APhA-APRS Forensic Pharmacy Webinar

September 30, 2014
Webinar Information

- This webinar does not offer CPE credit for participation
- Submit questions in the question box provided in your control panel on the right hand side of the screen; Questions will be answered at the conclusion of the presentation if time allows; Unanswered questions and answers will be compiled and forwarded via email within the next few weeks
- This webinar is intended to provide general information only; Legal advice regarding personal or professional legal issues will not be given; Questions related to personal or professional legal issues will not be addressed
Webinar Information

- The webinar will be recorded and made available online at www.pharmacist.com/apha-aprs within the next few weeks; Presentation slides will be made available online as well.
- Webinar scheduled for 90 minutes
  - 15 minutes per topic
  - 15 minutes for logistics/questions
Objectives

• Understand ways in which the expertise of pharmacists and pharmaceutical scientists can be of value to civil and criminal courts
• Become aware of the expectations for pharmacy experts in providing testimony or opinions regarding standards of practice, causation, damages, and patent law
• Understand what an attorney expects if you are asked to review a case or provide a professional opinion
• Discover the opportunities available in forensic pharmacy
Pharmaceutical Litigation Support

William E. Fassett, PhD, RPh, FAPhA
Professor Emeritus of Pharmacy Law & Ethics
Washington State University - Spokane
Overview of the role of the expert in litigation

• In Court – the expert serves as a resource for the “trier of fact” (judge or jury) who can help the trier of fact understand and evaluate evidence that is beyond the normal understanding of a lay person

• In preparation for litigation – the expert assists the attorney in understanding professional and scientific issues involved in the case and make a proper assessment of factors which influence his or her advice to the party he or she represents

• Major activities of the expert include
  • Case review
  • Research
  • Developing opinions from his or her research and the review of the evidence
  • Writing reports: (1) confidential for the attorney; (2) to be submitted during discovery
  • Testifying by declaration, affidavit, at deposition, or at trial
Criminal cases

Criminal cases pit the state against an individual who is presumed innocent unless the prosecution can prove every element of the crime beyond a reasonable doubt

- Prosecutors use experts to develop their theory of the crime and to help interpret evidence
- Defense attorneys use experts to support alternate interpretations of the evidence that might exculpate their clients and to anticipate the prosecutor’s case
- The defense does not have access to all of the prosecutor’s information, except that the prosecutor is required to inform the defense of any exculpatory evidence in its possession
Administrative and civil cases

- Administrative agencies
  - Due process specified in the Administrative Procedures Act
  - Registrants entitled to a hearing before the agency
  - Evidentiary burden for the agency is either preponderance of evidence or “clear and convincing” evidence
- Civil cases involve two or more private parties who are presumed to be equal, and to prevail the plaintiff must prove liability by a preponderance of evidence
  - All states but Oregon have extensive pre-trial discovery where every party is entitled to understand all the evidence in possession of the other parties
  - Generally, any evidence, opinion, or research provided by an expert to one party will be disclosed to the other parties
  - Depositions are conducted by the opposite parties, at their discretion, to learn an expert’s opinion(s) and the basis therefore, prior to trial
Negligence (malpractice) actions

To prove negligence, and to obtain a judgment against a health care provider, the plaintiff must prove each of the following elements:

• Duty – a duty owed by the defendant to the individual, either as a matter of law, or as required by the standards of practice of the profession
• Breach – that the defendant failed to carry out the duty at the requisite level of care
• Injury – that the plaintiff suffered an injury, and the amount or value of that injury
• Proximate cause – that the injury to the plaintiff was proximately caused by the defendant’s breach of the duty owed
Defenses to negligence claims

- The defendant may seek to limit the damages owed for the injury by establishing a “defense,” such as
  - That the plaintiff contributed in some amount to his own injury
  - That some third party was also responsible in some amount to the cause
    - Expert may be retained to establish contribution of a non-named defendant (“empty chair defense”)
  - That some action by another party intervened between the actions of the defendant and the injury
- The defendant may avoid liability altogether by, among other strategies, showing that the plaintiff failed to file the lawsuit within the time limit specified by statute.
  - For this purpose, evidence as to when the injury first occurred, or when the plaintiff should have reasonably discovered the injury, is important
Importance of expert

• For each of the elements just described, if the facts needed to support or refute it require interpretation before a lay person can reasonably decide the issue, a qualified expert will be required

• An expert is a person qualified by such education, training, and experience as the Court determines will make him or her recognized to assist the trier of fact

• In many states, a person testifying to the duty owed by a health care provider must be a member in good standing of the same profession as the defendant, with experience in the same specialty
Standard of care testimony

- Expert testifies to two elements relating to the standard of care in an individual case:
  - The general duty or duties owed by the defendant to the plaintiff
  - The specific level of care required
    - By a reasonable and prudent provider of the same profession as the defendant
    - Performed by a competent member of that profession (not a super star or ultra-specialist)
    - Under the same or similar circumstances as faced the defendant
  - The opinions of the expert must be supported by reference to widely recognized authorities and to specific facts in the case
  - In many states, experts may not appeal to law or regulation (the province of the Court) but to standards of practice
Standard of care expertise

• Member of the profession in good standing
• Currently licensed in the US
• Practice experience relevant to the case
  • Community or hospital distributive practice - generalist experience, preferably can demonstrate how he or she knows what should be done in the setting
  • Specialty setting (LTC, compounding, anticoagulation, etc.) – relevant practice experience, certifications, training
• Some states require that the expert be actively engaged in practice for at least a certain percentage of the total work week
• Scholarship and teaching relevant to the practice setting will often be recognized by the Court
Causation

Daniel E. Buffington, PharmD, MBA, FAPhA
Associate Professor
University of South Florida, Colleges of Medicine and Pharmacy, Tampa, FL
Causation Testimony

• Clinical & forensic pharmacology analysis
• Diverse range of cases (Medical Malpractice, Criminal, Estate, etc.)
• Professional opinion based upon a blend of scientific evidence, published literature, training and experience
• Root Cause Analysis (Pharmacologic Principles)
• Inferred association is insufficient foundation
Causation

Actual, Direct, or Proximate

• Often referred to as “but-for” causation. “It is likely that injury X would not have occurred “but for” the actions/effects of a medication.

• Proximate cause is an event which is closest to, or immediately responsible for causing, some observed result.

Ultimate (aka Distal)

• This exists in contrast to a higher-level ultimate cause (or distal cause) which is usually thought of as the "real" reason something occurred.
Causation Case Mix

- Effects of medications (alone or in combination)
- Mechanism of adverse side effects
- Motion in limine (to ensure that evidence or data is included or excluded)
- Adverse Effect vs Negligence
- Intoxication
- Impairment
- Toxicology
- Cause of death
Opportunities to Provide Professional Support with Legal Cases

• Pretrial case review
• Pretrial hearings (i.e., Motion in Limine)
• Mediation support
• Deposition testimony
• Trial testimony
Opinion Standard

“With a reasonable degree of medical or pharmacologic certainty”

“More likely than not”
(Greater than 50%)

Caused or Contributed to a Ultimate Cause or Condition
Attribution Theory

• Attempts to explain the an outcome and to determine the cause of an event or sequence of events
Sequence of Events & Attribution
Occam’s Razor

- **Occam's razor** (also Ockham's razor; and in Latin *lex parsimoniae*) is a problem-solving principle devised by William of Ockham (c. 1287–1347).
- It states that among competing hypotheses, the one with the fewest assumptions should be selected.
- Translated – If you have to make assumptions about variables, then correlation can serve as a foundation for explaining causation.
- Flawed concept that should not be applied in legal proceedings.
Buffington’s Theorem

Correlation $\neq$ Causation
### Rule of Evidence “Expert’s Testimony” Standard

**Daubert vs Frye Standard**

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<tr>
<th>Frye</th>
<th>Daubert</th>
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<td>• To meet the <em>Frye</em> standard, scientific evidence presented to the court must be interpreted by the court as &quot;generally accepted&quot; by a meaningful segment of the associated scientific community.</td>
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<td>• More opinion and less facts or scientific foundation</td>
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<td>• <strong>Scientific knowledge = scientific method/methodology:</strong> A conclusion will qualify as <strong>scientific knowledge</strong> if the proponent can demonstrate that it is the product of sound &quot;scientific methodology&quot; derived from the scientific method.</td>
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<td>• Pursuant to this standard, a party may raise a Daubert motion, which is a special case of “motion in limine” raised before or during trial to exclude the presentation of unqualified evidence to the jury.</td>
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<td>• <strong>Relevance and reliability:</strong> This requires the trial judge to ensure that the expert's testimony is &quot;relevant to the task at hand&quot; and that it rests &quot;on a reliable foundation&quot;.</td>
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Motion In Limine

- A written motion to a judge that can be used for civil or criminal proceedings, and at the state or federal level.
- Pre-trial hearing or during an actual trial, requesting that the judge rule that certain testimony regarding evidence or information may be included or excluded.
- The motion is always discussed outside the presence of the jury and is always decided by a judge.
- The reasons for the motions are wide and varied, but probably the most frequent use of the motion in limine in a criminal trial is to shield the jury from information concerning the defendant that could possibly be unfairly prejudicial to him if heard at trial. Some others arise under the Federal Rules of Civil Procedure for failure to comply with discovery.
Rule 702. Testimony By Expert Witness

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

a) The expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

b) The testimony is based on sufficient facts or data;

c) The testimony is the product of reliable principles and methods; and

d) The expert has reliably applied the principles and methods to the facts of the case.
Balance of Expert Witnesses
Confusion over Same Specialty

- Some attorneys presume or interpret that this means same terminal degree or identical board certification.
- Questions & issues involving pharmacology, such as the practical application, therapeutic selection, and prescribing decisions are a blend of physician & pharmacist roles and not a specialty issue.
- Pharmacology becomes the unifying factor.
Case 1: Misbranding Case

- Boyfriend & girlfriend = pregnancy
- He gave the girl a prescription bottle labeled as an antibiotic, but really contained misoprostol (Cytotec®).
- Following consumption = pregnancy was terminated
- Testified for Federal prosecutors, confirming that pharmacologic effects and that the risk factors literature and outcome was, based upon the facts of the case, more likely than not a direct result of the administration of misoprostol.
Case 2:
Potassium Supplementation Errors (Inpatient)

- 19 year old female, admitted for possible infection and identified hypokalemia
- Initial ED physician ordered K+ supplementation per hospital protocol
- Next day staff reviewed original labs (hypokalemia) and continued K+ supplementation, actual labs revealed K+ was WNL
- K+ supplementation continued for multiple with no reassessment, developed s/s consisted with hyperkalemia
- Developed cardiac arrhythmias and stat labs confirmed severe hyperkalemia.
- Multiple breeches in hospital’s K+ supplementation protocol and failed to order/administer K+ lowering agents and cardiac stabilization therapy.
- Patient expired
- Testified for plaintiff’s to explain the pharmacologic mechanisms of action and the sequence of errors and omissions by staff that lead to the death.
Damages:
An Expert’s Perspective

Stephen W. Schondelmeyer, PharmD, MAPubAdm, PhD, FAPhA
Professor & Director, PRIME Institute
CMC Endowed Chair in Pharmaceutical Management & Economics
University of Minnesota
Goals

• To provide the perspective of an experienced Expert.
• To describe potential roles of an expert in pharmaceutical economics

Disclaimer

• I do not have any conflicts or interest related to my presentation.
• The Damages or Economic Expert is not typically a lawyer and thus does not provide legal opinions.
• I am not a lawyer and I am not offering any legal opinions.
Considerations for Involvement in a Case from the Expert’s Perspective

- Timing of the Engagement & Time Commitment to the Case
- Appropriateness & Relevance of Expert
- Role of the Expert
  - Consulting expert, primary expert, rebuttal expert, tutorial expert, testifying expert
- Scope of the Engagement
- Information to Ask the Lawyer
The Three “R”s of Being an Expert

• Review the complaint and pertinent pleadings of all parties.
• Request discovery input and copies of all (or selected) documents.
• Research the issues based on your experience and knowledge in the field and connect the research to the facts of the case.
Forming Expert Opinions

- Based on experience and expertise applied to the facts of the case.
- Use standard method for your discipline and the issues being addressed.
- Expert should provide information & perspective that adds to the facts already in evidence.
- Effectively tell the story of harm & damages based on facts of the case.
- Use graphic demonstratives when possible to make detailed and complex information more visible and easy to understand.
Types of Economic Damages

“Arguably all damages are economic or can be reduced to monetary terms.”

• Actual Damages – “compensation for losses that can readily be proven to have occurred and for which the injured party has the right to be compensated.”
  
  Compensatory (General or Special)
  • Nominal
  • Liquidated

• Punitive Damages — are damages intended to provide “deterrence or retribution; they punish a defendant’s unlawful conduct and deter its repetition.”
  
  • Statutory
  • Treble
  • Discretionary
Potential Approaches to Economic Damages

- Actual Data and Records
- Comparable Data in Similar Setting and Situation
- Benchmark or Yardstick Case(s)
- Before and After Analysis or Similar Situation
- Historical Trend Data or Multiple Regression Modeling
- Net Present Value & Time Value of Money
- Other Considerations
Types of Medical & Pharmacy Experts Potentially Relevant to Damages

- Pharmacology & Mechanism of Action
- Medicinal Chemistry or Pharmaceutics
- Medical Clinician and/or Medical Practitioner
- Pharmacy Clinician, Pharmacy Practitioner, and/or Pharmacy Manager
- Pharmaceutical Manufacturing & Marketing
- Organization & Structure of the Pharmaceutical & Health Market
- Pharmacy Benefit Management (PBM & Insurance)
- Pharmaceutical Economics
- Other Related Experts:
  - Forensic Economist, Forensic Accountant, Big Data Cruncher
Types of Cases That May Utilize a Pharmaceutical Expert

• Breach of Contract:
  - Manufacturer licensing a product to be marketed by another firm using best efforts; if “best efforts” are not used what is the economic damage to the first firm?

• Professional Conduct
  - A pharmacist dilutes the cancer medications being dispensed and thus deprives patients of life-saving drug therapy.
  - If the drug salesman for the drug knew that his sales did not equal the number of patients being treated over time does he have an duty to warn of (and liability from) the potentially harmful pharmacist’s professional mis-conduct?
  - Assuming the sales rep knew, or could have known, what was going on, what is the economic value and impact of the his failure to warn?
Types of Cases That May Utilize a Pharmaceutical Expert (2)

- Consumer Fraud & False Claims
  - If a pharmacy is billing for medications using a patient’s Medicare number, but the patient never had or filled such a prescription, what is the amount of harm and damages to the government from such a pharmacy Medicare mill?

- FDA Regulation & Compliance
  - If a drug company has a manufacturing factory out of compliance with FDA’s GMP regulations and that factory is the only source of a scarce drug in short supply and the scarce drug can still be made in the factory, what economic sanction can the FDA impose on the manufacturer?
Types of Cases That May Utilize a Pharmaceutical Expert

- Intellectual Property Rights
  - If a drug company holds a patent that is challenged by a generic firm, but the patent is later found to be valid, what is the economic harm to the patent holder from the generic drug company who entered the market “at risk” [i.e., before the issue of patent validity was resolved by the courts]?
  - What is the amount of harm and damages owed to the patent holder by the first generic firm?
  - What about a second, or a third generic who entered the market at risk?)

- Criminal Behavior
  - If a drug company makes and distributes a counterfeit for drug product in the U.S. market which is still under patent, what is the harm to the patent holder?
  - What is the harm to patients who unknowingly used the counterfeit drug, particularly if the counterfeit is of low quality, purity and safety?
Pharmaceutical Economics vs Classical Economics

• Classic Economic Principles Apply But . . .
• Many Standard Assumptions & Conditions Are Not Met . . .
  • It’s Sometimes About Life and Death—Not Just a Simple Consumer Choice
  • Many Drug Products Have a Real or Effective Monopoly
  • Legal & Structural Barriers Prohibit Arbitrage and Competition
  • Profound Lack of Transparency in Distribution, Pricing and Insurance
  • Very Asymmetric Economic Market:
    “one party in a transaction has more or superior information compared to another.”
Many Types of “Reverse Perverse” Economics in Pharmaceutical Market

• Physician-Administered Drug Prescribing & Use Influenced by Higher Profit to Physician (or Clinic) from Higher Priced Drugs

• PBMs Formulary Influenced by Non-Transparent Manufacturer Rebates

• PBMs Operate Self-Dealing & Exclusive Mail Order & Specialty Pharmacies

• Manufacturer’s Coupons to Consumers Induce Use of Higher Cost Drugs & Pass Cost on to Health Plan Payer Which Ultimately Increases Premiums
What is the Price of a Drug?

• What is the price of a specific prescription drug product?
  • A single drug product has many prices at many levels in the market
  • A single drug product has many prices to different end-customers
• Prices & Pricing Terms:
  ➢ Usual & Customary Price of a Prescription is not usual or vary customary these days.
  ➢ AWP – the Average Wholesale Price is Not an Average or a Wholesale Price.
  ➢ AWP has come to be known as “Ain’t What’s Paid”.
  ➢ AWP should not be represented is an “actual price paid” or as the “basis for calculating savings”
What is the Price of a Drug?

- Types of prices
  - Benchmark price (AWP, WAC)
  - Transactional price (price in purchasing and reimbursement records)
  - Invoice price (the price shown on an invoice before invoices)
  - Discounts and rebates (price factors that are often hidden)
  - Contributions of operating costs (retail, wholesale, & manufacturer gross a net margins)
  - Actual net price (What is the net price after all economic considerations are considered?)
Flow of Prescription Drug Products

Drug Manufacturers & Marketers

- Chain Warehouse
- Regional Wholesalers
- National Wholesalers

Bulk Sales

Chain Pharmacy
Mass Merchant Pharmacy
Food & Drug Pharmacy
Independent Pharmacy
Mail Order Pharmacy
Health Plan Pharmacy
Clinic & Drs’ Office
Long Term Care Pharmacy
Hospital
Government Facilities & Other

Manufacturer Direct Sales

Source: Compiled by PRIME Institute, University of Minnesota from data found in DDD Annual Class of Trade Analysis (Plymouth Meeting, PA: IMS, 2006) and reported in The Chain Pharmacy Industry Profile.
Flow of Prescription Drug Dollars

Source: Compiled by PRIME Institute, University of Minnesota.
Impact of Drug Product Selection

- Interface of Federal and State Laws & Regulations
  - Generic substitution
  - Bioavailability & bioequivalence
  - Federal law and regulation (e.g., Hatch-Waxman, PDUFA, FDA’s Orange Book, etc.)
  - State law and regulation (e.g., pharmacy practice act, dangerous drugs, definitions or therapeutic equivalents, pharmacist’s discretion in substitution, etc.)
- Bio-similar Utilization
  - Federal law and regulation—just emerging (ACA, FDA’s Purple Book, definitions, naming, etc.)
  - State law and regulation—not well developed,
    - Lack definitions of ‘bio-similar’
    - Lack provision for bio-similar utilization or substitution
The Many Faces of a Generic Drug

- Generic means many different things depending upon context
- Generic $\rightarrow$ multiple source drug products that can be substituted
- Generic $\rightarrow$ a drug product sold by the generic name
- Generic $\rightarrow$ a drug product approved under an ANDA
- Branded Generic $\rightarrow$ an ANDA drug product sold with a Brand Name
- Authorized Generic $\rightarrow$ an NDA drug product sold as a Generic
Role of Drug Data Bases

- Drug data bases are critical to the functioning of the pharmaceutical market
  [Data bases such as: MediSpan, First DataBank, Red Book]
- Report benchmark pricing data in a timely manner (i.e., AWP, WAC, FFP)
- Classify drug products by therapeutic category
- Report FDA Therapeutic Equivalence Codes (e.g., AB, BC, NR-not rated)
- Report regulatory & exclusivity status (single source, IMS, NMS)
Role of PBMs

• The role of a PBM includes:
  • Network formation
  • Claims processing
  • Benefit design
  • Formulary Development & Maintenance
  • Utilization Management (e.g., Prior authorization, Step therapy)
  • Mail order pharmacy and specialty pharmacy
Patent Litigation

Walter G. Chambliss, PhD, RPh, FAPhA
Director of Technology Management
Professor of Pharmaceutics
University of Mississippi
Background

• Pharmaceutical scientists generally do not testify on standards of practice issues.
• They are relied upon in litigation for their:
  • in depth knowledge of pharmaceutical sciences and practical experience in pharmaceutical R&D.
  • ability to interpret test results and to explain the strengths and limitations of the methodology.
  • ability to extrapolate test results to real world situations using validated models.
• An example is patent litigation.
Background on Patent Litigation

• Most branded pharmaceutical products are covered by one or more patents.

• A generic product needs to either not infringe the patent rights of the branded product or have permission from the branded product to market a generic version (an “Authorized Generic”).
Background on Patent Litigation

- Whether a generic product infringes a patent owned by the branded product is the subject of a complex lawsuit that often takes 3 or more years to resolve.
- The brand company will sue a generic company that has submitted an ANDA to the FDA if they have reason to believe the generic product would infringe the patent rights when marketed.
- The generic company often asserts that the patent is not valid and therefore cannot be infringed.
Role of a Pharmaceutical Scientist Expert in Patent Litigation

• One or more pharmaceutical scientists are retained each by the generic and the brand company.

• Expertise required depends on the subject matter of the patent(s) and most commonly involves expertise in formulations, physical pharmacy and pharmacokinetics.

• Provide honest opinions that are supported with science and are based on the facts of case.
Why is an Expert Needed in Patent Litigation?

- Two major questions:
  - Is the patent(s) valid?
    - i.e. should the Court rule that the patent should not have issued under U.S. patent laws?
  - Will the generic product infringe 1 or more claims of one or more of the patents?
    - i.e. does the generic company intend to make, use, sell or import a drug product that falls within one or more of the patent claims?
Why is an Expert Needed in Patent Litigation?

• Is the patent(s) valid?
  • Usually this question boils down to whether the claimed invention would have been obvious to a person of ordinary skill in the art.
  • A pharmaceutical scientist is not an expert in patent law and a judge is not an expert in pharmaceutical sciences.

• Simple example:
  • Known in the art that aspirin is unstable in water.
  • A patent issues that claims an aspirin tablet formulation containing less than about 1% water to stabilize aspirin.
  • Question: was minimizing the amount of water in a tablet formulation an obvious way of addressing the stability problem? Is there something surprising or unexpected?
Why is an Expert Needed in Patent Litigation?

• Will the generic product infringe 1 or more claims of the patent(s)?

• Using the simple aspirin tablet example:
  • Will the generic aspirin tablet contain less than about 1% water?
  • Sounds simple! But…
  • What method is used to quantify the amount of water?
    • One method = 0.8%, another method = 1.4%
  • What does “about 1% water” mean?
    • Is 1.2% water “about 1% water”? How about 2% water?
Patent Litigation Steps for an Expert

• Review the patent(s) to:
  • Provide an overview of the technology to the attorneys, the Judge and/or jury.
    • e.g. A direct compression tablet containing aspirin
  • Provide an overview of what was generally known about the technology at the time the patent application was filed.
  • Describe the problem that was being solved and how the inventors solved the problem in comparison to previous approaches.
Patent Litigation Steps for an Expert

• Review terms that define the invention in the patent claims and explain how each term would be understood by a person of ordinary skill in the art.
  • Example: “about 1% water”

• Compare the limitations of the patent claims to what was known in the prior art (using publications, book chapters, and patents as examples)

• Compare the generic product to the patent claims.
Patent Litigation Steps for an Expert

- Write an expert report containing detailed opinions with scientific support.
- Review the expert report prepared by the expert on the other side and write a rebuttal report.
- Reply to the rebuttal report prepared by the expert on the other side.
- Answer questions about opinions at a deposition.
- Testify in Court (direct examination, cross and redirect)
The Role of the Expert Witness

Ken Baker, BS Pharm, JD
Past President, American Society for Pharmacy Law
Experience includes Prosecutor, Criminal Defense, Civil (Plaintiff and Defense)
Of Counsel / Pharmacy Consultant
Renaud Cook Drury Mesaros, PA
Phoenix, AZ
Federal Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if

(1) the testimony is based upon sufficient facts or data,
(2) the testimony is the product of reliable principles and methods, and
(3) the witness has applied the principles and methods reliably to the facts of the case.
Federal Rule 702. Testimony by Experts

FOUR PARTS:

• qualifications;
• reliability;
• helpfulness; and
• foundation.
Federal Rule 702. Testimony by Experts

- Expert’s testimony must “assist the trier of fact” in resolving the case. The Daubert court determined that this helpfulness element required as a precondition of admissibility that the opinion have “a valid scientific connection to the pertinent inquiry.”

- An expert’s opinion may fail to be helpful if:
  - The opinion based on assumptions that do not “fit” the actual facts of the case.
  - The opinion may not be sufficiently related to or derived from the expert’s stated factual foundation, assumptions and reasoning—the problem of the analytical gap.
  - The opinion may simply state the obvious or attempt to rehash the evidence—matters within the ability of the lay factfinder.

Quoting Practicing Law Institute PLI.edu: Expert Witness Answer Book 2012, Footnotes omitted
Federal Rule 703. Testimony by Experts

- An expert’s opinion must have **supporting facts or data that reasonably comport with the evidence** in the case.
- Background information be “of a **type reasonably relied upon by experts** in the particular field.”
  - an automobile accident reconstructionist could not rely solely on statements of bystanders.
  - A psychiatrist could not rely on phases of the moon to determine a person’s proclivity to behave irrationally.
- Foundational data must be accurate
- Must accurately reflect the undisputed circumstances of the case.
- Testimony “based upon sufficient facts or data.” {2000 ammd}
- **Daubert:** “methods and procedures of science.” [No Junk Science]

Quoting Practicing Law Institute PLI.edu: *Expert Witness Answer Book 2012, Footnotes omitted*
What real trial lawyers say . . .

Question – “What do you look for in an expert witness?”
• you would want someone to support your case,
• be "readily" available to respond, and answer, your questions during case preparation,
• have a good "bedside manner" with the jury,
• be able to educate the jury on why they should support your position; don't want one that will just spew facts and data, and leave it up to the jury to sort it out.
Carol Romano
Partner, Renaud Cook Drury Mesaros, PA
Adjunct Assistant Professor at Arizona Summit Law School in Phoenix
{Carol has defended and tried several pharmacy cases}

• To answer your question—“What do you look for in an expert witness,” I’d say, first, obviously, that they firmly support your position in the case.
• I also look for someone who has experience as an expert, but not a reputation for testifying only on behalf of the defense.
• I also look for someone who makes a good witness – is likeable, credible, knowledgeable without being arrogant, and has a nice demeanor.
• Someone local is also better because you can meet them as often as necessary without incurring travel expenses (although Skype and the like help).
• “Jury can relate to someone local.”
I think it is important for the expert to have practical experience that is relevant to the subject matter he is testifying about. The expert needs to be able to speak from his own experience. For example, a medical doctor opining that the treating doctor failed to make the proper diagnosis should have had a similar patient present to him in his own medical practice such that he made the proper diagnosis.

I also think it’s important that the majority of the expert’s professional time is spent practicing medicine and not being an expert. The expert’s ability to connect with the jury is essential.
• Experts who are good teachers and who can break down complex principles into simple, easy to understand concepts are the best experts. And finally, experts who are “expert savvy,” meaning that they can anticipate where the plaintiff’s attorney is going by the questions asked, are ideal although sometimes hard to come by.

• In terms of the role of the expert, I think one of the fundamental roles is for the expert to tell you where you have problems. I don’t want an expert who’s going to say whatever I need him to say. I want an expert who is a straight shooter and who will tell me if I have problems and where I have problems.
In terms of the role of the expert, I think one of the fundamental roles is for the expert to tell you where you have problems. I don’t want an expert who’s going to say whatever I need him to say. I want an expert who is a straight shooter and who will tell me if I have problems and where I have problems.

Straight shooter: straight shooter and who will tell me if I have problems
Mike Wolford
Partner, Renaud Cook Drury Mesaros, PA, Phoenix, AZ
{My “Head of Chambers”}

“Someone who is honest and has a solid foundation for his or her opinion. Also, I often look at the expert’s fees and expense requirements to see if they are reasonable for the circumstances and whether the client is likely to agree to those terms.”
Tom Whitsitt

General Practice Trial Lawyer, former Prosecutor, Managing Partner in Whitsitt and Williams, Lebanon, Indiana

{First Jury Trial I ever tried was against Tom Whitsitt – Tom likes to win!}

• The main reason for retaining an expert is to present the trier of fact with opinion testimony.

• That means for me that my fact witnesses are inadequate to support the theory of my case.

• If I am going to present opinion testimony I want it to be as credible as possible. I want someone with experience who is capable of explaining the basis for his or her opinion.

• In summary, I want someone who is knowledgeable, credible, likable and speaks well to the trier of fact.
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• I don’t want someone who testifies as an expert for a living and is likely to have rendered a contradictory opinion in the past.

• Cost is almost always a factor and the first question is whether you really need an expert. Many times the fact alone, if well presented, may be enough. In pharmacy cases it is more likely that an expert will be needed than in many other cases. (standards of practice)

• Causation is often an issue and opinion testimony is the way to go. I want someone who knows what they are talking about.
Ken Baker
[my own thoughts – criminal and civil practice]

• Someone who is not afraid to tell me when I am wrong
• Impressive credentials – make the jury listen and believe
• Someone who can tell a story – makes the jury lean forward
Questions?

- Submit questions in the question box provided in your control panel on the right hand side of the screen
- Unanswered questions and answers will be compiled and forwarded via email within the next few weeks
Thank you for your participation!