Medical Device Litigation

Primer

core
legalconcepts

MEDICAL DEVICE LITIGATION | Primer

The following primer is a basic overview of product liability, serial pharmaceutical litigation and medical device litigation.

WHAT IS PRODUCT LIABILITY?

Product liability is a term used to describe the legal liability of companies who manufacture, sell, package and distribute products to compensate buyers, users and sometimes family/friends or bystanders for injuries or damages suffered because of alleged defects in the goods they purchased.

WHAT IS SERIAL PHARMACEUTICAL LITIGATION?

Pharmaceutical companies often face many trials on the same medication or product. When a drug compound or product allegedly causes injury, multiple individuals can separately file lawsuits against a manufacturer, seller, packager, distributor, doctor and pharmacy.

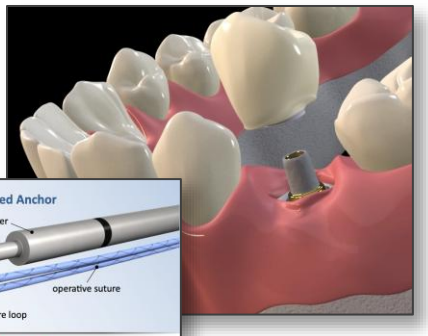
Both plaintiff and defense parties call fact witness to testify, and hire expert witness to opine, on the facts in the case. These witnesses will likely testify in multiple cases in one serial litigation.

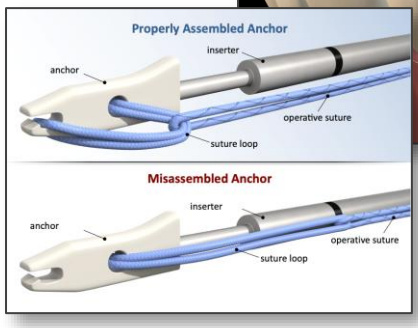
Plaintiff experts are typically "serial" or "professional" witnesses who have made a career of testifying in litigation. Defense experts are typically more qualified, distinguished members of their field.

WHAT IS MEDICAL DEVICE LITIGATION?

Medical device litigation is a type of pharmaceutical litigation, but instead of a drug compound, it centers on devices used in medical treatment.

Some medical devices, such as joint replacement (hip, knee, shoulder), are more well-known. However, devices under this umbrella also include tools used to perform surgery and install implants, repair soft tissue and regulate organ function.





Examples include:

- cPAP machines
- dental implants
- hernia repair mesh
- insulin pumps
- laparoscopic surgery instruments
- pacemakers
- stents
- suture tacks and inserters
- tools: drills, screws, saws, screwdrivers, hammers

and many more . . .

CASE THEMES

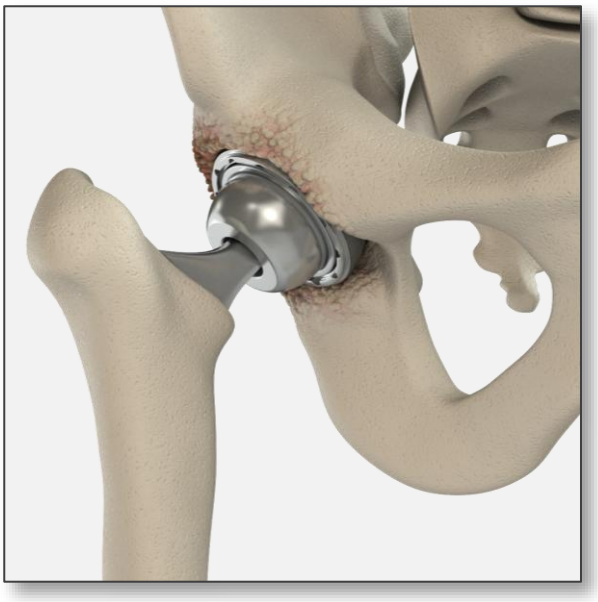
In working on pharmaceutical/medical device serial litigation, you will encounter common themes that resound throughout the cases.

Common Plaintiff Themes

Failure to warn. Plaintiffs claim that the defendant(s) did not adequately warn consumers about risks, typically an alleged defect, side-effect or injury.

FDA approval. All medical devices on the U.S. market must be approved by the FDA. Plaintiffs often claim that the device was "fast-tracked," meaning it went through an expedited approval process to get to market faster. A recent example of fast-tracked pharmaceutical products are COVID 19 vaccines.

Testing (inadequate). Before a company can apply for FDA approval, they must provide proof of comprehensive testing of the device. Plaintiffs often claim that testing was inadequate.



Alleged defect/side effect. Plaintiffs often claim that the device has a defect or side effect that the defendant *knew about* and marketed the product with this knowledge.

Common Defense Themes

Co-morbidities. Health conditions specific to an individual plaintiff can cause device failure or side effects. Medical conditions, such as spinal disease, can cause hip pain, thus be true the source of a plaintiff's pain instead of the hip implant. If a plaintiff has an autoimmune disorder, substance abuse problem, or does not make life-long behavioral changes post-operatively, this can also contribute to the failure of an implant. These factors are called co-morbidities and are important in demonstrating that product failure is not the reason for the claimed injury.

FDA approval. To counter the plaintiff claim of "fast-tracking" the defense presents evidence that supports appropriate FDA application and approval protocol.

Adequate warning. The defense presents evidence in the form of clinical trial data, FDA approval documentation and the labeling (often erroneously referred to as "the label"). Every medical product sold—whether prescription or over-the-counter—is required by the FDA to include instructions for use, dosage and adverse/side effect warnings. Medical devices are no different; they are all sold with labeling.

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CASE THEMES

Common Defense Themes (continued)

Adequate testing. In addition to the previous types of evidence, the defense will also present evidence the device was rigorously tested, not only in laboratory conditions, but also *in vivo* (testing in a living being such as animals or humans). Graphics on this topic typically include graphs, documents, 3D animations and testing site video. Also important are graphics that demonstrate the historical and on-going success of the device, showing that the plaintiff and/or surgeon are outliers.

DEFENSE STRATEGIES

There are common defense strategies in a serial litigation, some of which are discussed above. These include:

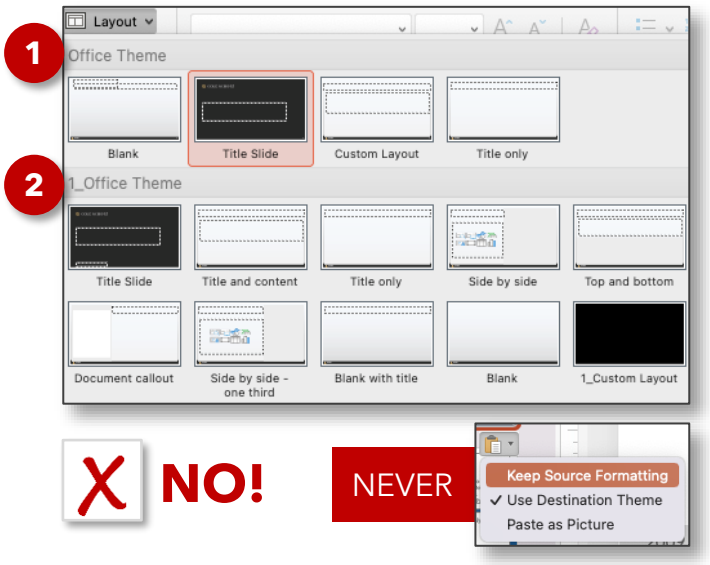
- **Plaintiff:** The defense never attacks the plaintiff. It makes us look like bullies to a jury. They will, however, present evidence that the alleged failure was the fault of the plaintiff, not the device.
- **Doctors/Surgeons:** The defense never attacks doctors or surgeons because they are our customers; we want them to continue buying our products. However, if the alleged failure is a result of a surgeon's judgment or mistake, the defense presents this through their deposition testimony, allowing the jury to see/hear the evidence from the source.
- **Stewardship:** The defense demonstrates this by showing the product was properly designed, tested and FDA approved. The historical success and benefits of the device, and fact witness testimony (company engineers, product designers, testing managers, etc.) also support a company's stewardship.
- **Expert testimony:** Both sides hire experts to opine on different elements in the case. Defense experts tend to be more credible because they are leaders in their field, whereas plaintiff experts have mediocre credentials and often testify for a living. Thus, during trial closings, this offers the opportunity to create graphics that contrast the qualifications and testimony of experts on both sides.

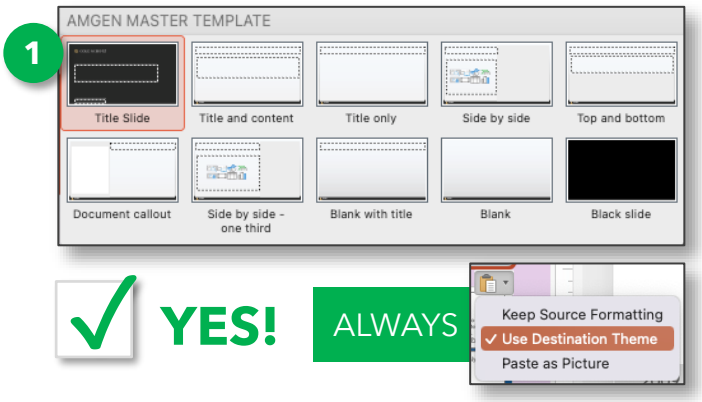
BEST PRACTICES–GRAPHICS

Whether you are leading, managing or working on a serial litigation, it's important to start out right by maintaining design and production protocols. This ensures that there is graphic continuity across cases, and as important, that anyone can jump in at any time with little direction.

Design a Strong Template and Style Guide

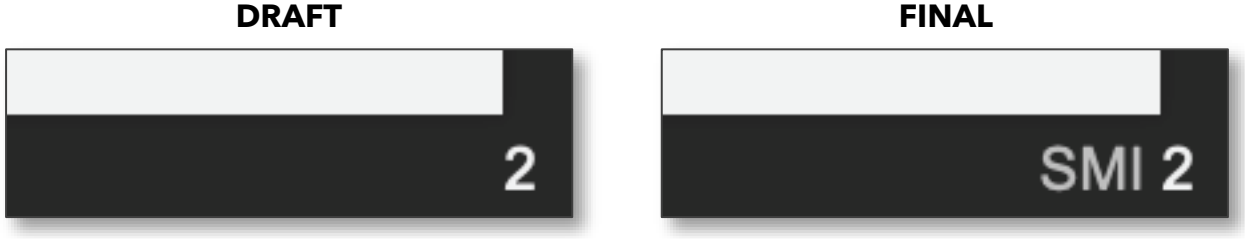
The case lead should not only design a custom PowerPoint template but also several style layouts for all types of graphics: bullet points, graphs, document callouts, tables, side-by-side content, section headers, etc. It is critical to keep the master template "clean." This means that a file should not contain multiple copies of the master template.





Code Slide Sets

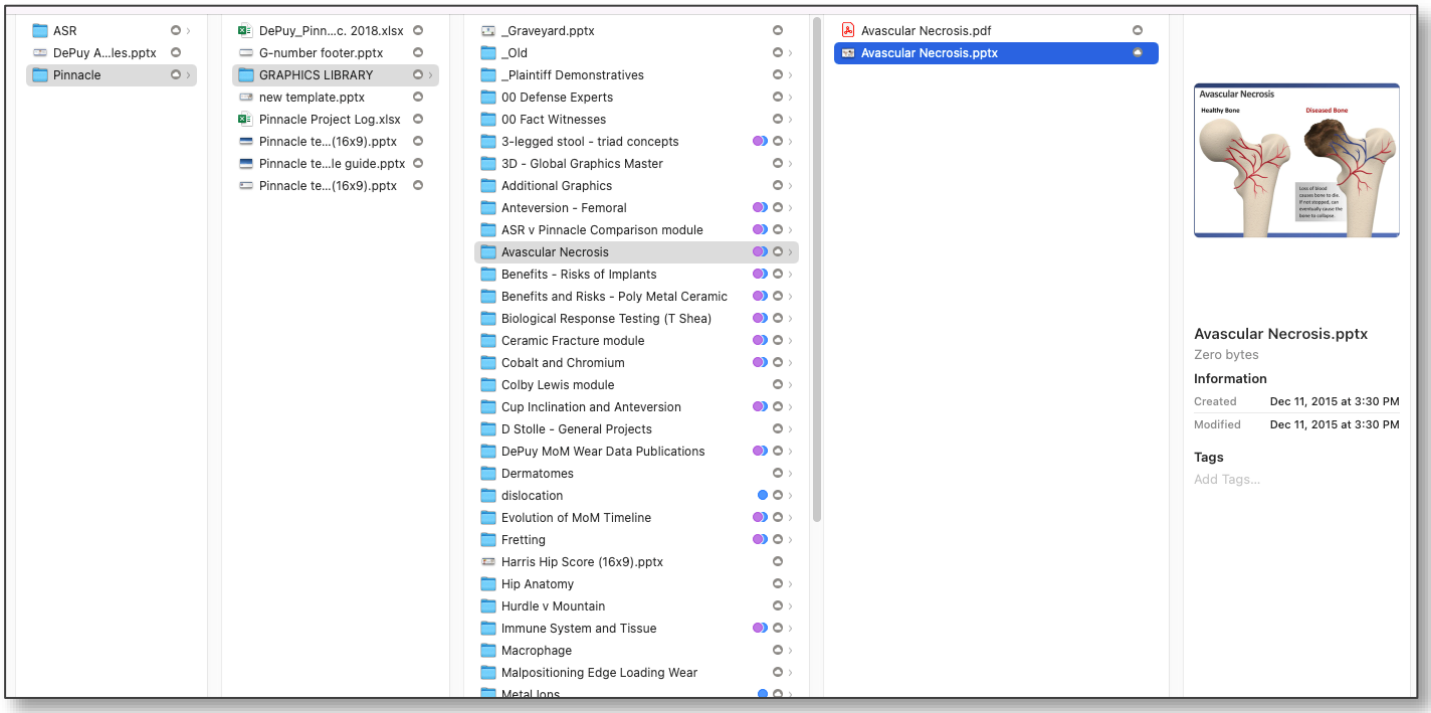
Prior to finalizing slide sets for court, add the first three letters of the plaintiff's last name before the slide numbers, in a lighter color. If you've developed and maintained a strong master template, this is easily accomplished by adding a text box to the master slide. By doing this, you can better track in which case slides were used. Without fail, an attorney will approach you with a copy of a slide at 2:00am and want to use it in court the next day. Save yourself from having to hunt through past cases with this method.



BEST PRACTICES–GRAPHICS

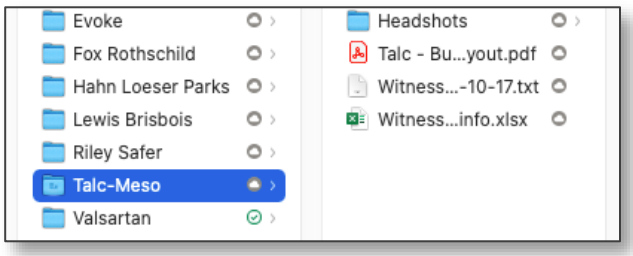
Develop a Graphics Library of Common Case Themes

In a serial litigation, there will be common themes across cases. Early in the litigation, start a library of these common graphics, filed in folders. This way, a slide can be easily located when working on future cases. With each case, update the library, including adding new versions of an existing theme. If you use the previously mentioned coding method, it will be easy to find the version that was used in a particular case.



Develop a Library of Witness Headshots

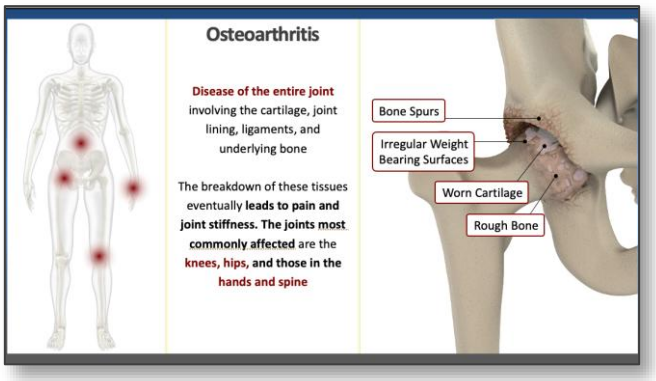
In the root of the case folder, create a folder for headshots. Many of the same witnesses will testify in multiple cases in a serial ligation so it's helpful to have these in one place. Taking this a step further, create a PowerPoint file with all the witness headshots along with their the names and titles, with the appropriate style treatment applied. This way, there's no guesswork as to which side a witness is on, or how their photo should be styled.

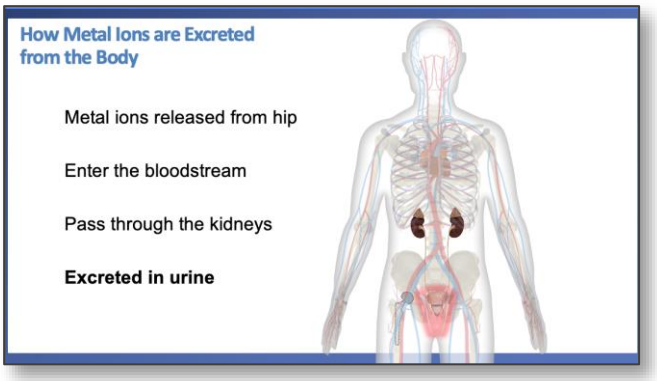


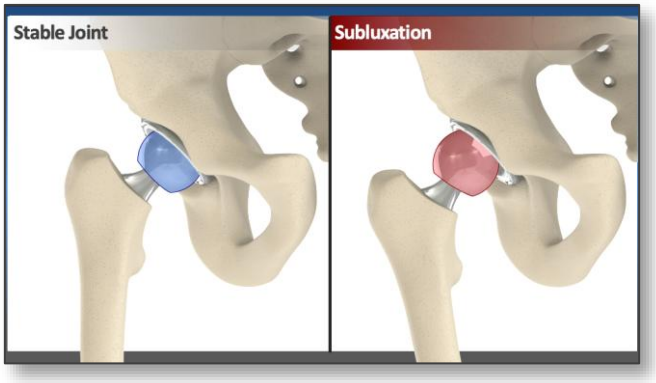
BEST PRACTICES–GRAPHICS

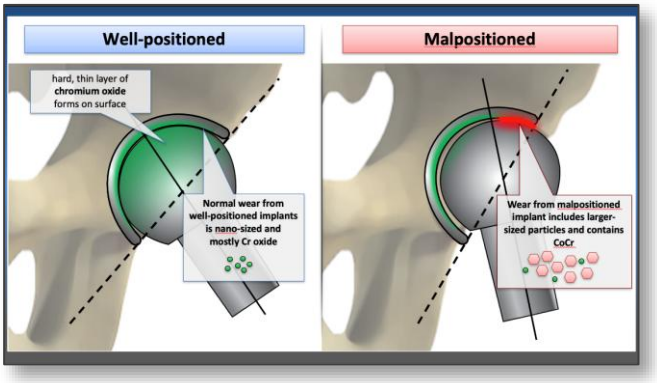
Talk to Our Experts

During or after witness prep, in hallways, at dinner, talk to our experts. Be curious, ask them questions. You will learn so much from them (they love to talk!), which will help in the design of accurate, specialized graphics.









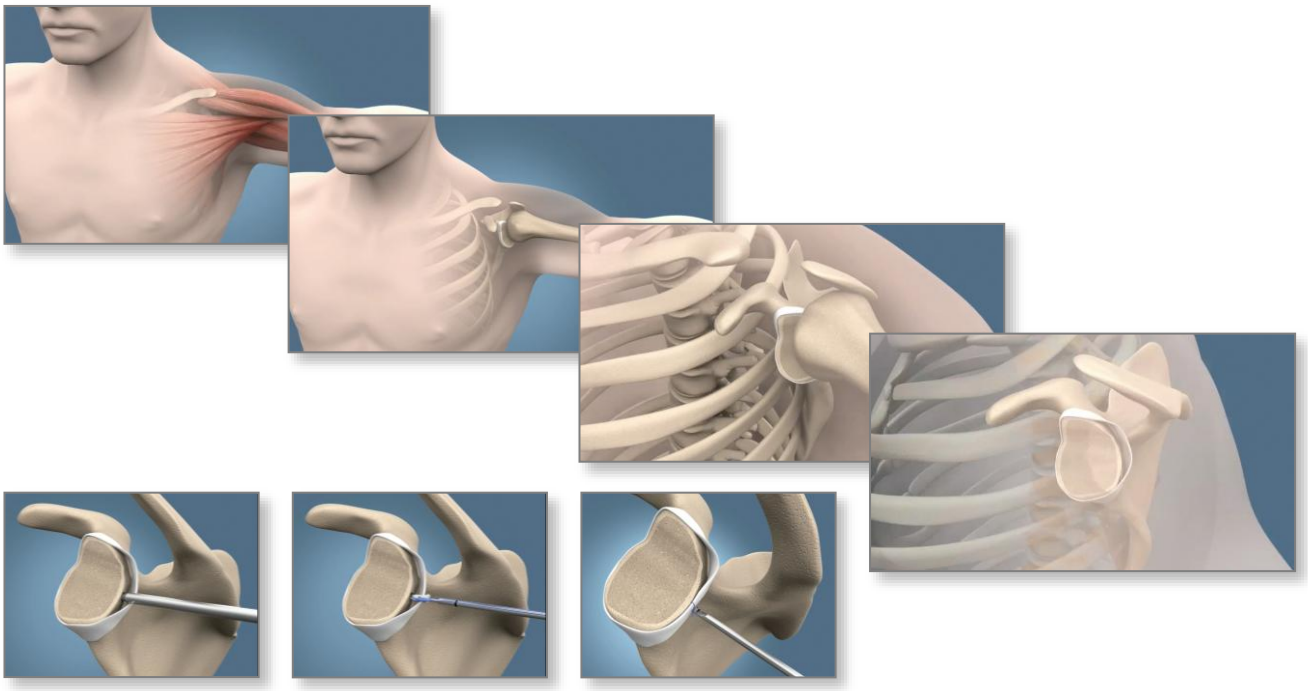
Study The Physical Demonstratives

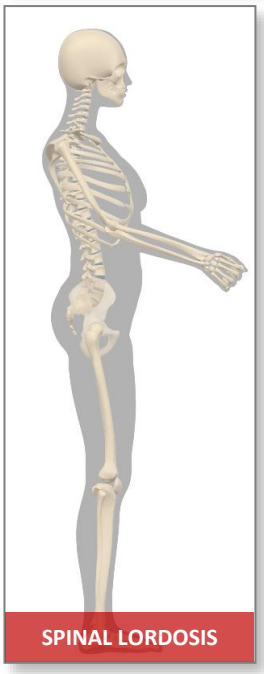
There will always be exemplars of the device(s) in suit on-site at trial. Getting to know them and how they work will help you create better graphics. Again, talk to our experts about them; you will learn so much! (Yes, that's a Corey's reflection in the head.)

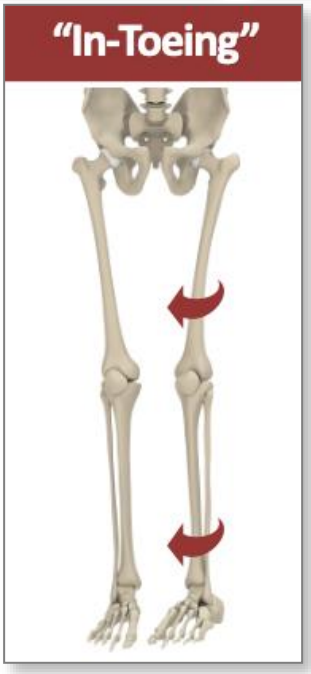
BEST PRACTICES–GRAPHICS

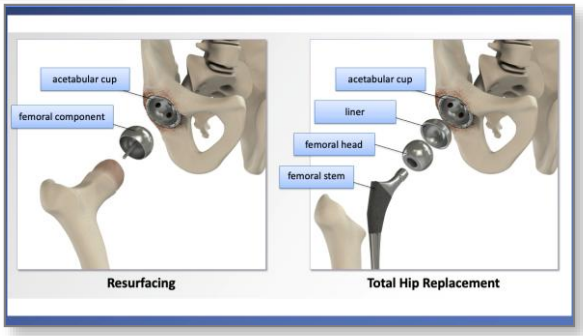
Develop 3D Models and Animation

Medical device litigation is where 3D excels in teaching about a device, a surgical procedure and co-morbidities; always work closely with our experts to ensure accuracy and get CAD drawings if they are available. An attorney once stated that for as long as he'd worked on the case, he didn't understand the anatomy until he saw our 3D animation!









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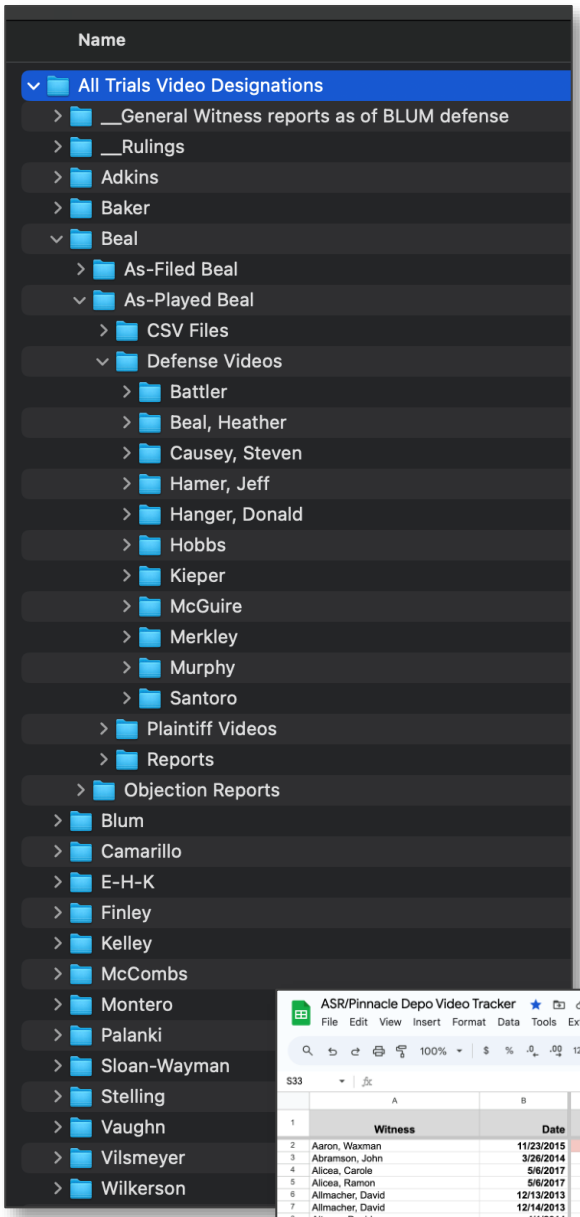
BEST PRACTICES–TECHNOLOGY



OnCue Case Management

To ensure seamlessness across cases, organize deposition video into folders by witness and track in a Google sheet. Also, keep a perfect record of all video that is filed with the court and then subsequently played. You should have it broken down by affirmatives and counters and party. It is best to keep a record of all run times from each trial as well.