# From the Laboratory to the Courtroom:

## Forensic Challenges in Drug Testing

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This review of some of the legal issues in drugs of abuse testing is intended for informational use only.

Any legal information or opinions presented herein are not intended to be considered legal advice from the author, nor to substitute for professional legal advice.

Consult your own legal counsel for professional guidance.

Dr. Kadehjian is engaged by Siemens Healthineers to make educational presentations to customers regarding forensic testing for drugs of abuse.

This presentation expresses only the views of Dr. Kadehjian and not the views of any other person or company.

Dr. Kadehjian is solely responsible for the presented content.

#### Forensic Issues for Laboratories / Toxicologists

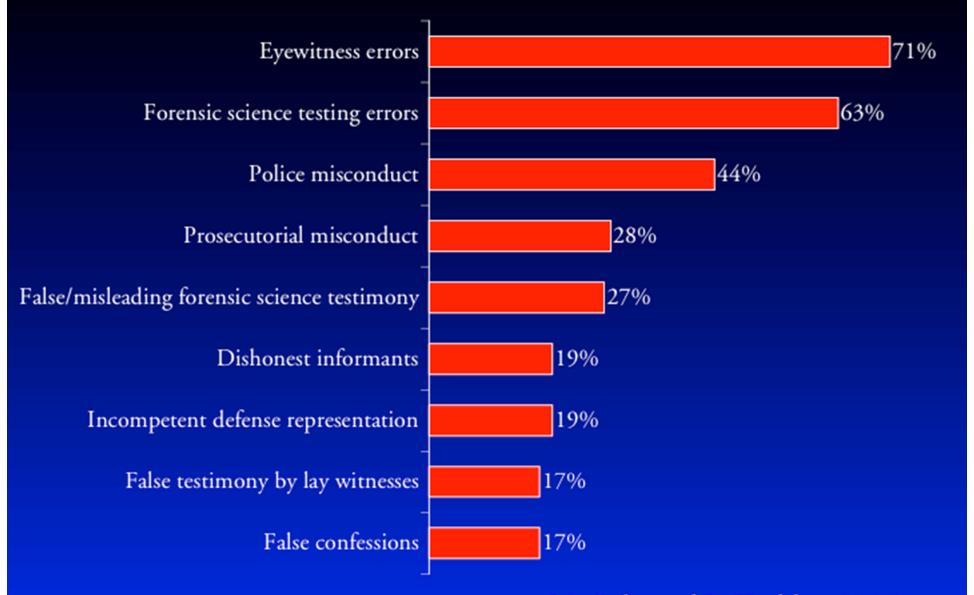
- Admissibility of evidence
   Legal standards: peer review, known error rate, standards, ...
- Evidentiary weight
   Chain of custody, laboratory performance, interpretation, ...
- Legal requirements for decisionmaking Beyond a reasonable doubt, preponderance, ...
- Laboratory liability
  Duty owed, negligence, privacy of records/HIPAA ...
- Expert liabilityPeer oversight

# Forensic Challenges: Specimens, Technologies

- Urine: Adulteration, substitution, dilution, interpretation
- Oral fluid: Adulteration, interpretation
- On-site: Subjectivity, performance
- Hair: Contamination, bias, ADA, standards
- Sweat: Contamination, tampering, standards
- Oculomotor: Science, standards



#### 86 DNA Exoneration Cases: Wrongful Conviction Factors



M. Saks and J. Koehler, 2005









# Laboratory Liable

- 10/91 Elliot v. Laboratory Specialists (LA Appl.)\$25K damages for inadequate procedures
- 11/91 Lewis v. Aluminum Co. of America (LA Appl.)

  Laboratory owes a duty to the employee
- 10/91 Dick v. Koch Gathering Systems and Roche Biomedical Laboratories (KS Dist. Ct.) (appealed)

\$675K damages, \$3.4m punitive award for improper procedures and invalid results

2/95 Stinson v. Physicians Immediate Care (IL Appl.)

Lab owes duty to employee to use reasonable care

# Laboratory Not Liable

Santagada v. Lifedata Medical (SDNY) 9/93 Lab not liable for collection service errors 3/94 Caputo v. CompuChem (3rd Cir.) No duty for lab to serve as MRO, unless in contract 6/95 Devine v. Roche (ME S. Ct.) Employee not a beneficiary to lab/employer contract Lab owes a tort duty to employee 8/95 Willis v. Roche Biomedical Laboratories (5th Cir.) Lab owes no duty to employee to use reasonable care Salomon v. Roche Compuchem (EDNY) 12/95 No private action for lab not providing certification

# Laboratory May Be Liable

1/94 Devine v. Roche Biomedical Laboratories (ME S. Ct.)

Contract unclear regarding duty to interpret results

7/95 SmithKline Beecham v. Doe (TX S. Ct.)

Possible interference with employment contract

Lab owed no duty to employee to interpret results







#### History of Science in Legal Proceedings

2030 BC Trial by ordeal (fire, poison, battle)

Parliament did not formally abolish trial by battle

until 1819

1000 BC Forensic psychology

(King Solomon, threatened to cut baby in half)

287–212 BC Metallurgy

(Archimedes detects silver alloying in gold

coins by water displacement, "Eureka")

15 BC–19 AD Forensic chemistry

(non-combustibility of heart as indication of

poisoning in murder of Germanicus;

defense claimed prior heart ailment)

### History of Science in Legal Proceedings

1591	Forensic microscopy
1727	Forensic photographs
1822	Daguerreotypes
1836	Forensic chemistry / toxicology (English chemist, Marsh, test for arsenic)
1858	Fingerprints
1860	Spectrographic analysis (flame ionization of inorganics)
1895	X-rays (Roentgen)
1900	Forensic immunology (Landsteiner, blood grouping)

## History of Science in Legal Proceedings

1901	Precipitin test for human blood (human or rabbit blood?)
1906	Sound recording
1912	Ballistics, firearms (photos of bullets)
1921	Lie detector
1931	Drunkometer (blood alcohol)
1945	Radar
1948	Truth serum (scopolamine, barbiturates–sodium pentothal, amytal)
Current	Drug tests: Urine, hair, oral fluid, sweat, oculomotor testing, onsite tests, DNA, brain scans (fMRI),













"It is better to permit the crime of a guilty person to go unpunished than to condemn one who is innocent."



"...commanded that no punishment be carried out except where there are witnesses who testify that the matter is established in certainty beyond any doubt, ..."

"...it is better and more desirable to free a thousand sinners, than to kill one innocent."

Maimonides, re. Negative Commandment #290, 1135 – 1204

"It is better that ten guilty persons escape than one innocent suffer." "If the standard is set at so high a level that the probability of an innocent person's being convicted is zero, the conviction rate for guilty people will also be zero, since only with a zero conviction rate can all possibility of an innocent person's being convicted be eliminated."

"... there simply is no constitutional guarantee that all executive decisionmaking must comply with standards that assure error-free determinations."

# Evidence

Admissibility

Weight

# Admissibility of Scientific Evidence

#### Federal courts:

1975 Federal Rules of Evidence

1993 Daubert v. Merrell Dow Pharmaceuticals, Inc. (509 U.S. 579)

#### State courts:

Follow Federal Rules / Daubert

Frye rule (Kelly-Frye in CA) 1923 U.S. v. Frye (D.C. Cir.)

"Just when a scientific principle or discovery crosses the line between experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs. ..."

## Federal Rules of Evidence (1975)

### Evidence / Admissibility

Rule 401. Relevant evidence

Rule 402. Admissibility of relevant evidence

Rule 403. Exclusion of relevant evidence

### Expert opinions

Rule 702. Testimony by experts

Rule 703. Basis of expert testimony

Rule 702. 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.

Rule 703. The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type of reasoning relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

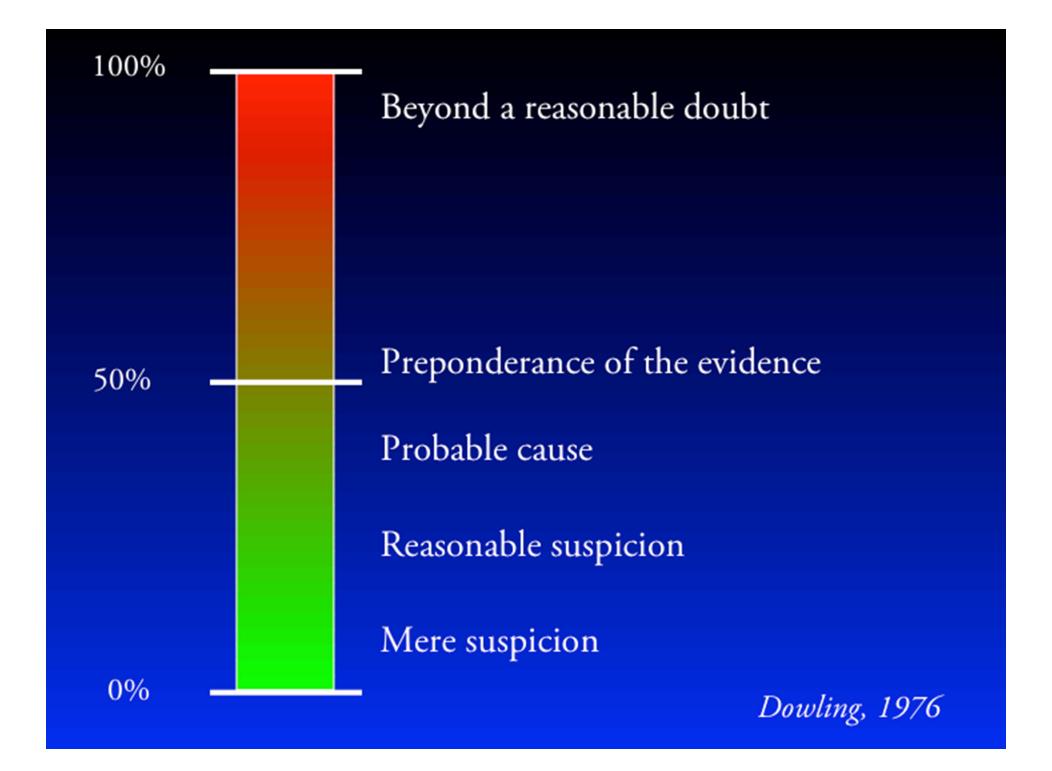


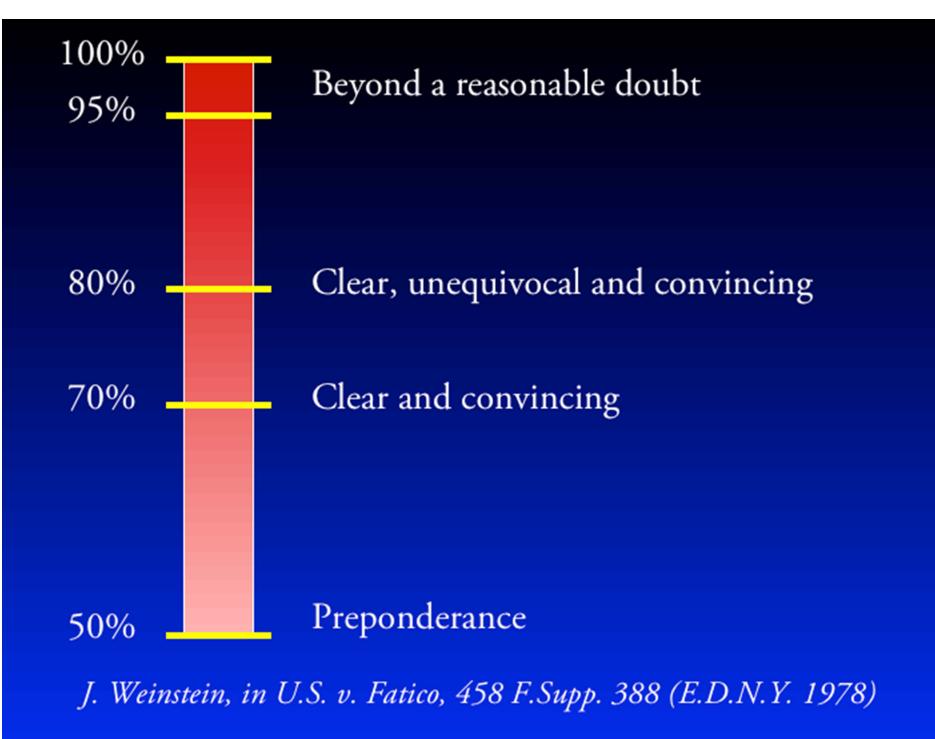
## Is the theory or technique scientific knowledge which will assist the trier of fact?

- Testing
- Peer review or publication
- Known or potential rate of error
- Standards controlling operation
- General acceptance

Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993)

"Of course, it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science."









# Scientific Foundations of Laboratory Methods and

Demonstration of their Proper Performance

### Pharmacokinetics Pharmacodynamics

Dose — Blood — Receptors — Effects

Absorption

Distribution

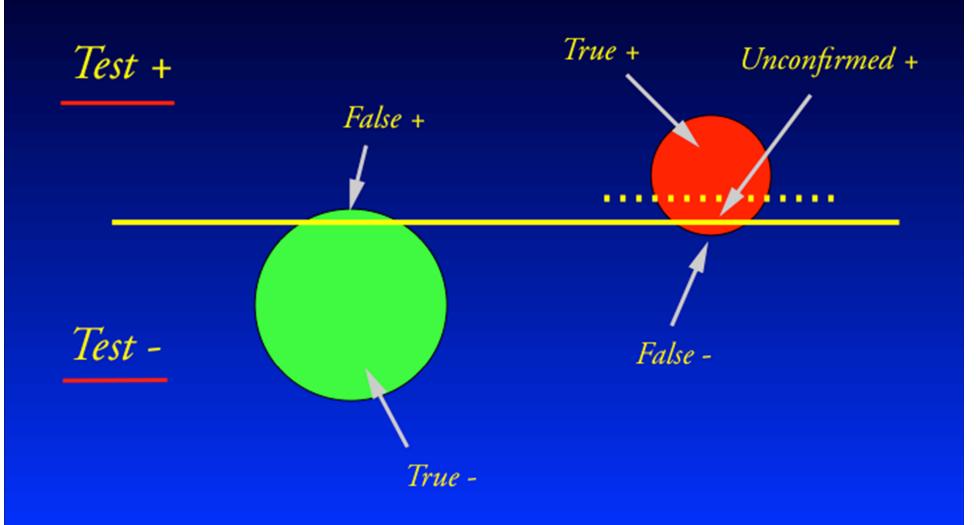
Metabolism

Elimination

Urine, sweat, oral fluid, hair, ...

#### Non-Users

#### Users



# Qualitative (positive, negative)

VS.

#### Quantitative

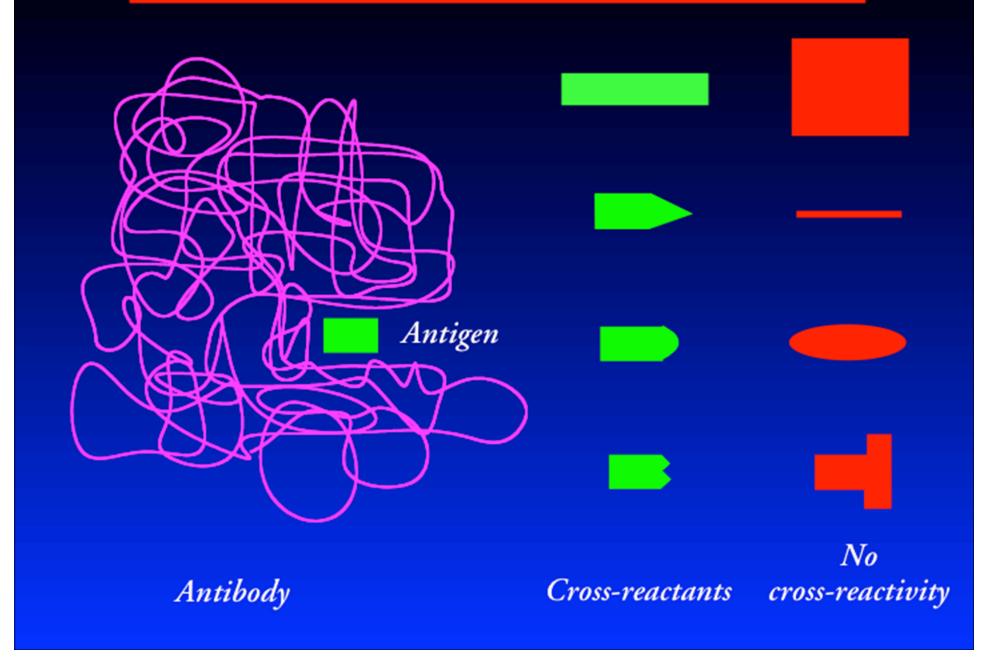
(ng/mL, immunoreactive equivalents, rate units)

VS.

"Semi-quantitative"

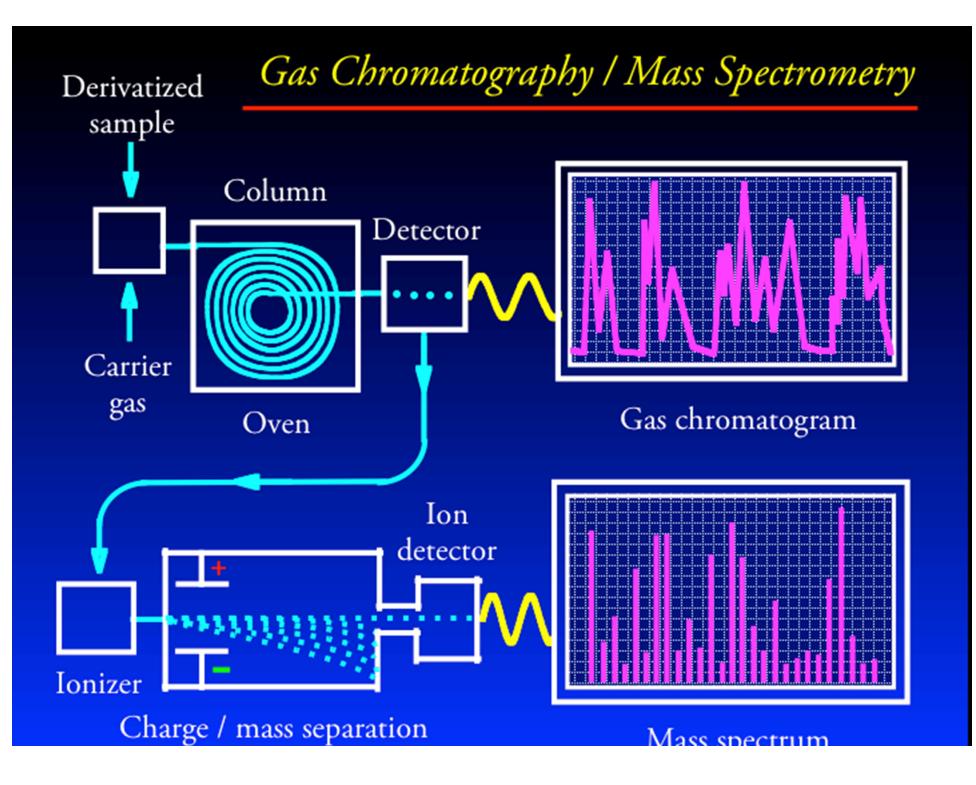
(no such thing!?)

#### Antibody Specificity: Cross-Reactivity



"The Package Insert is Your Friend"

(but may also be your enemy!)







#### Centers for Disease Control

Studies on Emit®

97 – 99% Accuracy

Jensen v. Lick, 589 F.Supp. 39 (1984)

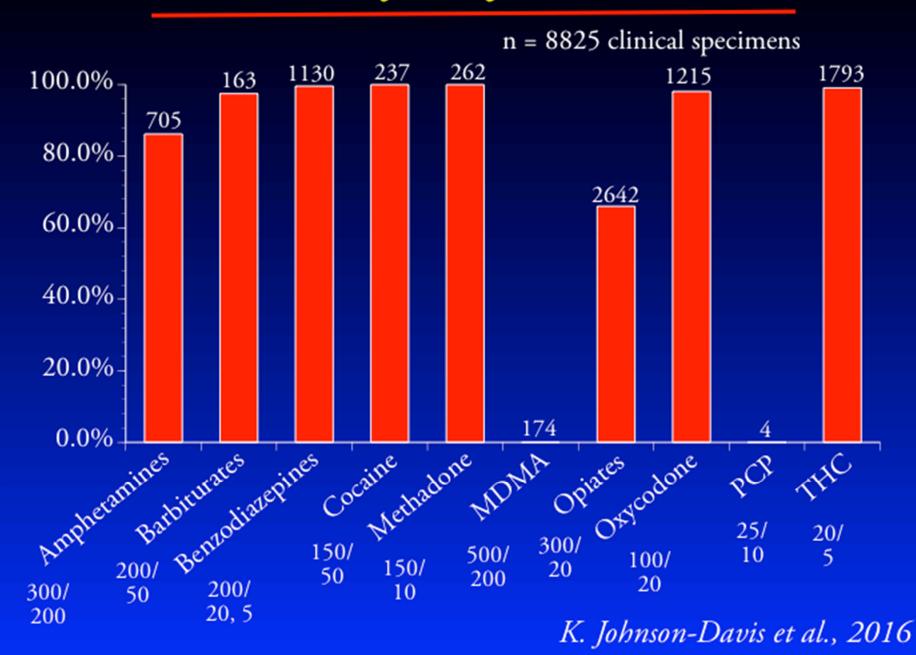
96% Accuracy, Survey of 64 labs

Peranzo v. Coughlin, 608 F.Supp. 1504 (D.C.N.Y. 1985)

"Indeed, the two studies involving the largest sample sizes place the Emit test at a level of certainty even *higher* than the reasonable doubt standard."

Peranzo v. Coughlin, 608 F.Supp. 1504 (D.C.N.Y. 1985)

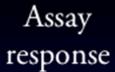
#### Immunoassay Confirmation Rates

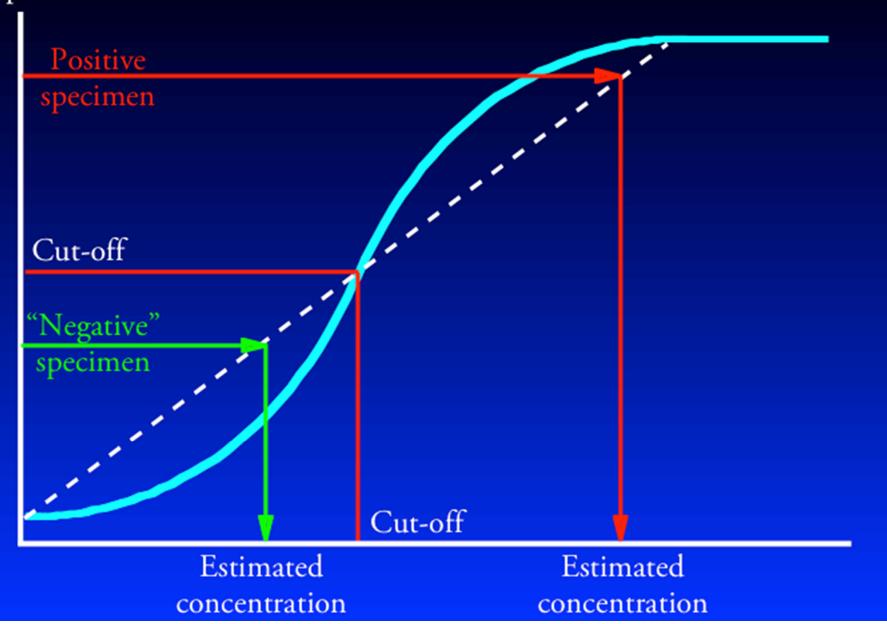


"Negative"

does NOT mean

"No drug"

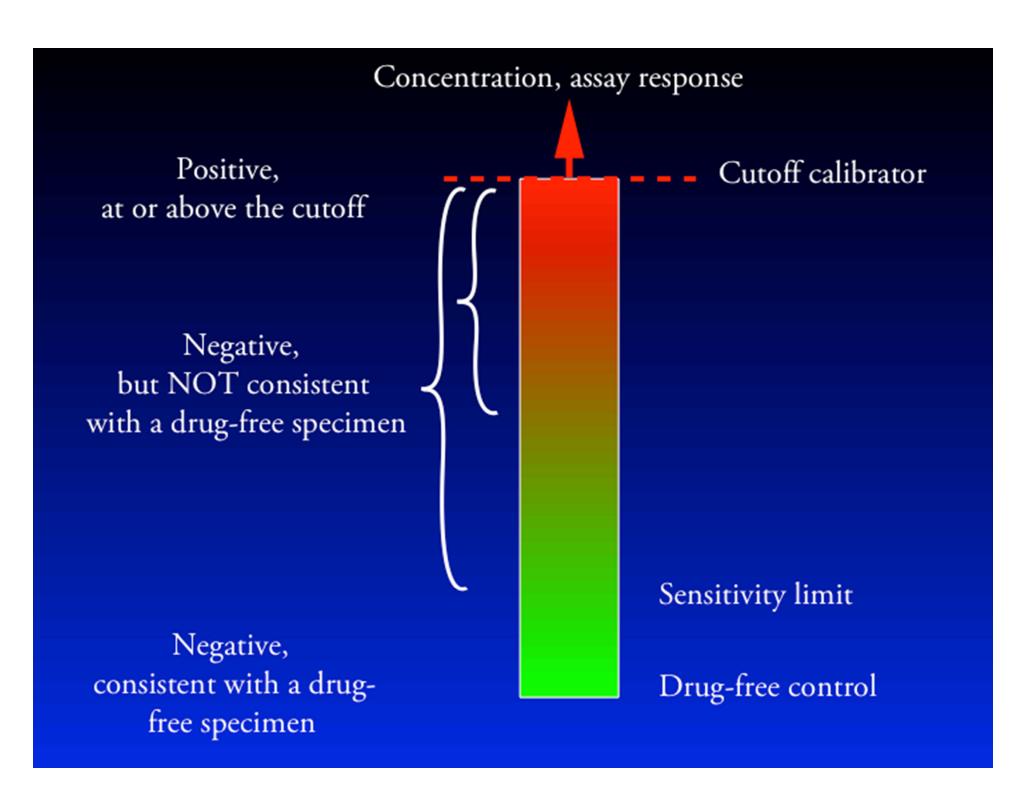




#### In re Brown, CA Supreme Court, 1998

- Positive immunoassay
- "Negative" GC/MS confirmation
- Positive immunoassay not automatically a "false positive"
- Concentration of drug may have been below the laboratory's GC/MS cutoff

17 Cal.4th 873, 72 Cal.Rptr.2d 698, 952 P.2d 715

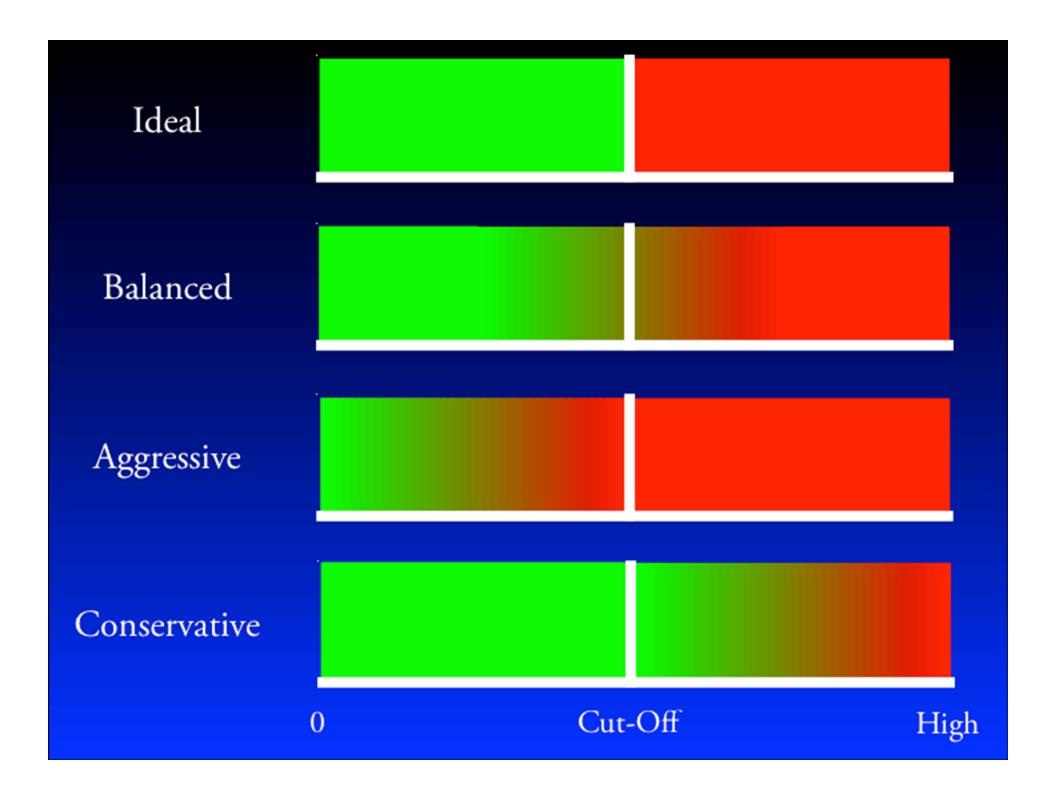


#### Reporting Test Results

Positive:At or above the administrative cutoff

Negative:Consistent with a drug-free specimen

Negative:
 But not consistent with a drug-free specimen











#### Key Criteria for Laboratory Accuracy and Reliability

▶ Internal:

Personnel

Chain of custody

Methodologies

QA/QC

Recordkeeping

External Oversight:

On-site Laboratory Inspections

Blind Proficiency Testing







#### Chain of Custody

Prove the identity and integrity of the specimen from receipt until reporting of the result

- Collection
- Transportation
- Analysis
- Reporting

# Drug Tests in Revocation Hearings: 5th Circuit Requirements

Provide 5 days prior to hearing:

- Test results
- Chain of custody
- Laboratory employee affidavit

Reports made part of record

U.S. v. Grandlund, 5th Cir. 1995

# Corrections Chain of Custody: Federal Cases

Wykoff v. Resig (D.Ind. 1985)

3–4 hr delay in unlocked refrigerator before transport: Allowed

Soto v. Lord (S.D.N.Y. 1988)

Incomplete COC form: Not allowed

U.S. v. Burton (8th Cir. 1989)

Urine in unlocked box in desk for 1 day, 2 week delay in mailing (in locked refrigerator): Allowed

# Corrections Chain of Custody: Federal Cases

Pella v. Adams (D.Nev. 1989)

56 day delay in testing, results not challenged: Allowed

Harrison v. Dahm (8th Cir. 1990)

No review of evidence log to establish COC: Allowed

Easton v. U.S. Corrections Corp. (6th Cir. 1994, unpublished)

Error in time (3 hr storage before collection): Allowed

# Corrections Chain of Custody: State Cases

Lugo v. Gaines (N.Y.S.Ct. 1981)

No evidence of COC, 6 inmates' collection together, unlabeled bottles: Not allowed

► Stahl v. Pa. Bd. Prob. Parole (Pa.Cmmw.Ct. 1986)

Urine left in office and refrigerator without security: Allowed

Berrios v. Kuhlman (N.Y.App. 1988)

Minor deficiencies in COC entries: Allowed

# Corrections Chain of Custody: State Cases

McDonald v. State (Md.S.Ct. 1988)

Insufficient COC testimony: Not allowed

▶ Bourgeois v. Murphy (Id.S.Ct. 1991)

No documentation of COC: Not allowed

Curry v. Coughlin (N.Y.App. 1991)

Specimen unattended 6 hr, but only speculation: Allowed

"The requirement of reasonable certainty is not met when some vital link in the chain of possession is not accounted for, because then it is as likely as not that the evidence analyzed was not the evidence originally received. Left to such speculation, the court must exclude the evidence." "When it is the barest speculation that there was tampering, it is proper to admit the evidence and let what doubt remains go to its weight."







Doe v. Roe (N.Y.App. 1990)

Employer liable for not hiring applicant as testing didn't distinguish between unlawful opiate use and poppy seeds

Lab performed GC/MS for morphine/codeine, but not 6-MAM

Caputo v. Compuchem Laboratories (E.D.Penn. 1994)

Lab has no duty to interpret result unless contractually obligated

Employee argued for 6-MAM, but the court held that the laboratory reported the results accurately

Devine v. Roche Biomedical Laboratories (Me.S.Ct. 1995)

Employee had no claim against lab for not interpreting

Lab may be liable to employer for negligent misrepresentation, and breach of contract, but not tort claims

2nd positive 2 days later @ 2174 ng/mL, laboratory doctor indicated impossible for poppy seeds, but earlier laboratory technical publication indicated as high as 5000 ng/mL possible for poppy seeds

SmithKline Beecham v. Doe (Tx.S.Ct. 1995)

Lab owed no duty to employee or employer to interpret result Lab may be liable for tortious interference with prospective employment contract

Price v. City of Bossier City (La.S.Ct. 1997)

Disallowed medical malpractice claims by employee against MRO and hospital in post-accident test

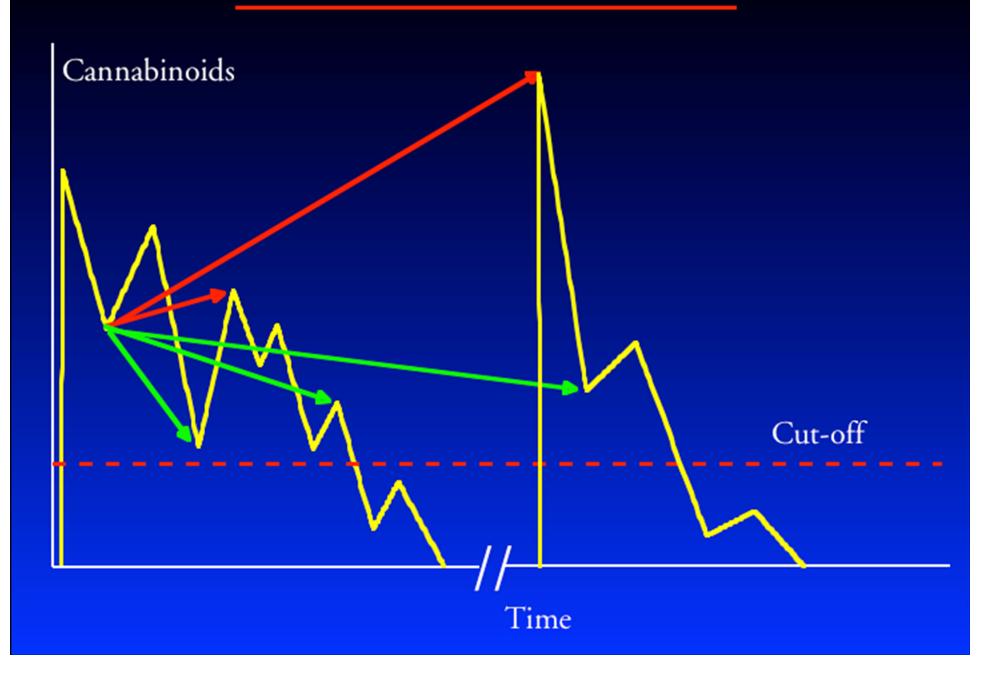
Employee was not a patient, testing is not receiving healthcare; a drug test cannot be analogized to a medical exam

434 ng/mL, donor noted consumption of poppy seeds, laboratory reported stated that <2000 ng/mL may be poppy seeds, but MRO reported as positive

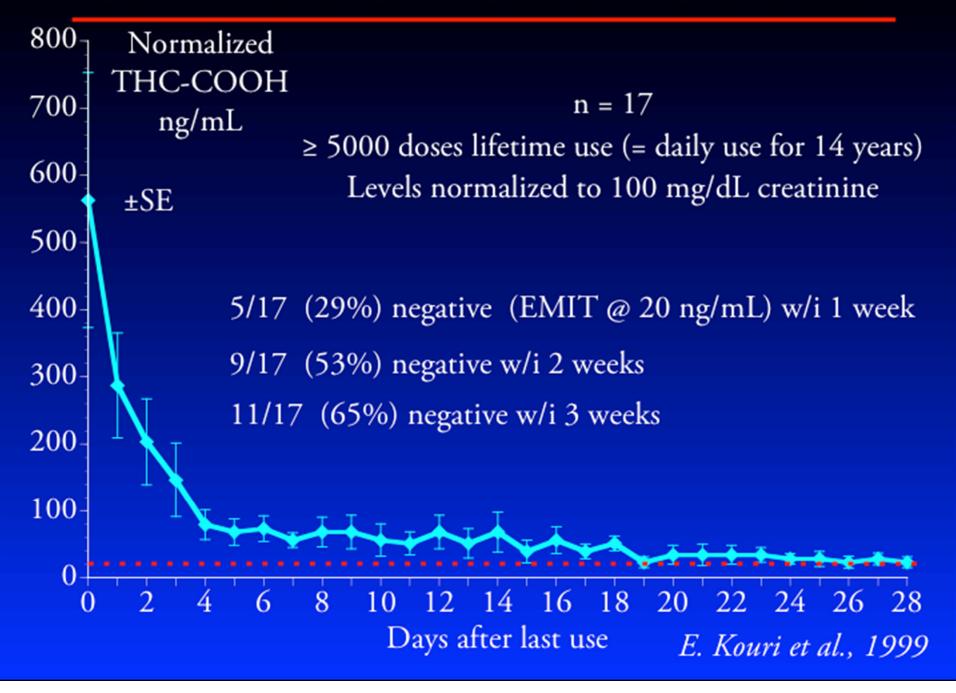
Court did note that alleged negligence was a violation of NIDA Guidelines



# Renewed Use vs. Residual?

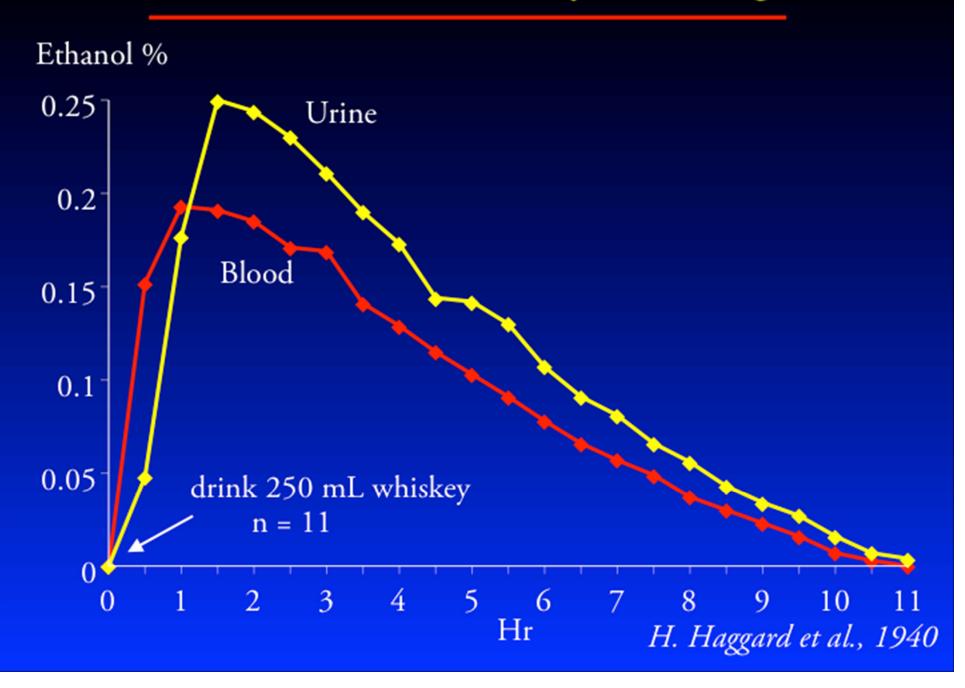


#### Creatinine Normalized THC-COOH in Chronic Users

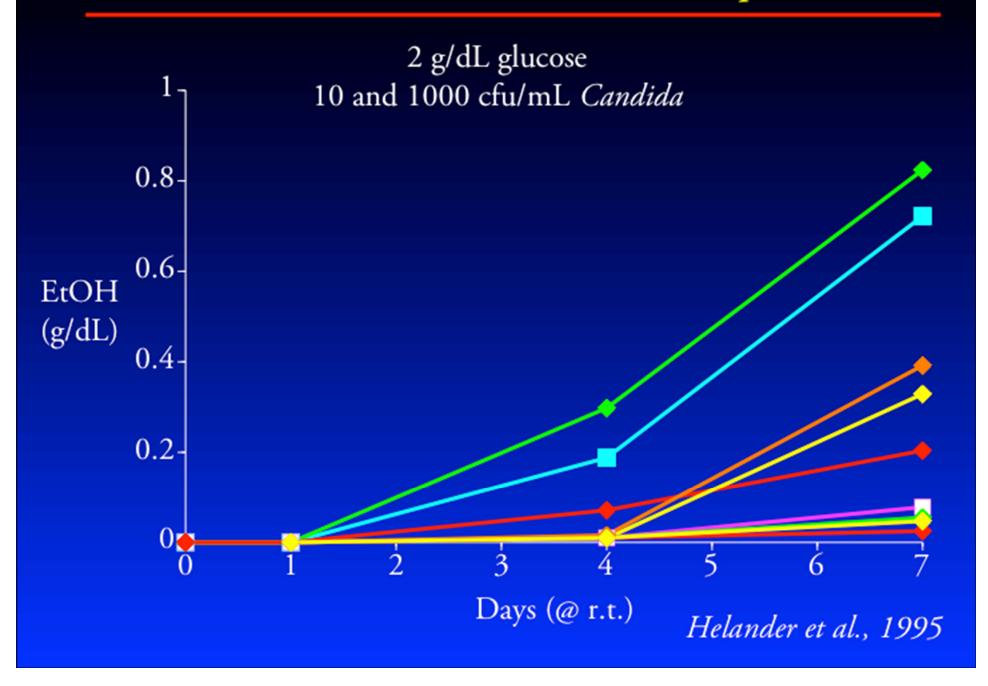




### Urine, Blood EtOH Levels After Drinking



#### EtOH Formation in Glucose- and Candida-Spiked Urines



# Ethanol Formation in Infected Urine

Sugar in urine

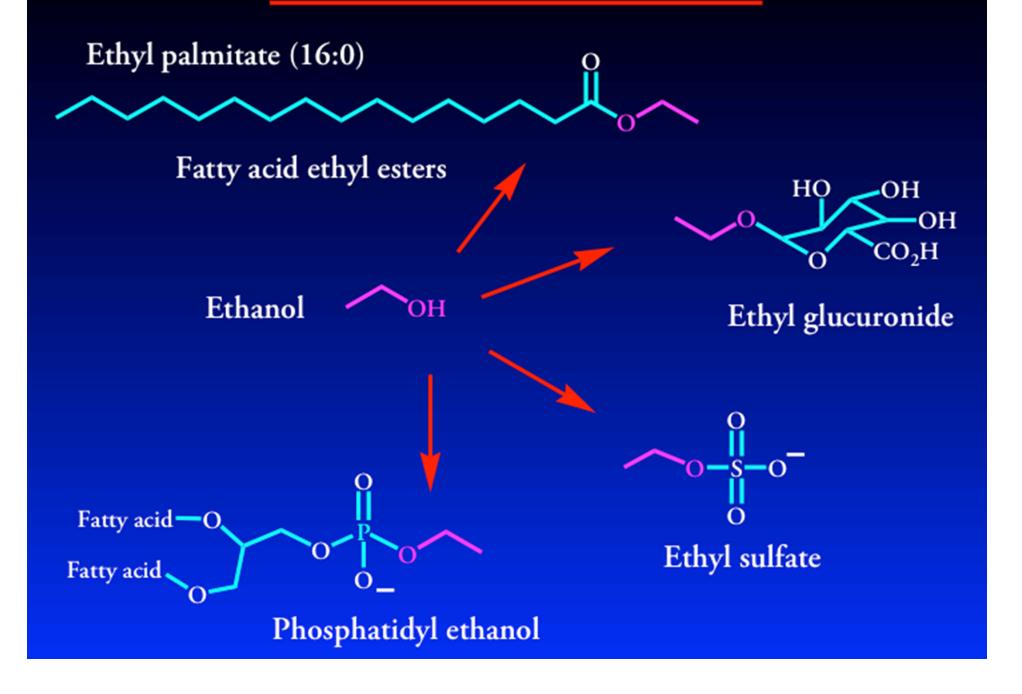
and

► Infection

and

► At least one day storage at room temperature

# Markers of Ethanol Ingestion



"Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this Advisory, is inappropriate and scientifically unsupportable at this time. These tests should currently be considered as potential valuable clinical tools, but their use in forensic settings is premature."

SAMHSA, Substance Abuse Treatment Advisory, 5 (4), September 2006.

Although further research is needed before firm cutoffs for EtG can be established, sufficient research has been completed to reach the following conclusions:

A "high" positive (e.g., >1,000 ng/mL) may indicate: Heavy drinking on the same day or previously (e.g., previous day or two). Light drinking the same day.

A "low" positive (e.g., 500–1,000 ng/mL) may indicate:

Previous heavy drinking (previous 1–3 days).

Recent light drinking (e.g., past 24 hours).

Recent intense "extraneous" exposure (within 24 hours or less).

A "very low" positive (100–500 ng/mL) may indicate:

Previous heavy drinking (1–3 days).

Previous light drinking (12-36 hours).

Recent "extraneous" exposure.

SAMHSA, The Role of Biomarkers in the Treatment of Alcohol Use Disorders, Advisory, 11 (2), 2012 Revision.

## State v. Damiano, Cherokee County, 3/7/12

EtG: Positive (immunoassay: 500 ng/mL cutoff): >2,000 ng/mL

Confirmed (LC/MS/MS): EtG: 3,997 ng/mL

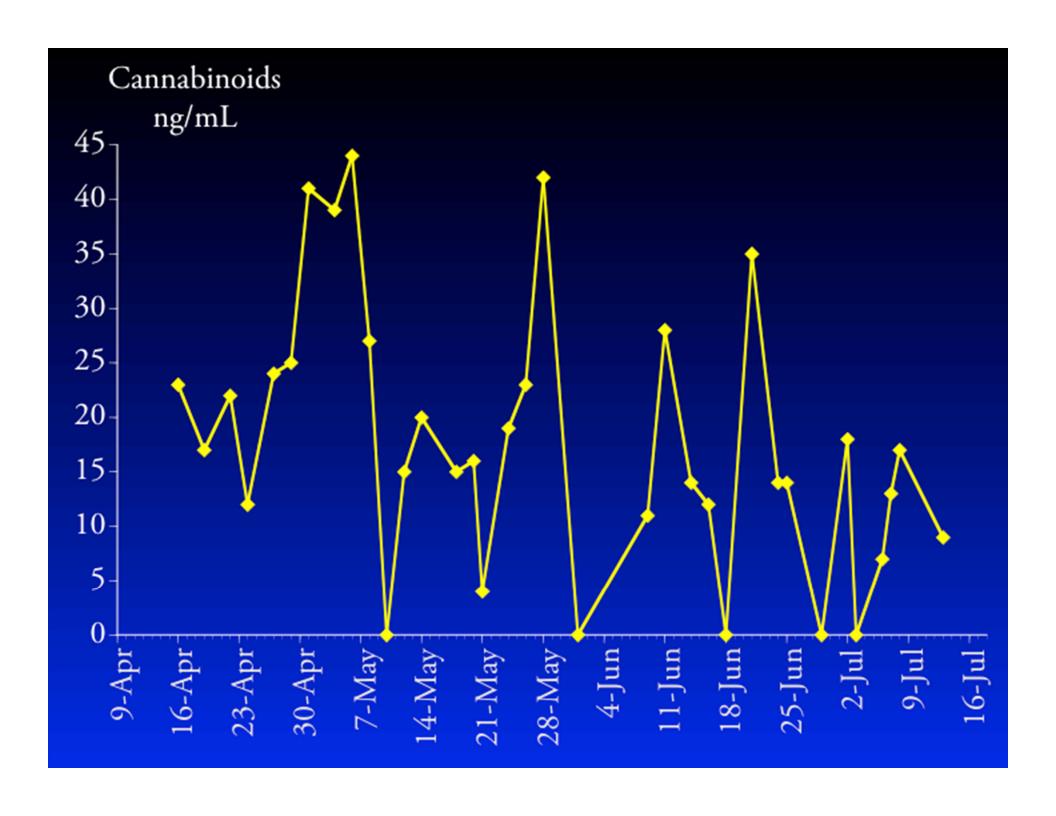
EtS: 622 ng/mL

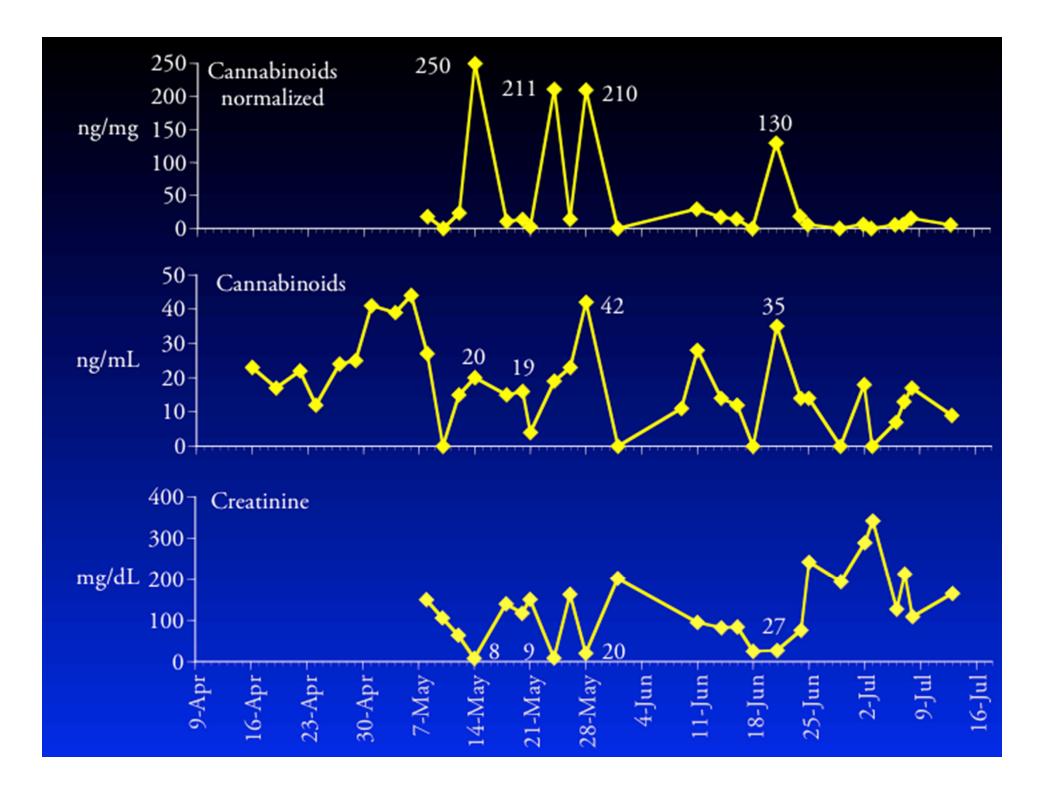
"From the evidence presented, the Court concludes that the above testing for ETG to determine alcohol consumption to be a procedure which has reached a scientific stage of verifiable certainty for use in criminal cases."

"Furthermore, the Court finds that the ETG testing employed by the Cherokee County DUI/Drug Court Lab meets the *Daubert* standard for admissibility in civil matters,..."









- Drug use violation of supervised release
- "Positive" on-site immunoassay (300 ng/mL cut-off)
- "Negative" laboratory screening immunoassay (181 ng/mL)
- "Negative" GC/MS confirmation (118 ng/mL BE)
- Creatinine 29.6 mg/dL
- s.g. 1.003 = "diluted, invalid"

"The results of a drug test ... shall be subject to confirmation only if the results are positive, ..."

"A drug test confirmation shall be a urine drug test confirmed using gas chromatography/mass spectrometry techniques ..."

18 USC §3563(e) (probation)
18 U.S.C. §3583(d) (supervised release)

"The program shall include such standards and guidelines as the Director may determine necessary to ensure the reliability and accuracy of the drug testing programs ..."

18 U.S.C. §3608

P.L. 103-332 Violent Crime Control and Law Enforcement Act of 1994

"However, the test result did not mean that Klimek did not have cocaine in his system."

"Here, a GC/MS test was performed, and it confirmed that cocaine metabolite was present in Klimek's system."

"It should go without saying that it violates the terms of Klimek's supervised release to have ANY cocaine metabolite in his system."

"Even if I assume that the fixing of a "cut-off" level for GC/MS represents the Director's conclusion that Klimek's test result is questionable, that is simply a factor going to the weight of the drug testing evidence before me."

"... there is nothing magical about the cut-off level selected by the AO; equally reputable organizations involved in drug testing specify lower cut-off levels."

"The results of the specimen validity test strongly suggest an effort to beat the test and are most persuasively interpreted in that way."

"And because I find that the results of the GC/MS test conducted on Klimek's urine sample satisfy the Congressionally-mandated requirement that a contested drug test be "confirmed" using GC/MS ..."

## U.S. v. Klimek, 2nd Cir., 6/8/05

"Even assuming that the cutoff level specified in the contract between the AO and STL was a "standard[]" or "guideline[]" of the sort contemplated by Section 3608—an assumption that is in tension with the uncontradicted testimony before the District Court that the cutoff level had no particular scientific significance—nothing in the language of that provision precludes a district court from considering the totality of the evidence before it when a confirmatory test result falls below this cutoff level."

## U.S. v. Klimek, 2nd Cir., 6/8/05

"Even more significantly, the confirmation test performed on defendant's sample—once it was "normalized" for dilution—would have evinced a cocaine metabolite concentration of 406 nanograms per milliliter, well above the cutoff level of 150 nanograms per milliliter."

## U.S. v. Klimek, 2nd Cir., 6/8/05

"We need not decide at this time whether Sections 3583(d) and 3608 preclude a district court from revoking a defendant's supervised release based solely on a test result that fell below the cutoff level."

## Utility of Urine Drug Concentrations

- Evidence of use ("negative" vs. "no drug")
- "Unconfirmed positive" vs. "false positive"
- Consistency of results with claims of donor
- Renewed use vs. residual
- Likelihood of dosing scenarios
- Likelihood of impairment



## 6th Amendment: Right to Confrontation

### Hearsay exception:

Public records

Police reports, birth certificates, ...

Business records

Lab reports

U.S. v. Grandlund (5th Cir. 1995)

Must provide:

Test results

Chain of custody

Lab employee affidavit

Indicia of reliability



### Melendez-Diaz v. Massachusetts, 129 S.Ct. 2527, 6/25/09

Do laboratory reports satisfy 6th Amendment rights to confrontation?

#### 6th Amendment:

"In all criminal prosecutions, the accused shall enjoy the right ... to be confronted with the witnesses against him; ..."

- Are laboratory analysts "witnesses" against the accused?
- Are crime laboratory reports "testimonial"?

### Melendez-Diaz v. Massachusetts: Case Facts

- Confiscated drugs analyzed by State Laboratory Institute of the Massachusetts Department of Public Health
- Test results reported in notarized certificate: "... drugs found to contain: cocaine."
- No data provided regarding methods, analyst qualifications

## Melendez-Diaz v. Massachusetts: Majority

#### Defendant:

- Knew well in advance of introduction of test results
- Made no effort to mount a defense against test results
- Did not challenge test results
- Had opportunity but did not request independent testing
- Did not challenge test reliability: methods, analyst qualifications

## Melendez-Diaz v. Massachusetts: Majority (5–4)

- Notarized laboratory reports were affidavits = "testimonial"
- Reports were not public or business records granted exception to hearsay rule
- Reports were created for sole the purpose of providing evidence against defendant
- Medical reports created for treatment purposes are not "testimonial"
- Laboratory analysts are "witnesses against"
- ▶ Defense power to subpoena is no substitute for right of confrontation
- Confrontation Clause may not be relaxed because of burden to the government
- ▶ Thus, violation of 6th Amendment right to confrontation, remanded

## Melendez-Diaz v. Massachusetts: Majority Footnote

- Do not hold that anyone whose testimony may be relevant in establishing the chain of custody, authenticity of the sample, accuracy of the testing device must appear
- Prosecution must establish chain of custody, but not everyone must be called
- Gaps in the chain of custody normally go to the weight of the evidence rather than its admissibility
- Prosecution decides what chain of custody steps are so crucial as to require evidence; but what testimony is introduced must (if defendant objects) be live

## Melendez-Diaz v. Massachusetts: Majority

- Forensic evidence not as neutral or as reliable as respondent suggests
- Cite 2009 report:

"Strengthening Forensic Science in the United States: A Path Forward"

National Research Council, National Academy of Sciences

- Analysts who swore the affidavits provided testimony against the defendant and are therefore subject to confrontation
- "We would reach the same conclusion if all the analysts always possessed the scientific acumen of Mme. Curie and the veracity of Mother Theresa."

## Melendez-Diaz v. Massachusetts: Majority

"Many states have already adopted the constitutional rule we announce today"

Colorado

District of

Columbia

Florida

Georgia

Illinois

Minnesota

Mississippi

Missouri

Nevada

Oregon

- Sweeps away 90 years of established rule across 35 states and 6 Federal Courts of Appeal
- Real differences between laboratory analysts and conventional "witnesses"
- The word "testimonial" does not appear in the text of the Confrontation Clause
- Vast potential to disrupt criminal procedures
- "... the Court has, for all practical purposes, forbidden the use of scientific tests in criminal trials."
- "... transforms the Confrontation Clause from a sensible procedural protection into a distortion of the criminal justice system."

### No accepted definition of analyst:

- One person prepares sample, places in analyzer, retrieves printout
- Another person interprets test printout
- Another person calibrates analyzer (perhaps independent contractor?)
- Laboratory director certifies that proper procedures were followed

Not at all evident which is the analyst to be confronted; all four?

- All 6 Federal Courts of Appeal who have considered the issue (1st, 2nd, 4th, 5th, 8th, 10th) agree that analysts are not required to testify
- 24 State Courts and the Armed Forces Court of Appeals
- 16 States' Rules of Evidence allow scientific tests without testimony
- 6 State courts' hearsay rules require analysts to testify
- "The Confrontation Clause is not designed, and does not serve, to detect errors in scientific tests."

"Laboratory analysts are not "witnesses against" the defendant as those words would have been understood at the framing."

- Witnesses recall events in the past in response to questions under interrogation, but analysts provide near contemporaneous observations
- Analysts don't observe crime or any human activities related to it; analysts often don't know the defendant's identity
- Scientific tests are conducted according to scientific protocols, not dependent nor controlled by interrogation
- There was no indication that analysts were adversarial nor that adversarial officers played a role in formulating the analysts' certificates



## Bullcoming v. New Mexico, U.S. Supreme Court, 6/23/11

- DWI conviction (BAC = 0.21 g/100 mL)
- Laboratory reported admitted, but without live testimony from the analyst who performed the test
- Analyst's associate testified
- Associate was qualified as an expert on gas chromatography and the laboratory's procedures

#### BUT,

- Associate did not participate in nor observe the testing
- Associate's testimony held as insufficient
- Violation of 6th Amendment right to confrontation
- Reversed conviction and remanded

# Right to Confrontation of Laboratory Technicians: Probation Revocations

"However, as Minnitt recognizes, Melendez-Diaz interprets a defendant's right to confrontation under the Sixth Amendment in a criminal prosecution, not the limited due process right to confrontation afforded a defendant in a revocation proceeding. Compare id. at 2531-32, with McCormick, 54 F.3d at 220-21. While standards of the Sixth Amendment may extend to a revocation proceeding, because a revocation proceeding is not a criminal prosecution, the Amendment does not fully apply. See United States v. Hodges, 460 F.3d 646, 650 (5th Cir. 2006). Melendez-Diaz does not change the analysis used in McCormick for applying the limited due process right to confrontation in a revocation proceeding. McCormick followed the Supreme Court's opinion in Morrissey v. Brewer, 408 U.S. 471 (1972), which is unaffected by Melendez-Diaz."

"Nor is a machine a "witness against" anyone. If the readings are "statements" by a "witness against" the defendants, then the machine must be the declarant. Yet how could one cross-examine a gas chromatograph?"

## Why Your Testing is Accurate and Reliable

- Trained/certified collectors, operators
- Chain of custody throughout operations
- Use established and recognized methods
   FDA clearance
   Extensive peer-reviewed publications (international)
   Legal recognition (at level of U.S. Supreme Court, 1989)
- Follow test system manufacturer specifications Calibration, daily controls, environmental/storage conditions, instrument maintenenace
- External oversight
   Confirmation testing, proficiency testing, inspections

Know what you know and present with confidence!

Know and accept what you don't know!

Know and acknowledge what you are uncertain about and why.

Credibility

