

### GARDNER

AN FDA LAW FIRM

# What's on File Could be on Trial

Mastering Document Risk

Monday, May 5, 2025



### Presenter Introduction



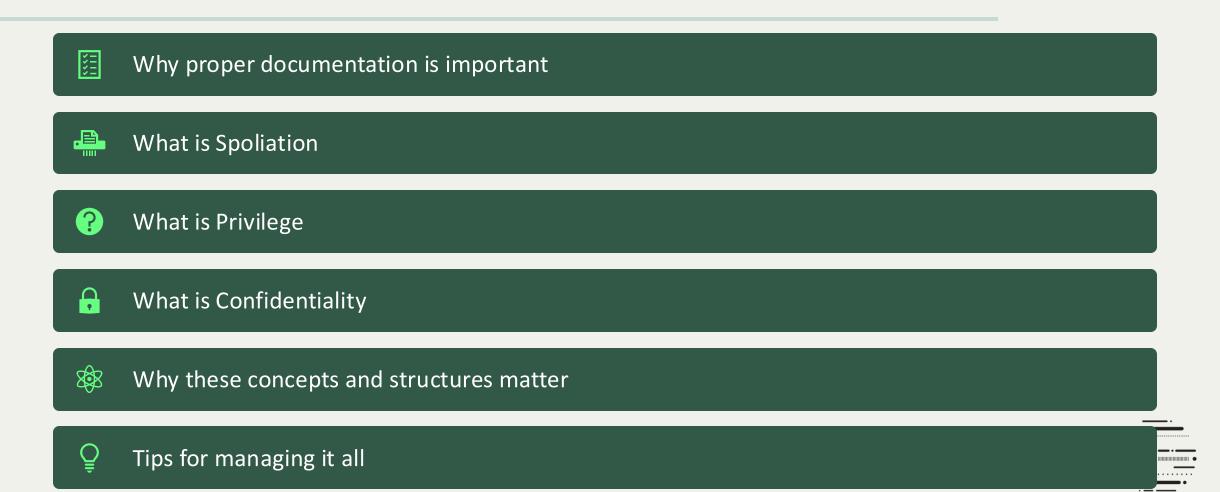
David Graham is an experienced litigator known for his success in high-profile cases related to food, medical devices, and pharmaceuticals. He has substantial expertise in defending companies against product liability claims and regulatory challenges, particularly concerning FDA and USDA regulations.

With a focus on strategic thinking and negotiation, David is dedicated to achieving positive results for his clients.

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# Agenda



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### Why is Proper Documentation Important

- Proper business management
- Protect and present your story in litigation
  - Defense of a case
  - Prosecution of your case
  - Accurate information for regulators
  - Avoid sanctions in litigation
    - Fines
    - Dismissal and loss of the case
    - Adverse evidentiary presumption against the company or individual



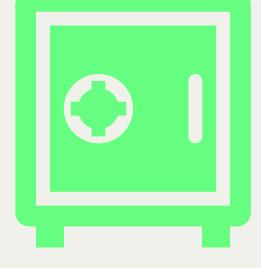
### Spoliation of Evidence

 Definition – Spoliation of evidence-the intentional or negligent destruction, alteration, hiding, or withholding of evidence that is relevant to a legal case. This act can occur before, during, or after litigation and can impact the outcome of the case.  Consequences – Spoliation can lead to adverse inferences against the spoliating party, meaning the court may assume the destroyed evidence was unfavorable to them. In severe cases, it can lead to sanctions, including dismissal of the case or default judgment.



# Spoliation (cont.)

• **Duty to Preserve** – The duty to preserve evidence, including documents, electronically stored information (ESI) or other tangible evidence that generally arises when a party is aware of pending litigation, litigation is threatened, or when litigation is reasonably foreseeable under the facts and circumstances in question.





# Spoliation (cont.)

Recent case law - Sanctions in these court decisions have ranged from denial of summary judgment and monetary penalties (<u>Maziar v.</u> <u>City of Atlanta</u>), to dismissal with prejudice (<u>Jones v. Riot Hospitality Group</u>) to an adverse inference instruction and permission to present evidence of spoliation (Armstrong v. Holmes).



**Intent** is often the driving factor.





### Privilege

- What information is Attorney-client privileged – Attorney-client privilege protects confidential communications between a lawyer and their client that relate to the client's seeking of legal advice or services.
- This protection extends to any information exchanged during these privileged communications,
- Encompassing not only verbal and written communication and correspondence, emails, text messages, voice mail and other forms of communication.





## Privilege (cont.)

#### Work product privilege:

The work product privilege protects documents and tangible things prepared in anticipation of litigation from discovery by opposing parties. This protection extends to

This protection extends to an attorney's mental impressions, conclusions, opinions, or legal theories.

Attorney Work-Product Doctrine







## Privilege (cont.)

#### Privilege exceptions

Attorney misconduct

Crime-fraud

Waiver







# A Plan for Privilege Documents and Communications

1

Mark or otherwise designate documents privilege if there is any question

2

Separate them and take steps to limit their dissemination

3

Do this as a matter of business practice before litigation





## Confidentiality

- **Definition** *Confidentiality* refers to the practice of keeping specific information private and inaccessible to unauthorized individuals or the public.
- This applies to:
  - data, including trade secrets
  - customer lists
  - financial records
  - research and development
- Confidentiality is crucial for maintaining a competitive advantage and protecting a company's interests.



### Confidential Information in Lawsuits

- Disclosable to the parties unless designated attorney's eyes only
- Court will prevent dissemination with proper protective order





### Confidentiality Plan

- Integral part of document retention policy
- Have an easy means to designate of destroy confidential information
- Train employees about rules for the protection of the company's confidential information
- Monitor compliance and execution periodically





### Confidentiality Plan



Essential component of the document retention policy



Establish a straightforward method for identifying and disposing of confidential information



Educate employees on the regulations governing the safeguarding of the company's confidential data



Regularly assess adherence and implementation of these measures



### Training

Train employees on these policies



 Provide information on the proper creation, designation and destruction of documents





### Document Retention Policy

- Have one, no matter how simple.
- Designate someone to implement it.
- Monitor it for compliance, even if it is just to make sure proper retention and destruction of information is happening.
- Train employees about it.



### Next time



Tuesday 5/13
Same link

for technical assistance: Czamastil@gardner.law Discussion of how not to create bad documents How we should communicate in emails, text, phone and voice mail

How we should document complaints and resolution of those complaints

What to do when bad documents are created





Questions?



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# Questions