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Introduction

The responsibilities of the medical device expert are extremely challenging and require knowledge of several different areas. The expertise required by an expert varies, based on whether he/she is consulting health care facilities, liability attorneys (either for the plaintiff or defendant side) or health insurance providers.
Some of the matters on which Experts are required to provide expertise include cybersecurity risks associated with various technological innovations, the effects that these threats have on patient safety, FDA regulatory protocols including premarket approvals and FDA design controls, other medical device regulatory bodies where the device is marketed (e.g. the United Kingdom or Canada), good design practices for all types of medical practice, expertise in the research and development of medical devices, and the proper use of medical devices.
The Expert Witness may be required to develop a written report, which should be based on a rigorous engineering analysis of the device, complete understanding and critical analysis of issues related to cybersecurity vulnerabilities/issues which may affect electronic medical record systems, medical emergency system alerts primarily used in critical care settings, knowledge of proper functioning of the device and all recent IT system updates, as they relate to the potential cause(s) of a device or system failure which poses risk to the safety of the patient or has not provided the appropriate therapy for which it had been designed.

The expert report needs to be well written and include a discussion of adherence or lack of adherence to FDA device controls as shown below, data systems used in a specific health care facility, cybersecurity vulnerabilities, electronic records systems being used, good manufacturing current manufacturing practices Current Good Manufacturing Practices (cGMP) as discussed in in part 820 (21 CFR part 820), all Manufacturer and User Facility Device Experience (MAUDE) listings related to the device in question, proper handling of evidence. Depositions, trial testimony, evaluation of post implant failure analysis conducted by the manufacturer (defendant), and other relevant issues/factors related to providing his/her opinions in either an Expert Report or in sworn testimony provided by that expert.

Working with Health Care Facilities and/or Health Insurance Providers

The mission of all care facilities is to ensure the safety of the patient and lower the costs of care associated with their care, and improving the quality of care provided to their patients. Unfortunately, medical devices and systems have been recently subjected to cybersecurity threats, IT systems, inadequate telemedicine systems, integrated alarm systems which have not functioned properly, and other threats which affect the therapeutic efficiency of these systems. Some of the issues related to the expert serving these types of clients will be discussed in the following sections.

Experts who are tasked to provide his/her opinions related to IT, electronic medical record system failures, and potential cybersecurity vulnerabilities have consulted previously on these types of data related issues and should possess expertise in data systems, programming and related experiences required to render their opinions in these areas.

In conducting training, communication for understanding across multiple departments is crucial. When it comes to healthcare systems, three major user groups are:

- Healthcare providers
- Health care facilitate staff (specific emphasis on hospital IT staff)
- Patients and caregivers

Trainings include communicating the following general categories of information among departments and user groups:

- Cybersecurity risks and threats (what can go wrong if recommended procedures, including those described by the FDA standardized, are not properly carried out)
- Cybersecurity controls

Pedagogy is a key component in the success of a training. Methodologies may include one or several of the following formats:

- Simulated scenarios where teams work together on practicing attacks and responses
- Hands-on exercises per individual, particularly for hospital IT staff members

Organizational opportunities and cybersecurity risks associated with various digital health innovations, such as:

- Telemedicine
- Network / Internet connected medical devices

- Electronic medical records
- Medical emergency alert systems
Internet connected medical devices

Security awareness training within a healthcare organization is an important part of medical device implementation practices. Training should be provided across multiple departments, including medical practitioners and IT staff.

Telemedicine enables quick and portable communication between healthcare providers and patients, enabling access from any location and more efficient data-driven decisions for healthcare providers.

Such remote access comes with associated cybersecurity and privacy risks for patients and medical facilities.

A cybersecurity consultant's explanation for each threat should include the following, in plain English, rather than in highly technical
terms: [
1] [2] [z3] * Effects on patient safety
* Attack surface
* Threat model (or similar explanation)
* Security controls and mitigation
* Corresponding employee training (and roles per department within an organization)

Working as a Medical Device Expert Witness for Attorneys

The Expert may be retained to provide their opinions related to a specific medical device or imaging system. The Expert in these types of cases will possess an engineering degree, usually an advanced degree in biomedical or related engineering discipline. Serving in this type of role will require an expertise in medical device design; medical device regulatory protocols; good current manufacturing design principles, and has designed and developed medical devices on his/her own. The next sections will be devoted to issues and the expertise required to provide opinions on a design related failure.

Working with Medical Device Manufacturers

Being retained by the manufacturer or an attorney to act as an expert on potential liability is obviously handled differently. But the expert should be professional in his/her dealings with a particular manufacturer. If the Expert is in need of documents related to the case which have not been provided; he or she should ask the attorney to request these documents, e.g. Bates Documents, on behalf of the expert.

Evaluating Information from Medical Device Manufacturing Sites

The Expert should be completely familiar with how the device has been designed, manufactured, its intended use and related matters as it pertains to the proper functioning of a medical device.

Understanding all case related US FDA Device Regulatory Protocols

The Premarket Approval Process
Premarket Approvals Premarket approval (PMA), as required by The Food and Drug Administration, is the regulatory protocol presently used to evaluate the safety and effectiveness of Class III medical devices, e.g., an implantable cardioverter defibrillator (ICD) system. The expert witness must thoroughly understand the entire premarket approval application process. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)", usually class III devices
PMAs are rigorous in nature and can take several years to complete.
"PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)".
The Required Elements of a PMA (§814.20) should include the following:
The name and address of the applicant.
A table of contents that specifies the volume and page number for each item referred to in the table.
A summary section in sufficient detail to provide a general understanding of the data and information in the application.

Summary of Safety and Effectiveness Data (§814.44)

The Summary of Safety and Effectiveness (SSED) is a document mandated by the Food, Drug and Cosmetic Act subparagraph 520(h)(1)(A) to be publicly available upon issuance of an approval order of a premarket approval application (PMA)

Understanding & Evaluating Potential Device Defects

Types of Medical Device Defects are due to the following
Defectively manufactured devices
Defective design (even though properly manufactured), or
Defectively marketed medical devices.
Medical Device Safety Communications
FDA Safety Communication
11/05/2019
The FDA Requests Allergan Voluntarily Recall Natrelle BIOCELL Textured Breast Implants and Tissue Expanders from the Market to Protect Patients: FDA Safety Communication
07/24/19
Certain Medtronic MiniMed Insulin Pumps Have Potential Cybersecurity Risks: FDA Safety Communication

07/01/19
FDA Warns People with Diabetes and Health Care Providers Against the Use of Devices for Diabetes Management Not Authorized for Sale in the United States: FDA Safety Communication
05/17/19
FDA Alerts Providers and Patients to Check for Premature Battery Depletion in Certain Medtronic Pacemakers: FDA Safety Communication
05/07/19
Mammography Problems at East Palestine Family Medical Clinic in East Palestine, Ohio: FDA Safety Communication
04/26/19
Use of the Stryker Wingspan Stent System Outside of Approved Indications Leads to an Increased Risk of Stroke or Death: FDA Safety Communication
04/25/19
The FDA Continues to Remind Facilities of the Importance of Following Duodenoscope Reprocessing Instructions: FDA Safety Communication
04/12/19
The FDA Recommends Only Using Cleared or Approved Medical Devices to Help Assess or Diagnose a Head Injury, Including Concussion: FDA Safety Communication
04/10/19
Letters to Health Care Providers
Device Name
Date
Programmable CSF Shunts and Magnetic Field Interference with Implanted Hearing Devices - Letter to Health Care Providers
07/16/19
UPDATE On Risk of Cross-Contamination From 24-Hour Multi-Patient Use Endoscope Connectors - Letter to Health Care Providers and Staff at Health Care Facilities Performing Gastrointestinal Endoscopy Procedures
05/23/19
UPDATE: Increased Rate of Mortality in Patients Receiving Abiomed Impella RP System - Letter to Health Care Providers
05/21/19
UPDATE: Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - Letter to Health Care Providers
03/15/19
Safe Use of Surgical Staplers and Staples - Letter to Health Care Providers
03/08/19

Medical Device recalls

There are three types of medical device recalls, that is type I, II, and III, respectively. Class I type recalls are the most serious are due from a device causing serious injury or death in the patient using that devices.
Evaluating FDA Issues and other Supporting Evidence (validation of expert opinions)

If the FDA is made aware of the correction or removal action, it will then review the strategy the manufacturer has proposed to address the problem, "Then assesses the health hazard presented by the product, determines if the problem violates FDA law, potential violations of FDA requirements, and if appropriate assigns the recall a classification (I, II, or III) to indicate the relative degree of risk". The 3 types of medical device recalls are listed below:
Class I: A situation where there is a reasonable chance that a product will cause serious health problems or death.
Class II: A situation where a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.
Class III: A situation where a product is not likely to cause any health problem or injury.
The FDA does have the legal authority to force a manufacturer to recall a specific device when it becomes know that the device may have caused significant harm or death to a patient, i.e., class I recall. A medical device recall does not always mean that you must stop using the product or return it to the company. A recall may mean that the medical device needs to be checked, adjusted, or fixed.

Corrections and Removals - 21 CFR 806

"Under 21 CFR 806, Medical Device Correction and Removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health".

Manufacturer and User Facility Device Experience (MAUDE)

A MAUDE(s) confirms whether a device actually caused a specific event, which 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."
It is important to understand that "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."

Health Canada Medical Device Protocols (if the device is marketed in Canada)

"Health Canada requires medical device manufacturers to use a quality system certificate as evidence of compliance to the appropriate regulatory quality system requirement. Health Canada will only accept quality system certificates that have been issued by special third-party auditing organizations called Canadian Medical Devices Conformity Assessment System (CMDCAS) recognized registrars".

European Medical Device Regulatory Protocols (if the device is marketed in any country which is under the European Medical Device Regulatory Authority)

"Medical devices are products or equipment intended generally for a medical use. They are regulated by national competent authorities, but the European Medicines Agency (EMA) is also involved in the assessment of certain categories of medical device under European Union (EU) legislation."

Types of Defects that Experts may be asked to provide their Expert Opinions on

Example(s) of Design Defects

Having been an Expert Witness on several cases involving the lead integrity of an ICD system, I was required to provide my Expert Comments, e.g. as the one shown below in order to demonstrate that a design effect was the primary cause for the malfunctioning of the system, e.g. listing of all potential lead failures, test protocols used, potential cases for lead failure which had been evaluated by the Expert:
Conductor Fracture Conductor break with complete or intermittent loss of continuity that could interrupt current flow (e.g. fractured conductors).
This type of malfunction includes any conductor fracture such as those associated with flex-fatigue or clavicular crush damage.
Insulation Breach Any lead insulation breach, such as: 1) proximal abrasion associated with lead-to-lead or lead-to-can contact in the pocket, 2) mid-lead insulation damage caused by clavicular crush or insulation wear in the region of vein insertion, 3) distal abrasion due to lead to-lead interactions or contact with anatomic structures, and 4) externalized conductors in the distal region. Crimps, Bonds, and Welds Any interruption in the conductor or lead body associated with a point of connection.
Other Includes specific proprietary lead mechanical attributes, such as lead incorporated sensors, connectors, and seal rings, as well as other analysis results not included in the alternate categories. Extrinsic Factors.
The lead was removed from service and returned for analysis, however analysis was inconclusive because (1) only portions of the lead were available, or (2) the returned lead was damaged by the explanation process, or (3) lab analysis could not determine an out of specification condition (typically with complaints such as dislodgements, perforations, or failure to capture). For this particular category, malfunctions

Marketing Defects-Examples of these types of defects are mislabeling of the device; lack of proper warnings or recommendations

Additional Potential Defects to consider
-Cybersecurity issues which may relevant to the case
-Software issues which may be relevant to the case
The Food and Drug Administration (FDA) Recalls, Advisories and Medical Device Reports

The FDA actively monitors all reports of adverse events and other related problems with medical devices and alerts health care providers as well as the public as required in order to ensure proper use of devices and the health and safety of patients. This is accomplished through the following:

The EXPERT MEDICAL DEVICE REPORT TEMPLATE FOR THE PLAINTIFF
Report prepared by (Expert's full name)
Prepared at the request of (Specific Law Firm)
Professional credentials of the Expert
Summary of Instructions given to the Expert who has engaged his/her
Summary of Case Related Key Dates
Factual background of the case
Investigation conducted by manufacturer involved
The Plaintiff's allegations if representing the Plaintiff's side
The Defendant's (Manufacturer's) allegations if representing the defendant side
Case related device description
Device Failure Mechanisms examined and evaluated by the Expert
Manufacturer's disclosure ant their analyses/testing performed
Device related advisories/recalls/incident reports
Range of Expert's opinions
Reasons in support of Expert's Opinions
Appendix Section
References Used
Exhibits
Websites reviewed
Documents reviewed, e.g. Bates Documents
List of Figures, Photos & Tables
Terminology used
Expert's CV as part of the Expert's Exhibits
Certifying Statement from Plaintiff's Expert
Potential formatting of your Expert Report (an example has been provided in the following section:

My name is George Yanulis. I have been engaged by manufacturers to conduct an independent expert analysis and provide my opinion with regard to the
I am over the age of eighteen (18) years, of sound mind, and fully competent to testify in this case. I am currently a resident of Lee County, Florida.

I. BACKGROUND

As more fully detailed in my current C.V., which is attached as Exhibit 1, I am a biomedical engineer with over 25 years of medical device experience and a member of several professional societies.
I have authored peer-reviewed publications, presented seminars and peer reviewed abstracts in the areas related to this specific matter.
I have been engaged as an expert for both medical device liability cases and patent infringement cases, including a neonatal support system infringement case.

A list of all publications; presentations and seminars that I have authored in the past ten years is also included in Exhibit 1 attached hereto. A list of all cases in which I provided expert testimony in deposition or at trial in the last four years is included as Exhibit 2. A list of all materials that I considered in the preparation of this report is attached as Exhibit 3.
I am being compensated for my services in this matter at my normal hourly rate of per hour. My compensation is not contingent on the outcome of this matter or the content of my conclusions or testimony.

II. SUMMARY OF OPINIONS

Based on my education, training, and experience, the materials that I have considered, and my independent analysis, I have reached the following expert opinions and conclusions in this matter, as supplemented by and including the other opinions, statements, and conclusions set forth in this report and am prepared to testify as follows.

The Expert should always incorporate a statement such as "The Expert is prepared to amend his/her opinions based on additional evidence that may be provided".

Your expert report should incorporate a certification statement at the end of the body of your Expert Report, e.g.

EXPERT CERTIFYING STATEMENT

- I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
- I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert as required.
- I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
- I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
- Wherever I have no personal knowledge, I have indicated the source of factual information.
- I have not included anything in this report that anyone, including the lawyers instructing me, has suggested to me, without forming my own independent view of the matter.
- Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
- At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
- I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
- I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.
- That I know of no conflict of interest of any kind, other than any which I have disclosed in my report.
- And that I do not consider that any interest which I have disclosed affects my suitability as an expert witness on any issues on which I have given evidence.

I therefore confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own knowledge I

confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.
Signature

DATE:

Depositions & Trial Testimony

Every expert may or may not be required to provide depositions and/or trial testimony related to a medical device for which they have been retained. There are some standards by which all experts are expected to abide. And the expert should be prepared to answer all questions which may be posed in a clear, concise fashion based on scientific evidence he or she may have used in generating their opinions. The expert should be responsive, non-argumentative, honest and ask for clarification if a specific question is being posed which is not completely understood.

The expert should always dress professionally and BE PREPARED! Lack of preparedness is no excuse and may jeopardize a case and/or adversely affect is credibility in the case.

Daubert Challenges (Best Practices for Avoiding Them)

Every Expert "cringe" when he/she hears that his/her testimony is being formally challenged in a legal proceeding is referred to as a "Daubert Challenge" Hearing.
A Daubert challenge is a hearing conducted before the judge where the validity and admissibility of expert testimony is challenged by opposing counsel."

In order to avoid to avoid a Daubert Challenge, the Expert should do the following:

-Provide opinions based on sound scientific evidence
-Provide all supporting evidence which substantiates his/her expert opinions in
    -Expert Reports
    -Depositions/Trial Testimony

Concluding Remarks

The expert witness should continue to increase his overall effectiveness in becoming the Expert Witness which the opposing side involved in the liability case respects. These should include taking seminars in FDA regulatory protocols including premarket approvals and FDA design controls; good design practices for all types of medical design practices; and becoming a member of professional societies such as the Heart Rhythm society; and be constantly reviewing professional journals relevant to his/her level of expertise.

If an expert does not feel that the case is within their realm of expertise, the expert should immediately indicate that he/she is not qualified to provide their opinions. As an illustrative example, if an expert is not credentialed as a materials scientist, they should not render opinions related to a tissue related medical device.

Appendix Section

Terminology/Abbreviations Used

A - atrial or atria
ACC - American College of Cardiology
AF - atrial fibrillation
AHA - American Heart Association
Aomean = mean aortic pressure
ARVC = arrhythmogenic right ventricular cardiomyopathy
AV - atrioventricular
AVD - atrioventricular delay
Bi-V - biventricular
BL - baseline during sinus rhythm
BPEG - British Pacing and Electrophysiology Group
BPM - beats per minute
CBF - Coronary blood flow (ml/min)
CDC - Centers for Disease Control and Prevention
CFR Code of Federal Regulations
CHD - coronary heart disease
CHF - congestive heart failure
CI the interval estimates of a population parameter
CO - cardiac output (L/min)
COC – chain of custody
CRT - cardiac resynchronization therapy
CS = coronary sinus
CVR - coronary vascular resistance (mmHg/ml/min)
D - Dual (for the ICD)
DBP - diastolic blood pressure (mmHg)
DFT - defibrillation threshold testing
EDV - end diastolic volume (mL)
EDX (analysis) - Energy-dispersive-ray spectroscopy
EF - Ejection Fraction
EGM - electro gram
EMI - electromagnetic interference
EOL - end of battery life (applicable to both cardiac pacing and ICDs)
EP - electro cardio-physiology
ESCA - Electron Spectroscopy for Chemical Analysis (ESCA)
ESV - end systolic volume (mL)
ETFE - ethylene-tetrafluoroethylene
FDA- Food and Drug Administration
FHS - Framingham Heart Study
GCV- great cardiac vein
HF - heart failure
HR - heart rate (min–1)
ICD -implantable cardioverter defibrillator
IE - infective endocarditis (IE).
I-Inhibited (for ICD)

I-Inhibited (for ICD)
L/min - liters per minute (unit for representing cardiac output)
LA - left atrial
LAD - left anterior descending coronary artery
LF - lead failure
LV - left ventricular
LV dP/dt- 1st derivative of LV systolic pressure development
LVE - left ventricular electro grams
LVEDP - left ventricular end-diastolic pressure (mmHg)
LVEDV - left ventricular end-diastolic volume (mL)
LVEF - left ventricular ejection fraction
LVESD - left ventricular end-systolic diameter (mm)
LVESV - left ventricular end-systolic volume (mL)
LVP - left ventricular pressure (mmHg)
MAUDE - Manufacturers and User Facility Device Experience
MDA - Medical Device Advisory
MHRA - Medicines and Healthcare products Regulatory Agency
MmHg-s - millimeters of mercury second
NASPE - North American Society of Pacing and Electrophysiology
NCHS - National Center for Health Statistics
NHDS - National Hospital Discharge Survey
NHLBI - National Heart, Lung, and Blood Institute
NYHA - New York Heart Association
O - None (for ICD)
P/S - Pace/sense
RA - right atrial
RCA - right coronary artery
RV - right ventricular RVE = right atrial electro gram
RVP - right ventricular pressure
SBP - systolic blood pressure (mmHg)
SR - sinus rhythm
SV - stroke volume (mL)
SVC - superior vena cava
TOF-SIMS - Time-of-Flight Secondary Ion Mass Spectrometry
VF - -ventricular fibrillation
V-ventricular
VVI - ICD designation which refers to setting the first 2 positions to ventricular chamber pacing and sensing, respectively only with the response to the mode of pacing to be inhibited
(XPS) - X-ray Photoelectron Spectroscopy (XPS)
(XRD) - X-ray Diffraction

References

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/quality-systems-13485/notice-transition-revised-version-13485-impact-compliance-quality-management-system-requirements-canadian-medical-devices-regulations.html

https://www.fda.gov/medical-devices/medical-device-safety/safety-communications

https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process

https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices

List of Medical Regulations/Directives/Guidance Documents that all Experts should have an Expert Level Familiarity include the following:

Directive 93/42/EEC covering medical devices modified by the directive 2007/47/CE

ISO 13485 Medical devices -- Quality management systems

ISO 10993-1 - Biological evaluation of medical devices - Part 1

ISO 14971 - Medical Device Risk Management

ISO 14937:2009 - Sterilization of health care products

ISO 9001:2015 Quality management systems — Requirements

EU-Medical Device Regulations MDR/2017

Directive 93/42/EEC covering medical devices modified by the directive 2007/47/CE

MEDDEV 2.7.1 rev 4 and Clinical Evaluation Reports (CER) for Medical Devices

ISO/TR 80002-2:2017 - Medical device software -- Part 2: Validation of software for medical device quality systems

90/385/EEC

Regulation (EU) 2017/745

Regulation (EU) 2017/746

Directive 98/79/EC

Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)

Council Directive 93/42/EEC on Medical Devices (MDD) (1993)

Council Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVDMD) (1998)

21 CFR 820

Establishment Registration - 21 CFR Part 807

Quality System Regulation (QS)/Good Manufacturing Practices (GMP) - 21 CFR Part 820

Medical Device Reporting - 21 CFR Part 803

Premarket Notification 510(k), unless exempt, or Premarket Approval (PMA)

Investigational **Device** Exemption (IDE) for clinical studies

Human Factors and Usability Engineering – Guidance for Medical Devices Including Drug-device Combination Products Ver.01 (MHRA Sep. 2017)

European Directive In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

The CE Marking/conformity assessment process

90/385/EEC regarding active implantable medical devices

Medical Device Directive 93/42/EEC regarding medical devices

MEDDEV 2.7.1 rev 4 and Clinical Evaluation Reports (CER) for Medical Devices