
Hot Topics in Tox Cases

Common Defense Challenges:

- Expired Vials
- Preservation Defects
- Underfilled Vials
- Off-Gassing

These Challenges Have Common Denominators

Foundation Challenge:

- RCW 46.61.506(3),
- WAC 448-14-010 & 02

Scientific Reliability

- ER 702, *Frye*

Require a Defense Expert

THIS INFORMS OUR STRATEGY OF ATTACK

What do I do?

STEP 1 – Assert the Procedural Bar

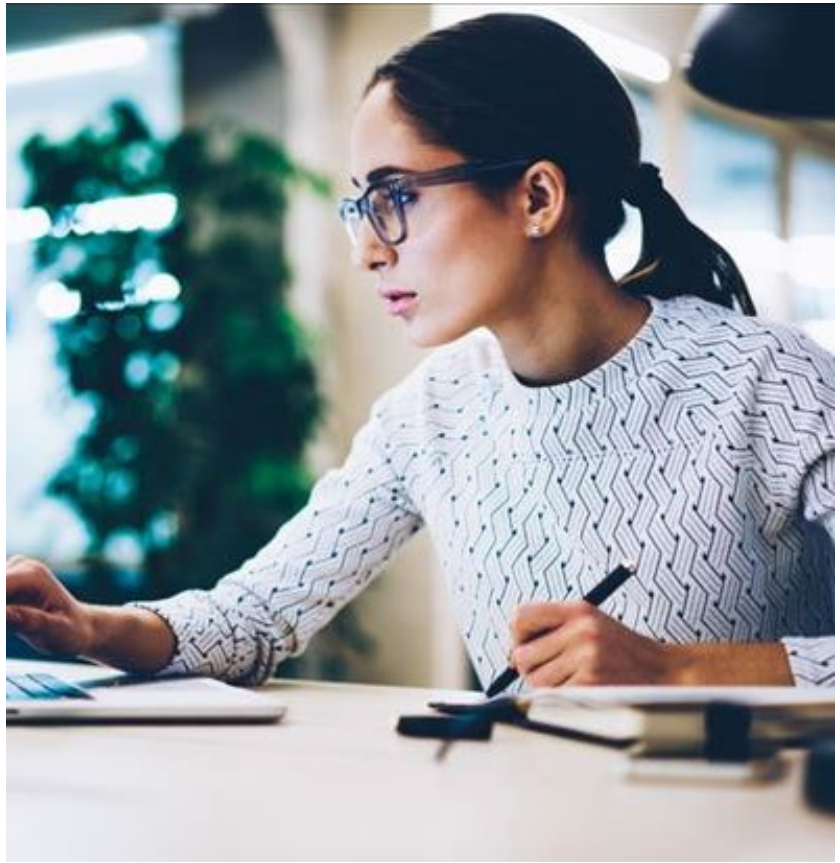
STEP 2 – Assert the Legal Bar

STEP 3 – Allege the Proper Facts

STEP 4 – Let’s work on the Expert

Check the Rules – *Does the pleading comply?*

Rule 3.6 - Motions to suppress physical, oral or identification evidence other than motions pursuant to CrRLJ 3.5 shall be in writing supported by an affidavit or statement as provided in GR 13, setting forth the facts the moving party anticipates will be elicited at a hearing." CrRLJ 3.6(a).



But what about the technical affidavit requirements?

"Whenever, under any law of this state or under any rule, order, or requirement made under the law of this state, any matter in an official proceeding" in which facts will be evidenced and supported by a sworn statement. RCW 9A.72.085

So what about the content requirements of an affidavit?

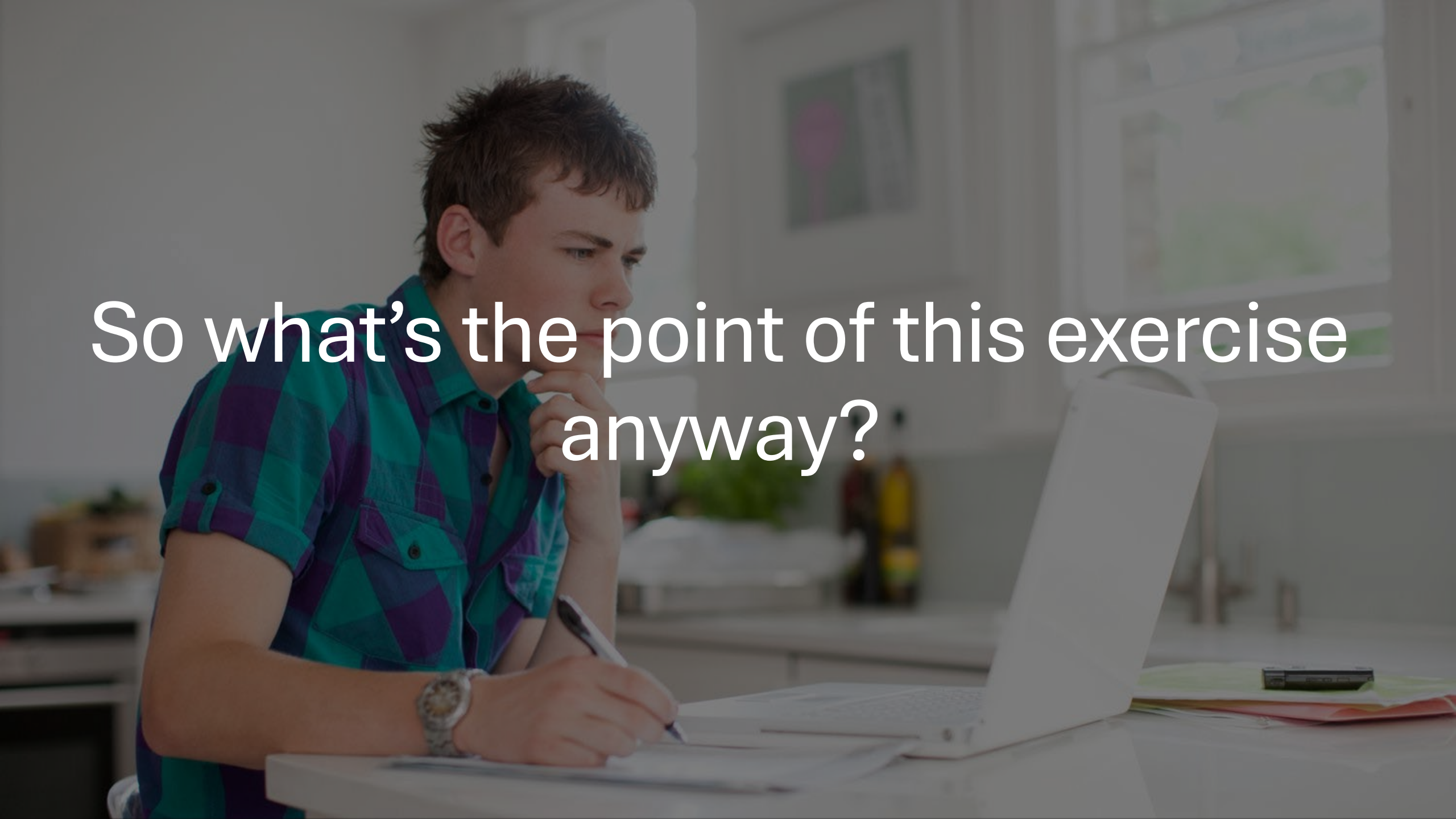
"If the petitioner's allegations are **based on matters outside the existing record**, the petitioner must demonstrate that he has **competent, admissible evidence** to establish the facts that entitle him to relief. If the petitioner's evidence is based on knowledge in the possession of others, he may not simply state what he thinks those others would say, but must present their affidavits or other corroborative evidence. The affidavits, in turn, must contain matters to which the affiants may competently testify." *State v. Bandura*, 85 Wash.App. 87, 93-94 (1997).

Take away:

1) the affiant have personal knowledge of facts asserted

2) the facts should be admissible, and

3) the affiant should be a competent witness to testify to those facts


So what’s the point of this exercise anyway?

Is this truly a legal issue or does this go to weight?

Does it go to weight vs. admissibility?

702 is an admissibility issue that usually becomes a weight issue that favors admissibility!

State v. Baity, 140 Wn.2d 1, 14 (2000)

Expired Vials

Mixed Foundation and Evidence Rule Challenge

1. Foundation Challenge:
   A. *Ethanol cases* – abrogated in Div I & II
   B. *Drug cases* – not a valid legal challenge
2. Evidentiary Gatekeeping
   A. ER 702
   B. *Frye – not novel*

Foundation?

WAC 448-14-020(3): Sample container and preservative - (a) A chemically clean dry container consistent with the size of the sample with an inert leak-proof stopper will be used. (b) Blood samples for alcohol analysis must be preserved with an anticoagulant and an enzyme poison sufficient in amount to prevent clotting and stabilize the alcohol concentration. Suitable preservatives and anticoagulants include the combination of sodium fluoride and potassium oxalate.

Challenge – *what does this look like?*

The State is seeking to introduce quantitative blood alcohol results from samples of blood that were housed in vials that expired before a toxicologist performed any tests on them. An expired vial is a vial that is no longer warranted to work, in that the manufacturer of the vial can no longer make any claim as to the vial being (a) chemically clean and dry or (b) containing the requisite amount of anticoagulant or anti-enzyme poison.

The Foundation Challenge should be dead as disco…

"Thus, we follow the reasoning of our Supreme Court in Keller and hold that the requirements for establishing the proper foundation for the admission of blood evidence in a criminal conviction are confined to the plain language of the relevant statute and code" *State v. Leer*, 86863-2-1; *Kanta v. Dep't of Licensing*, No. 58434-4-II.

Evidence-Based Challenge ER 702 or *Frye*

What this challenge looks like –

Introducing evidence related to the expired blood vials would be unhelpful to the jury because the toxicology testing was unreliable and lacked a sufficient foundation. For many of the reasons already explained above, the testing was unreliable since the testing occurred outside the date in which the manufacturer guaranteed that the blood samples were properly preserved. The manufacturer specified that the expiration date applies to all of the tube — not just the vacuum function of the tube.

So lets decide the nature of the "reliability challenge"…

Is it *Frye*? – probably not … what's the process?

Is it ER 702 regarding this test?

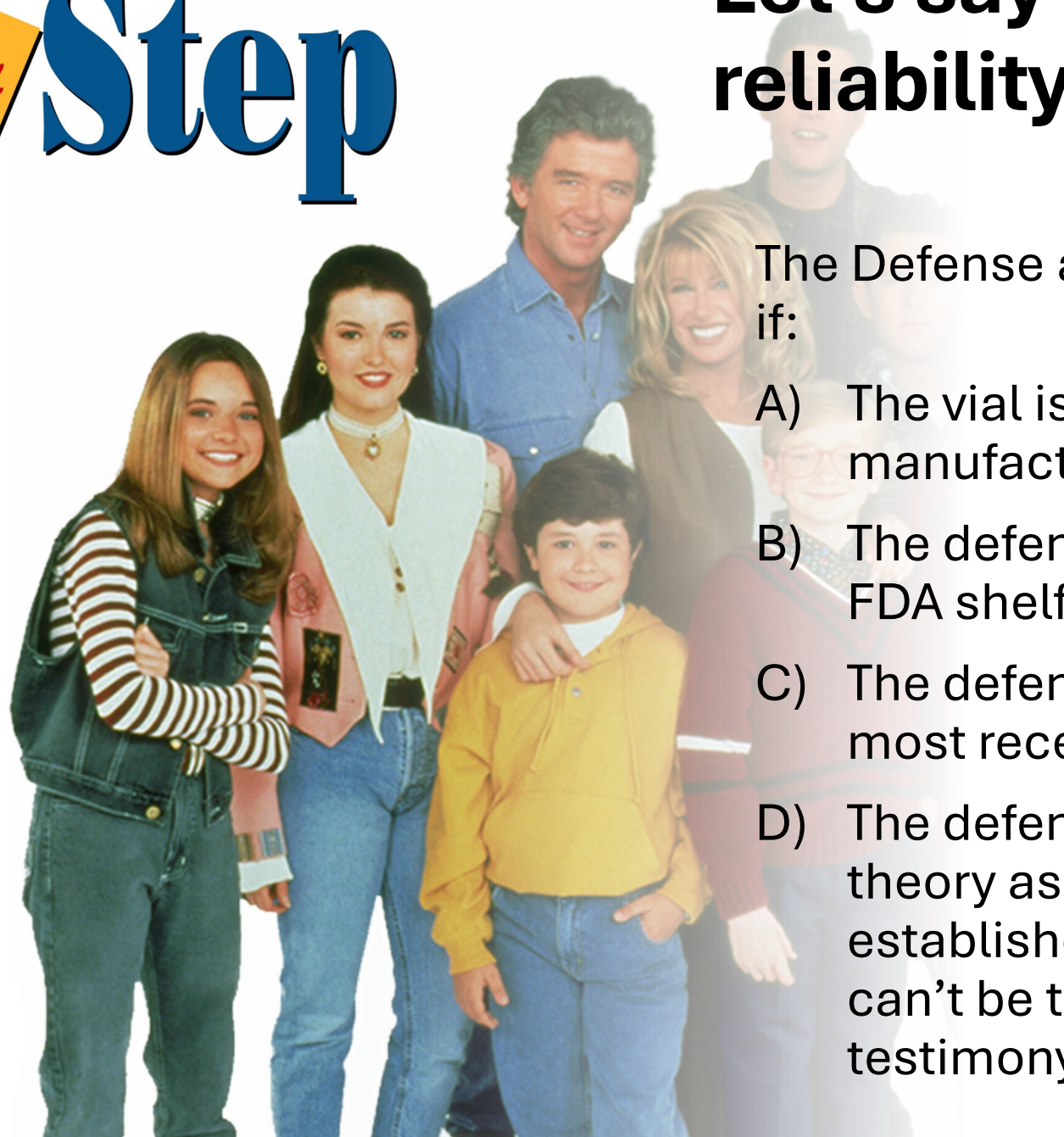
Is it ER 702 regarding the toxicologist's established protocol?

The state Toxicologist's acceptance of an administrative protocol is presumed valid unless found to be arbitrary and capricious. State v. Ford, 110 Wash.2d 827 (1988); State v. King County Dist. Court West Div., 175 Wash.App. 630 (2013).

What do we do if it's *Frye?*

1. Schedule a show cause hearing after the briefing schedule
2. Our approach is that this is not novel science and defendant's opinion does not a scientific consensus make
3. Minor changes in protocol which leave the discipline otherwise intact go to weight. *State v. Kalakosky*, 121 Wn.2d 525, 540-41 1993)

Let's say it's a 702-reliability contention...



The Defense argument ONLY works if:

A) The vial is expired and is manufactured by BD

B) The defense introduces the FDA shelf-life material

C) The defense introduces the most recent BD declaration

D) The defense provides some theory as to why well-established stability studies can't be trusted (expert testimony)

Step 1 – an Expired BD vial

A gray-topped glass vacutainer – why?

- Sodium fluoride (NaF) – preservative
- Potassium oxalate (C2K2O4) – anticoagulant

We're not concerned with the anticoagulant for the purpose of this exercise

Why does it have to be BD?

Step 2 – The FDA shelf life materials

Although this set of criteria applies specifically to the evaluation of drug product stability, it is useful as a starting point in developing a set of criteria to evaluate the stability of medical devices.

The following outline may be useful in identifying parameters that could significantly affect the shelf life of a device, even though all of the criteria will not apply to every device. This outline is based on the criteria listed above with the addition of biocompatibility.

1. Chemical

1.1 Degradation: Do any active ingredients or components of the device degrade over time in a manner which adversely affects device safety or performance?

1.2 Interactions: Do ingredients or components interact to alter the device? Does the device have interactions among the various components that cause degradation of the ability to perform the intended function?

1.3 Device and Packaging Interaction: Is there interaction between the device and package that has undesirable affects?

1.4 Radioactive Decay: Does the device contain radioactive material with a relatively short half-life? Do the radioactive decay by-products alter the safety or effectiveness of the device either by themselves or through further interaction?

22 23 24	**3) Does the expiration date apply individually to the vial, the stopper, the preservative, the anticoagulant and the vacuum seal as well as to the system as a whole?** The expiration date applies to the tube and its components as a whole.	

Step 3 – the BD declaration

Step 3 – the BD declaration cont.

8. The expiration date included on BD Vacutainer® Tubes is included to ensure the product is working properly from the date of manufacture up to the certain date of expiration as predetermined at the time of manufacture. Although scientific, in general terms, the expiration of BD Vacutainer® Tubes is determined according to a specific additive: blood ratio. Specific lab testing and/or expert analysis would be necessary to determine the efficacy of any BD Vacutainer® Tubes post-expiration date, as the Tubes' expiration date, alone, likely cannot be the only factor to their efficacy.

Step 4 – A “supportive defense theory”

Theory - Use of BD vials beyond expiration creates the risk of chemical reactions that would result in the breaking down of administratively required chemical additives

After expiration, fluoride can break apart, and when housed in a glass structure, can in turn interact with the walls of the glass container. As this happens, the amount of sodium fluoride in the blood decreases in quantity

But what about our sources???

1. Zittel, D., and Hardin, G., *Comparison of Blood Ethanol Concentrations in Samples Simultaneously Collected into Expired and Unexpired Venipuncture Tubes*, Journal of Analytical Toxicology, Vol. 30, (June 2006)

2. Tiscione, N., et. al., *Long-Term Blood Alcohol Stability in Forensic Antemortem Whole Blood Samples*; Journal of Analytical Toxicology 2015; 39; 419-425 (April 16, 2015).

3. Moynham, AF, et. al., *The Effects of Storage on the Accuracy of Blood Alcohol Readings*. International Conference on Alcohol, Drugs, and Traffic Safety, 9th, 1983, San Juan, Puerto Rico. Issue Number: DOT HS 806 814; Alcohol, Drugs, and Traffic Safety; Proceedings of the Ninth International Conference on Alcohol Drugs, and Traffic Safety, San Juan, Puerto Rico, 1983. (1985-9)

4. Winek, T.; Winek, C; Wahba, W., The Effect of Storage at Various Temperatures on Blood Alcohol Concentration, Forensic Science International 78; SSDI 0379-0738 (95)01844, (1996)

5. Rodda, N; Pearring, S; Harper, C;, Tiscione, N; Jones, A.W.; *Inferences and Legal Considerations Following a Blood Collection Tube Recall*; Journal of Analytical Toxicology; doi: 10.1093/jat/bkaa056; 00;1-4 (2020).

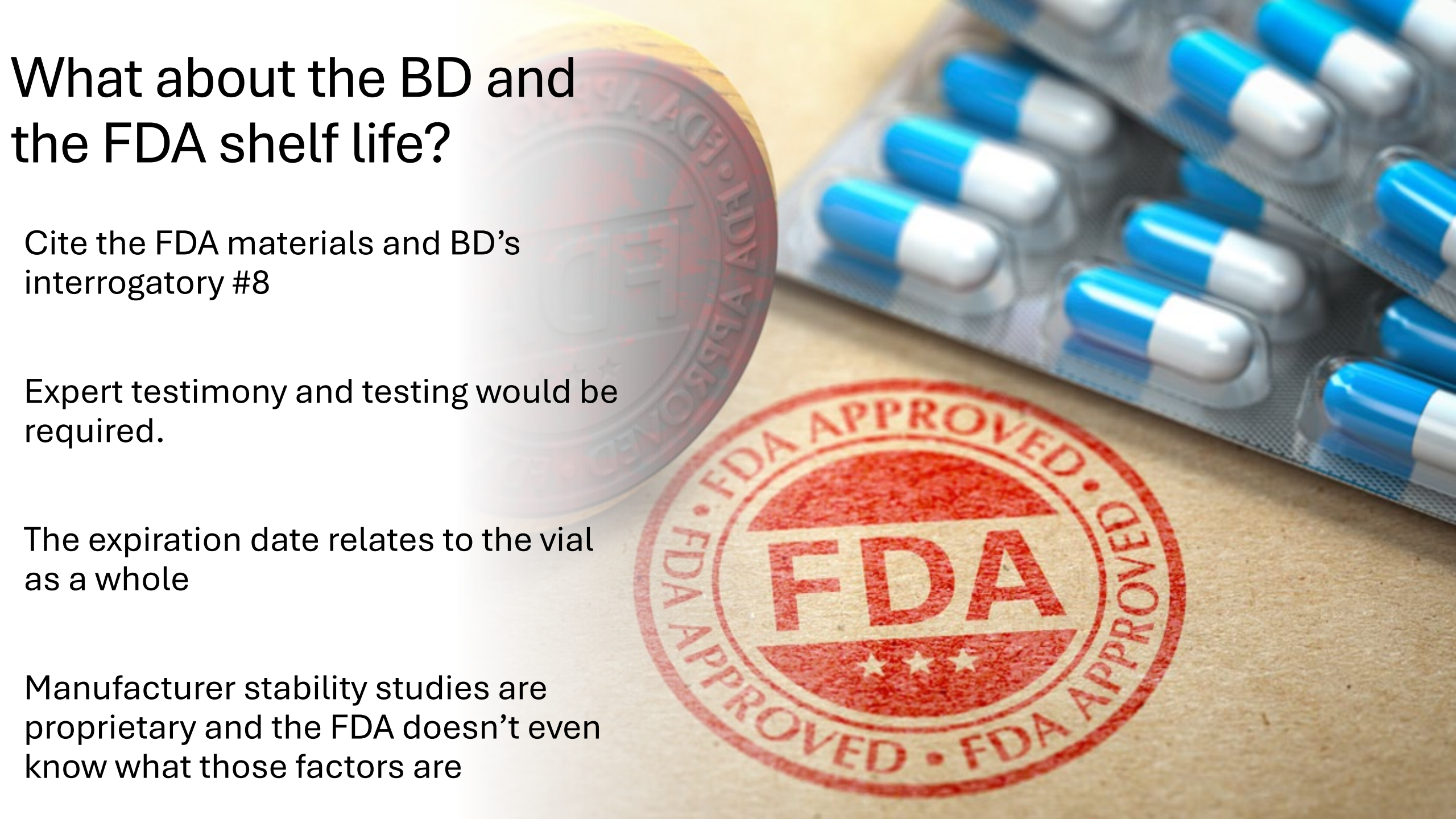
What about the BD and the FDA shelf life?

Cite the FDA materials and BD's interrogatory #8

Expert testimony and testing would be required.

The expiration date relates to the vial as a whole

Manufacturer stability studies are proprietary and the FDA doesn't even know what those factors are

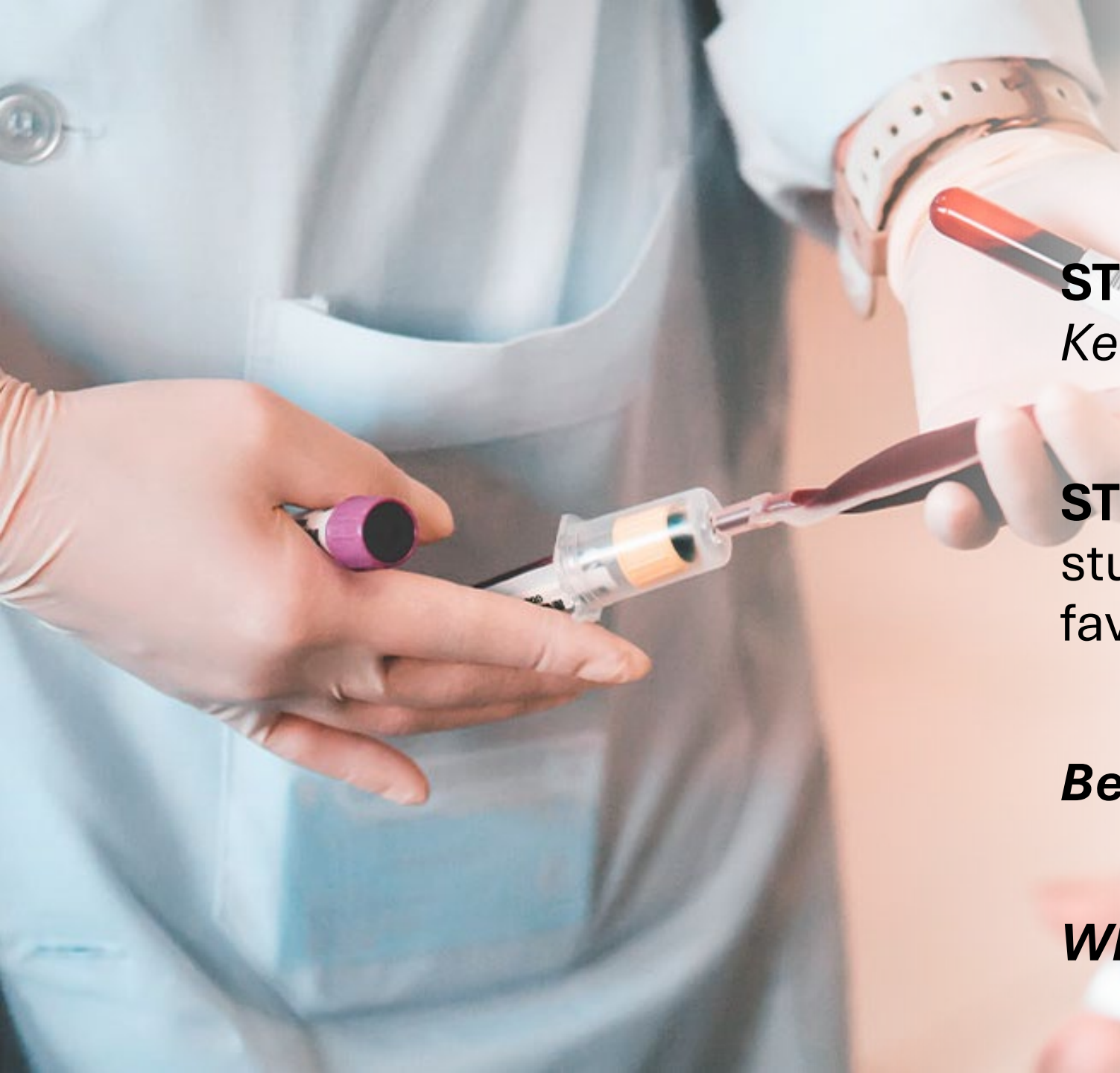


Don’t talk to me about Broken Fridges…

VARIATIONS ON A THEME

STEP 1 – it’s not in the WAC – *see Keller, Leer, Kanta*

STEP 2 – It doesn’t affect Stability – *see the same 5 sources from above* (caveats for judges)



You Wanna Talk About Underfilled Vials?

STEP 1 – it's not in the WAC – *see Keller, Leer, Kanta, etc.*

STEP 2 – Look at our stability studies, it doesn't matter and favors defense

Best Practices vs. Requirements

What about the 6th Amend?

Off-Gassing & “Inert” stopper issues

WAC 448-14-020(3)(a): A chemically clean dry container consistent with the size of the sample with an **inert leak-proof stopper** will be used.

What does this challenge look like?

During preservation isobutylene is **detectable** in the sample

Vacutainer gray-top tubes are made of chlorobutyl rubber

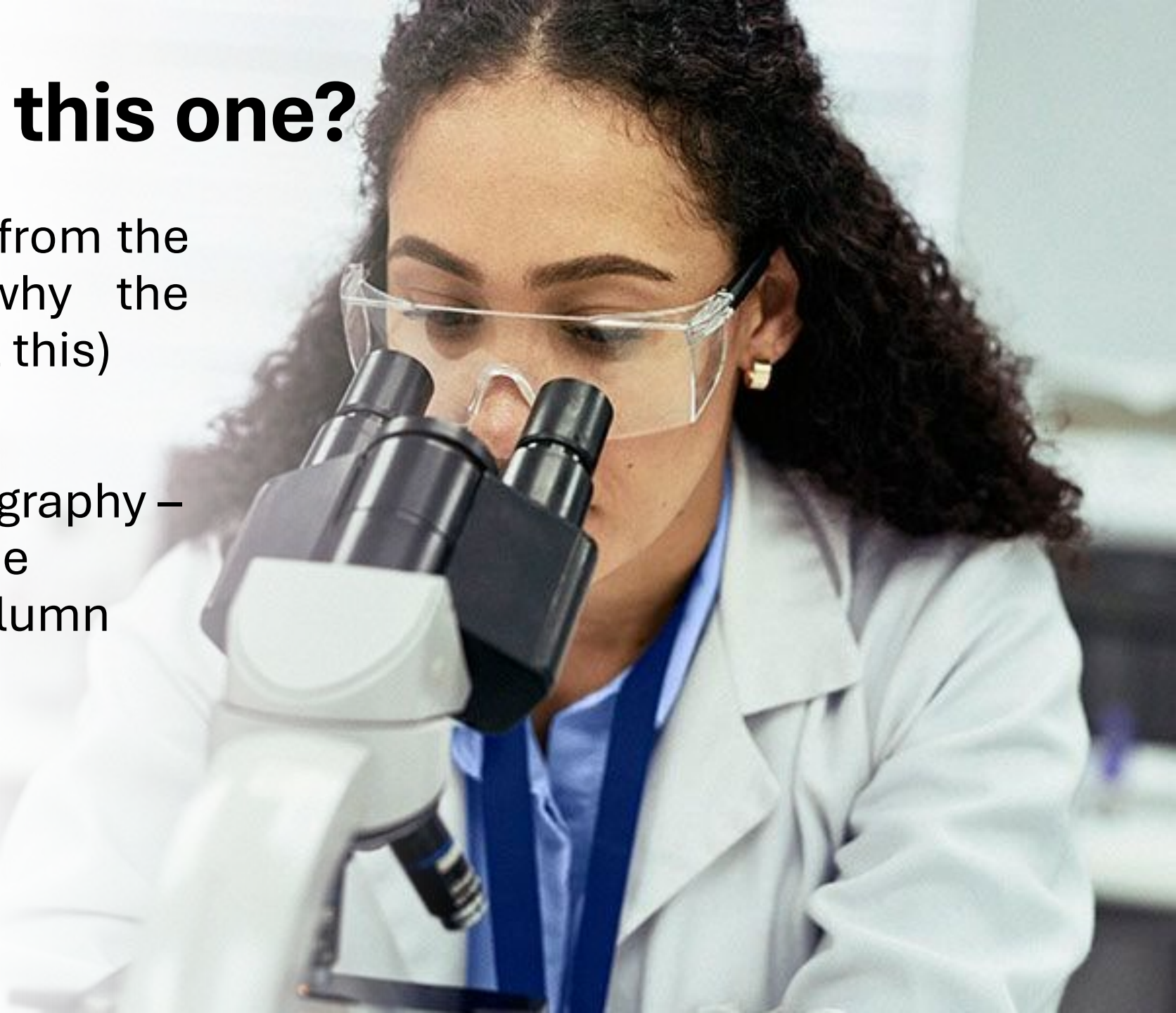
Therefore, because this stopper permits isobutylene to seep into this sample, it’s not inert under the WAC

How do we fight this one?

We send out a disclosure from the manufacturer (this is why the defense even knows about this)

On dual column chromatography – isobutylene's retention time mirrors methane in one column

Doesn't interfere with measurement of ethanol



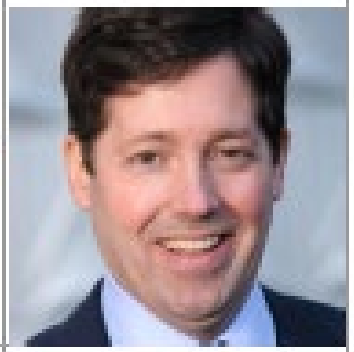
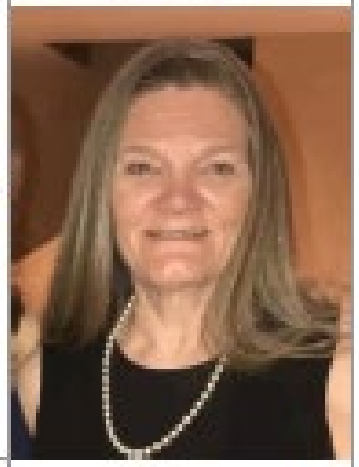
This comes down to the definition of “inert”

“Inert substances do not produce a chemical reaction when another substance is added; not reacting chemically with other substances.” - Cambridge Dictionary

This is the definition that our tox lab uses

How do we establish this to our judge’s satisfaction?

DEFENSE EXPERT BANK

oseph Anderson, PhD: Phone: 206-817-7346 joe@brainbasedinc.com Download CV HERE	Access Transcripts, Exhibits, Recordings, Briefs and Scripts HERE	
Janine Arvizu: 505-250-7422 arvizujk@aol.com Download CV HERE	Access Transcripts, Exhibits, Recordings, Briefs and Scripts HERE	
Robert Feldman, PhD:		

What about Experts...

QUESTIONS?