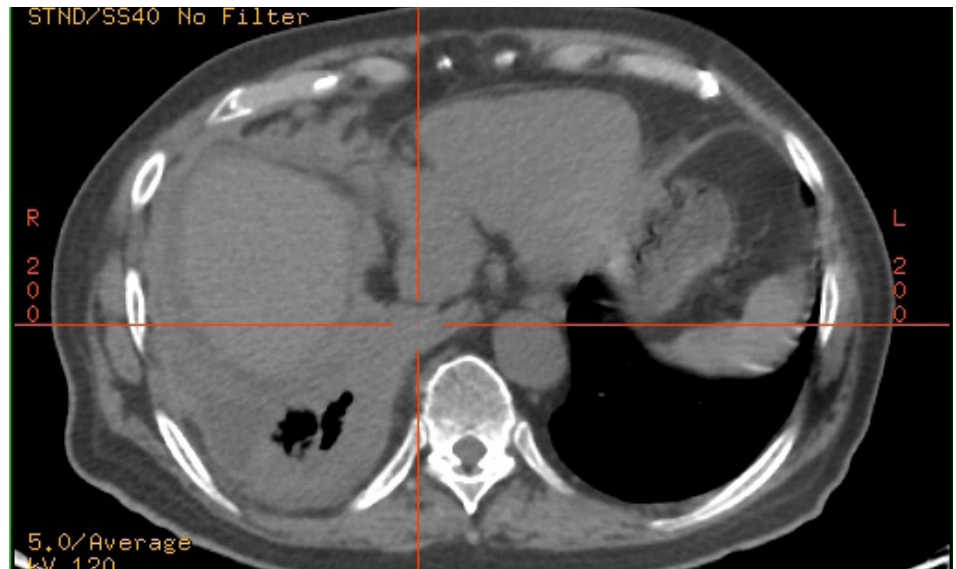
Any malignant tumor can metastasize to serous membranes. In the pleural cavity, lung and breast are the most common. In the peritoneal cavity, metastatic carcinomas of the ovary, gastrointestinal tract, and less commonly lung, breast, and uterus, and sarcomas can produce multiple small tumor nodules or occasionally encase viscera. (Churg et al., 2006)

## FINAL PATHOLOGICAL DIAGNOSIS

The pathologist makes a final diagnosis based on primary tumor of origin from IHC. The report should indicate how this diagnosis was made, and note any other spread of the tumor to surrounding organs or sites. If the primary tumor is a mesothelioma, the subtype and pattern(s) will be listed.

## CONCLUSION

Immunohistochemistry is an evolving science. PubMed is a great source for updated literature on new antibodies. Search by immunohistochemistry (for tissue specimens) or immunocytochemistry (for effusion specimens) and type of cancer in question, e.g. mesothelioma versus



squamous cell carcinoma. Understand which antibodies are positive in certain neoplasms, and which ones are negative.

To treat a patient accurately requires definitive diagnosis. Make sure the attorney is aware if an item is missing in the pathology report, e.g. antibodies, since the IMIG recommends at least five antibodies in a panel. The pathology expert can also review the slides and/or cell blocks. An expert should have experience in reviewing pleural and peritoneal pathology. The College of American Pathologists (CAP) 4, 5 has online protocols for specimen reporting that are easily downloaded by type of specimen, e.g. ovary, lung, etc.

## REFERENCES

Churg, A., Cagle, P. T., and Roggli, V. L. (Eds.) *AFIP Atlas of Tumor Pathology, Series 4 Fascicle 3. Tumors of the Serosal Membranes.* 2006. ARP Press. Silver Spring, Maryland.

College of American Pathologists (CAP) (2011) Protocol for malignant pleural mesothelioma. <http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/WebContent/pdf/mesothelioma-12protocol.pdf> Retrieved December 18, 2016.

CAP (2015) Protocol for tumors of the peritoneum. <http://www.cap.org/ShowProperty?nodePath=/UCMCon/>

[Contribution%20Folders/WebContent/pdf/peritoneum-15protocol-3201.pdf](#) Retrieved December 18, 2016.

Husain, A. N., Colby, T. V., Ordonez, N. et al. (2013) Guidelines for pathologic diagnosis of malignant mesothelioma: 2012 update of the Consensus Statement from the International Mesothelioma Interest Group. *Archives of Pathology & Laboratory Medicine*: 2013 May 137(5): 647-667. <http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.2012-0214-OA> Retrieved December 18, 2016.

Husain, A. N., Colby, T. V., Ordóñez, N. G., et al. (2017) Guidelines for pathologic diagnosis of malignant mesothelioma: 2017 update of the Consensus Statement From the International Mesothelioma Interest Group. *Archives of Pathology & Laboratory Medicine In-Press*. Accepted: May 5, 2017. <http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.2017-0124-RA> Retrieved September 17, 2017.

**Rhonda A. Fritz, BS, RN** is a licensed Registered Nurse in Missouri and Illinois, and holds a B.S. degree with academic distinction from the University of St. Frances. She is experienced in utilization management, clinical appeals, and health-care claims auditing. She also worked as a Medical Record Analyst for the law firm of Thompson Coburn LLP in St. Louis in defense of railroad asbestos litigation.

THE JOURNAL OF  
**Legal Nurse  
Consulting**

## **Looking Ahead...**

**XXIV.2, June 2018** — EHR revisited

**XXIV.3, September 2018** — Trials

**XXIV.4, December 2018** — Pediatric/Adolescent Issues AND  
New Nurse Author Supplement

**AALNC**

AMERICAN ASSOCIATION OF  
LEGAL NURSE CONSULTANTS