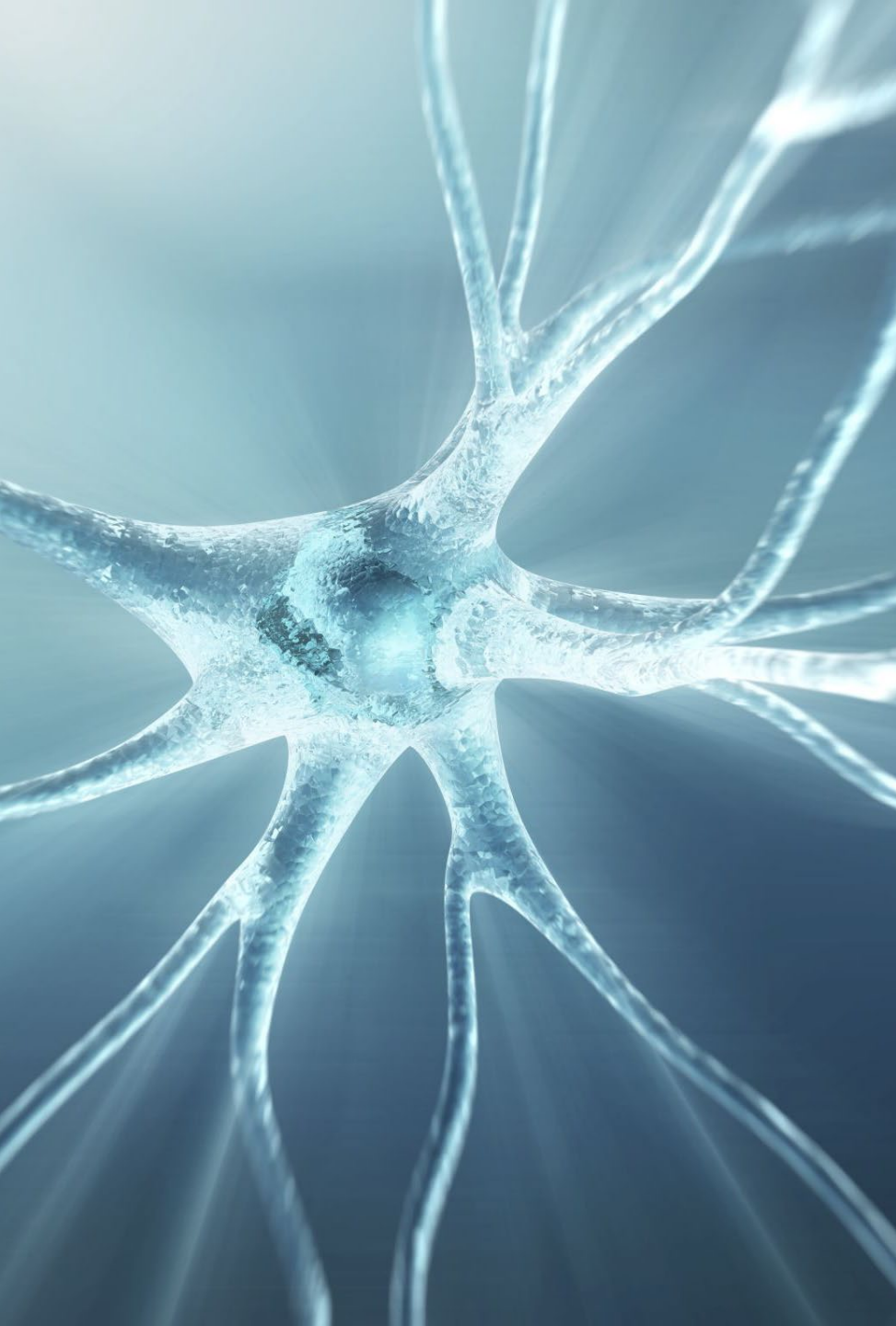



The interface of science and the law



A thorny interface

When
scientific
studies are at
the heart of
the lawsuit


**CONFLICT
OCCURS**



Scientists and lawyers
live in two different
intellectual universes

**"Many scientists
who testify in court
are disappointed by
the experience.....
([Bair, 2001](#))**

The legal system cannot attain
the same goal as the scientific
method



The primary purpose of a civil
trial is to end a dispute.



Experts are visitors; vocabulary
and rules used are foreign.



The legal system is designed to
resolve conflicts.

Scientific Method

Initial observations



Formulate question



Develop hypothesis



Experimentation to
test hypothesis



Conclusions to
accept or *reject*
hypothesis



Journal review to
determine acceptability
for publication



Evaluation by
scientific community
to accept or reject
hypothesis

Civil Lawsuit

Perceived injustice



Suggest causation



File complaint



Discovery to
gather information



Trial to
accept or *reject*
testimony



Jury deliberation to
assess liability

Similarities

Hypothesis
v
Petition

Discovery
v
Scientific
Methods

Differences


Jury of
Peers

Final
Decision



Research is
what I'm doing
when I don't
know what I'm
doing.

~Wernher Von Braun



Science and the law must rely on incomplete data and operate under uncertainty

Judge Lynn Hughes, L.N. 1999. Clients, cogency & candor: the complications of consulting in court. *Abstracts with Programs. Geological Society Of America Meeting*, 31(7). A181.

Velma West Sykes, Missouri Poet (1893-1976)

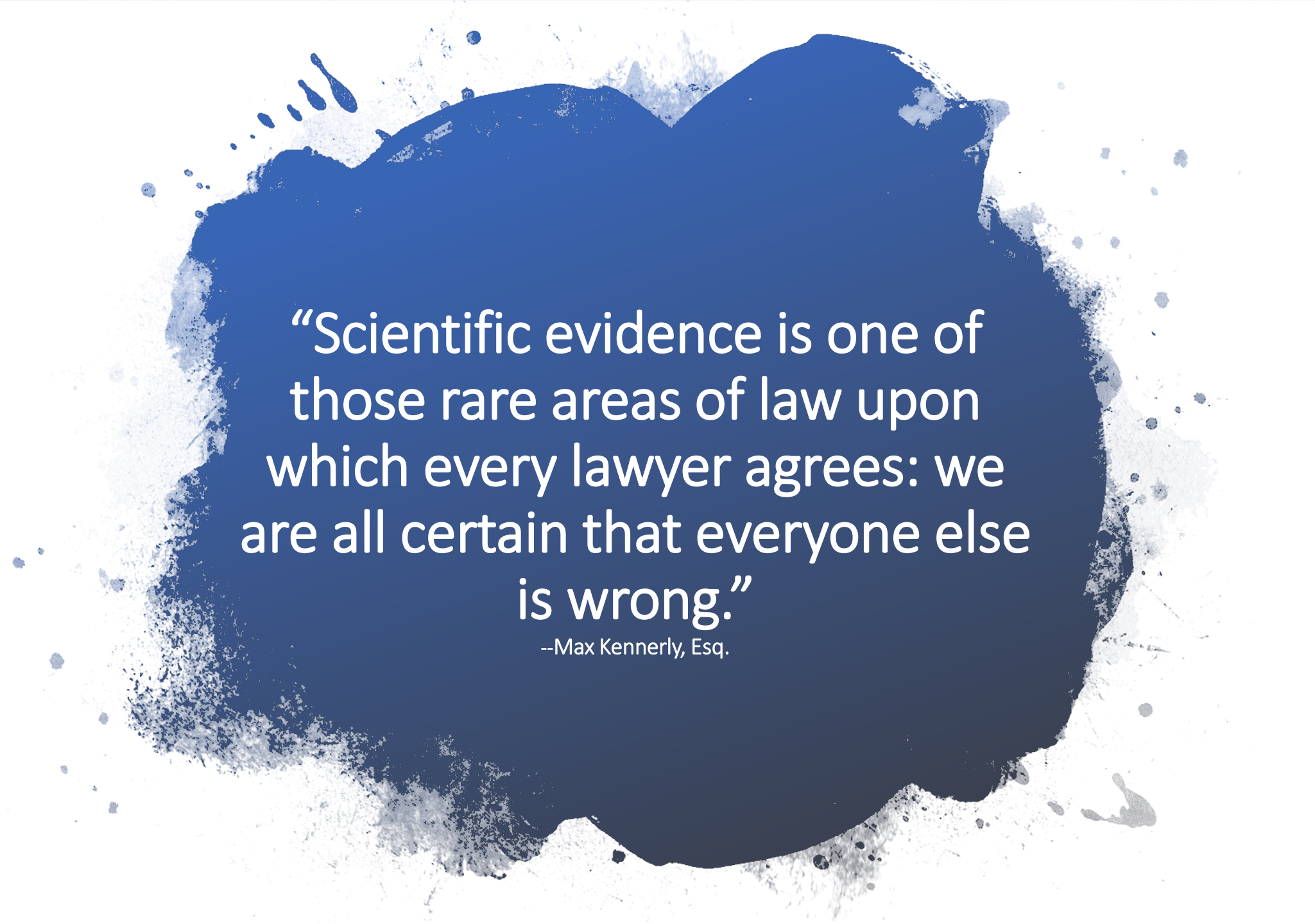


TWIN SNOWFLAKES

Two snowflakes never are the same,
the scientists agree;
But have they proved what they
proclaim?

I watch the myriads that fall
And leave it up to chance,
That here and there among them all
Twin snowflakes dance.

How do we prove what we
proclaim?



“Scientific evidence is one of
those rare areas of law upon
which every lawyer agrees: we
are all certain that everyone else
is wrong.”

--Max Kennerly, Esq.

What is scientific evidence?

DNA analysis

**fingerprint
identification**

**microscopic hair
comparisons**

**testimony of
handwriting
examiners**

**bullet and firearms
comparisons**

**bite mark
identifications**

polygraph test results

**and a variety of
clinical findings by
doctors, psychologists,
and psychiatrists**



“Junk” science
Pre-science
developing science



Public perception of experts

What does the jury think of experts?



The general public looks to scientists to explain the physical, chemical, and biological processes that operate day-to-day within our realm



The public is accustomed to scientists describing these processes in terms of laws



In allowing this perception to prevail, scientists have unwittingly encouraged the public to believe in the certainty of science



Afterall, science deals with definitive laws that are tested, proven, and repeatable



As a consequence, the jury pool is unaccustomed to the methods routinely used by applied scientists to deal with SCIENTIFIC UNCERTAINTY



Evidentiary Reliability Scientific Uncertainty

Frye versus Daubert

Frye v. United States, 1923

General Acceptance

FRE 702

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

- scientific knowledge presented as testimony **must be derived by the scientific method**
- **evidentiary reliability is to be based on scientific validity**

The Daubert guidelines include five factors of consideration:



Whether the theory or technique in question can be and has been tested



Whether it has been subjected to peer review and publication



Its known or potential error rate



The existence and maintenance of standards controlling its operation



Whether it has attracted widespread acceptance within a relevant scientific community

Differing Roles

“as a gatekeeper”
ensure



whether or not the
reasoning is
scientific and will
assist the jury



focus must be
solely on
methodology

The Law of Daubert

Courts review an expert's *methods*, rather than their *conclusions*, to ensure that the expert's testimony has an appropriate scientific basis.

Mere disagreements about the science itself, and about the expert's conclusions, are to be made by the jury in the courtroom.

In practice, the *Daubert* standard runs into problems when courts erroneously decide factual disputes about methodology and conclusions, issues which are better left to cross examination of the experts at trial.

Recent Daubert Opinions

Adams v. Toyota Motor Corp., 867 F.3d 903
(8th Cir. June 9, 2017)

*In re Zoloft (Sertraline Hydrochloride) Prod.
Liab. Litig.*, 858 F.3d 787 (3d Cir. June 2, 2017)

Wendell v. GlaxoSmithKline LLC, 858 F.3d
1227 (9th Cir. June 2, 2017)

Nease v. Ford Motor Co., 848 F.3d 219 (4th
Cir. 2017)

Rejected Arguments



- Defendants argued:
 - any difference renders the test unreliable
 - must have statistically significant evidence
 - opinions developed for litigation are inherently unreliable
 - a doctor's differential diagnosis is an unacceptable scientific methodology
 - must completely eliminate all potential alternative causes
 - and case studies are scientifically irrelevant
- The appellate courts rejected each and every one of those arguments

In re Zolof (Sertraline Hydrochloride) 858 F.3d 787 (3d Cir. June 2, 2017)

MDL – birth defects

struck the testimony of plaintiffs' perinatal pharmacoepidemiologist

relied on "statistical significance" when deciding Daubert

Statistical significance not a scientific principle, a conclusory term of art

refused to establish a bright-line rule requiring statistical significance

*Wendell v.
GlaxoSmithKline
LLC,
858 F.3d 1227
(9th Cir. June 2,
2017)*

Non-MDL
products
liability case – 2
drugs in
combination

Maxx Wendell
died at age 21
of HSTCL, a very
rare and
aggressive
cancer

Filed opinions
of 2 highly
qualified
physicians on
causation

Excluded
testimony and
granted
summary
judgment

As the Ninth Circuit explained:

no requirement
opinions be “developed
independently”

wrongly conflated
standards for
publication

animal and
epidemiological studies
not necessary

case studies are useful
in “support[ing] other
proof of causation”

no need to identify the
exact “mechanism
whereby a particular
agent causes a
particular effect”

“We do not require
experts to eliminate all
other possible causes of
a condition”



Hardeman v Monsanto Co., 997 F. 3d 941 (9th Cir. 2021)

The Roundup case – non Hodgkin's lymphoma

Denied motion to exclude Plaintiff's expert testimony

the district court's slight "deference to experts" with "borderline ... opinions" was proper under Daubert

Supreme Court directive has not changed in 28 years



*Wendell v.
GlaxoSmithKline LLC,*
858 F.3d 1227, 1233
(9th Cir. 2017)

Too Narrow

Did not account for broad picture overall
methodology

All together, the mistakes warrant reversal

Excessively atomistic analysis



Evaluation of Evidence

- **Holistically**
 - Forming a coherent mental representation of the case
- **Atomistically**
 - Assessing the probative value of each item of evidence

Excessive Atomism: A Tale of 2 possible errors

- ***Evidentiary:***

- “a brick is not a wall”
- Aggregation of multiple items of evidence, no one of which establishes causation alone
- a “smoking gun”

- ***Scientific:***

- Scientists can and do aggregate
- formal and methodologically rigorous
- informal or collective engagements by experts

On the one hand:

- **Excessively atomistic analysis**
- **Analyzes each item of evidence**
- **Inadequate assessment of total “weight of evidence”**



on the other hand:



- **Limitations in the aggregate**
- **Too many limitations**
- **Not adequate scientific basis**

*In re Incretin-
Based Therapies
Prods. Liab. Litig.*,
No. 21-55342,
2022 WL 898595
(9th Cir. Mar. 28,
2022).

- 9th Circuit affirmed exclusion of expert testimony
- Distinguished expert testimony from *Wendell*
 - no differential diagnosis
 - no opinions on specific causation
 - expert purported “weight of the evidence” methodology
 - no means to ensure conclusions were not mere subjective beliefs or speculation
 - expert was “alone” in his opinion

“The task at hand”

Legal criticism of the 9th
Circuits analysis

**The focus on whether the
scientific basis supports
the particular, concrete
testimony offered in court
was referred to the “task
at hand.”**

Both *Wendell* and
Hardeman involve
individual medical
causation testimony

Medical causation testimony

Two sperate levels of analysis:

General causation

- Whether scientific support exists for the proposition that a particular drug or substance can cause the illness

Specific causation

- Support for the proposition that a particular drug or substance caused the particular instance of that illness in this case

Amendments to FRE 702

Advisory Committee on Evidence Rules unanimously approved

Clarify the applicable standard of admissibility

Emphasize the importance of applying methods and principles to the facts of the case



Take effect by December 1, 2023

Amendments to FRE 702

- The amendment is as follows (the additional text is underlined and the deleted text is lined through):
 - 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 the proponent has demonstrated by a preponderance of the evidence that:
 - 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
 - the testimony is based on sufficient facts or data
 - the testimony is the product of reliable principles and methods
 - the ~~expert has reliably applied~~ expert's opinion reflects a reliable application of the principles and methods to the facts of the case

“the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.”

Althen v. HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005)

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