

Appendix I (Rose, May 2021)

BRANDON HILL CRITERIA FOR CAUSALITY SUMMARIZED:

Data source: VAERS/Analysis: Dr. Jessica Rose

Evidence of causation using Bradford Hill

2/5/22

1. **Strength (effect size):** A small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal.
2. **Consistency (reproducibility):** Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect.
3. **Specificity:** Causation is likely if there is a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship.
4. **Temporality:** The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay).
5. **Biological gradient (dose-response relationship):** Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence.
6. **Plausibility:** A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism is limited by current knowledge).
7. **Coherence:** Coherence between epidemiological and laboratory findings increases the likelihood of an effect. However, Hill noted that "... lack of such [laboratory] evidence cannot nullify the epidemiological effect on associations".
8. **Experiment:** "Occasionally it is possible to appeal to experimental evidence".
9. **Analogy:** The use of analogies or similarities between the observed association and any other associations.
10. **Reversibility:** If the cause is deleted then the effect should disappear as well.

CRITERIA 1: STRENGTH OF ASSOCIATION: Here we see a strong x-square association as see by the low P value:

Data source: VAERS/Analysis: Dr. Jessica Rose

Strength of association: Is A strongly associated with B?

2/5/22

"Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase"

	Moderna	Placebo	Total
SAE	83	31	114
No SAE	15101	15131	30232
Total	15184	15162	30346
%	0.5	0.2	

RR= 2.67 (0.37)
OR= 2.68 (0.37)
P= 0.00000111

SIGNIFICANT

CRITERIA 1: STRENGTH OF ASSOCIATION: Here we see a strong correlation as measured by a very high R value.

Data source: VAERS/Analysis: Dr. Jessica Rose

Strength of correlation: Is A strongly correlated to B?

2/5/22

DOSES vs DISABILITIES in VAERS by STATE

$R=0.99, p < 0.05$

$R = 0.99, p < 2.2e-16$
 $y = 20 + 2.1 \times 10^{-5} x$

DOSES ADMINISTERED

DISABLED (N)

Data source: VAERS Domestic Data/Analysis: Dr. Jessica Rose

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CRITERIA 2: CONSISTENCY: Comparing three major data bases (VAERS, Yellow Card, and EVS) we see that each show remarkably high numbers (over one million in each) of adverse events. This has never been the case in the past for any of these systems for a single product. This illustrates consistency.

Data source: VAERS/Analysis: Dr. Jessica Rose

Consistency: Do all the existing data indicate that A causes B?

2/5/22

VAERS ABSOLUTE COUNTS

766,623 (1,055,858)

The first number of the absolute count for Domestic data and the bracketed number is the total combined with the Foreign data. Note, these numbers represent the individuals who filed reports. The red boxes indicate greater than 200,000 VAERS IDs reported.

YELLOW CARD SUMMARY TO 8TH DECEMBER 2021

1,331,470 REPORTS

	France/ Belgium	Italy/Switzerland	Germany	Unspecified	Total
Report Start Date	08/01/2020	08/01/2020	07/04/2021	n/a	n/a
First Doses Administered	24.8 million	24.9 million	1.8 million	n/a	51.2 million
Second Doses Administered	21.2 million	24.1 million	1.4 million	n/a	46.7 million
Reactions Administered				21.7 million	21.7 million
Adverse Reactions	408,204	408,204	73,853	4,677	1,331,470
Deaths	655	5,149	19	38	5,853

New reactions this week > 16,801 New deaths this week > 31 Data source: 10/15

EudraVigilance System – 1,304,635 reports up to December 25th, 2021

2. **Consistency (reproducibility):** Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect.

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CRITERIA 3: SPECIFICITY: There are specific populations known to be healthy (athletes, and young children) who have had a spike in cardiac events explainable by the vaccine

Data source: VAERS/Analysis: Dr. Jessica Rose

Specificity: Is A causing B in specific populations?



Since December 2020, 183 professional athletes and coaches have suddenly collapsed, with 108 dead.

Background rate is 5 deaths per year.

Parys Haralson died suddenly and unexpectedly at 37.

2/5/22

11:22

3. **Specificity:** Causation is likely if there is a very specific population at a specific site and disease with no other likely explanation.

Data source: VAERS/Analysis: Dr. Jessica Rose

Specificity

Myocarditis background rate is 1/100,000 per year for children 12-15.

Expected vs. Observed reports after Pfizer-BioNTech dose 2, 7-day risk period (N=549)^a

Age group, years	Females		Males	
	Cases of myocarditis, expected	Cases of myocarditis, observed	Cases of myocarditis, expected	Cases of myocarditis, observed
12-15*	0-3	12	1-5	116
16-17*	0-2	15	0-3	120
18-24*	0-5	11	1-7	134
25-29*	0-4	4	1-5	30
30-39	1-13	7	1-11	40
40-49	1-13	12	1-11	26
50-64	2-22	9	2-19	5
65+	2-22	4	2-18	4

^a As of Aug 18, 2021, assumes a 7-day observation window, with 549 of 793 reports after mRNA vaccine occurring during Days 0-6 after vaccination, counts among 12-17 years from reports meeting case definition for myocarditis; expected estimates for females 12-17 years adjusted to reflect reduced incidence in this age group.

This is taken directly from the ACIP meeting COVID-19 Vaccines on August 30, 2021, By John Su.

2/5/22

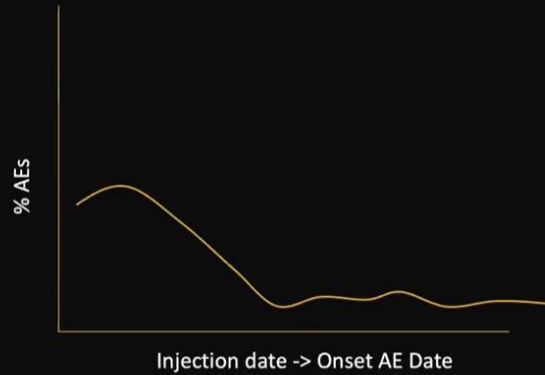
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CRITERIA 4: TEMPORALITY: These frequency time plots show 80% of all events occurring within the first few days, with frequencies well above the expected rate. The calculations yielded highly statistically significant results for deaths ($p < .001$), hospitalizations ($p < .001$), emergency visits ($p < .001$), cardiovascular events ($p < .001$), and neurologic events ($p < .001$).

Data source: VAERS/Analysis: Dr. Jessica Rose

Temporality: Does A come before B?

2/5/22

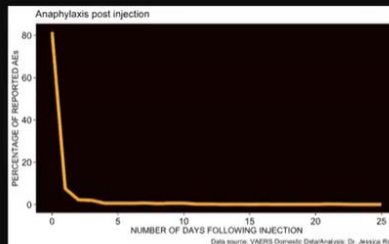


4. Temporality: The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay)

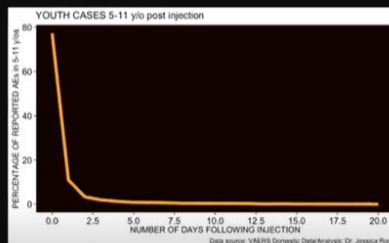
Data source: VAERS/Analysis: Dr. Jessica Rose

Temporality

2/5/22



- 87% of reports made within 24 hours
- 92% made within 48 hours



- 73% of reports made within 24 hours
- 84% made within 48 hours

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Figure 8.1 Time series plot — Percentage of reported deaths by time elapsed between the injection date and the reported adverse event

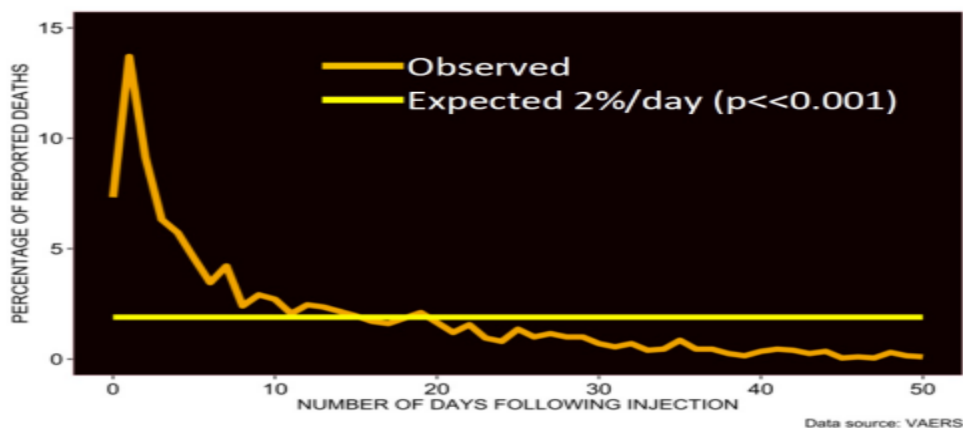


Figure 8.2 Time series plot — Percentage of reported hospitalizations by time elapsed between injection date and adverse event

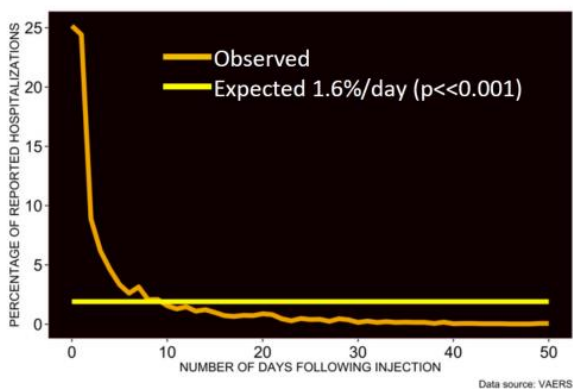


Figure 8.3 Time series plot — Percentage of reported emergency doctor visits by time elapsed between injection and adverse event

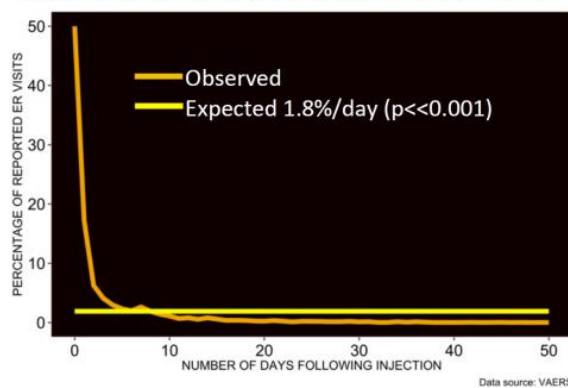


Figure 9.1 Time series plot — Percentage of reported cardiovascular AEs by time elapsed between injection date and adverse event

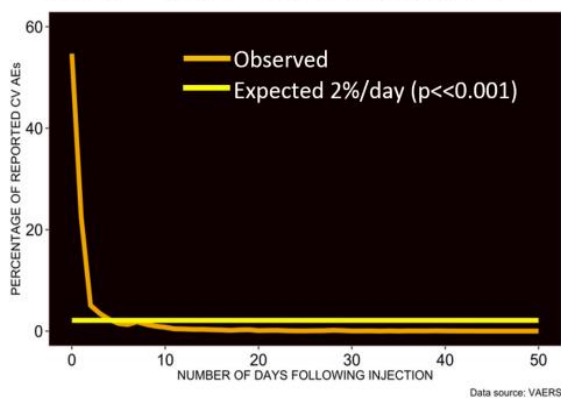
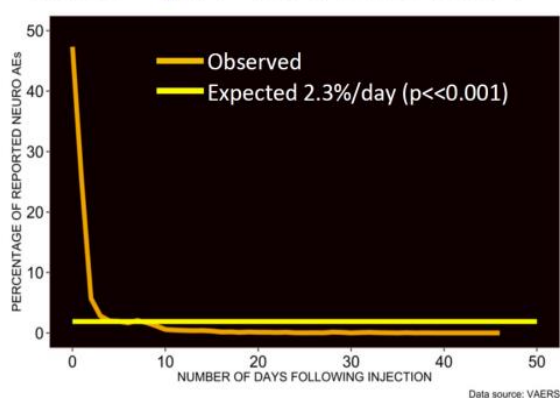
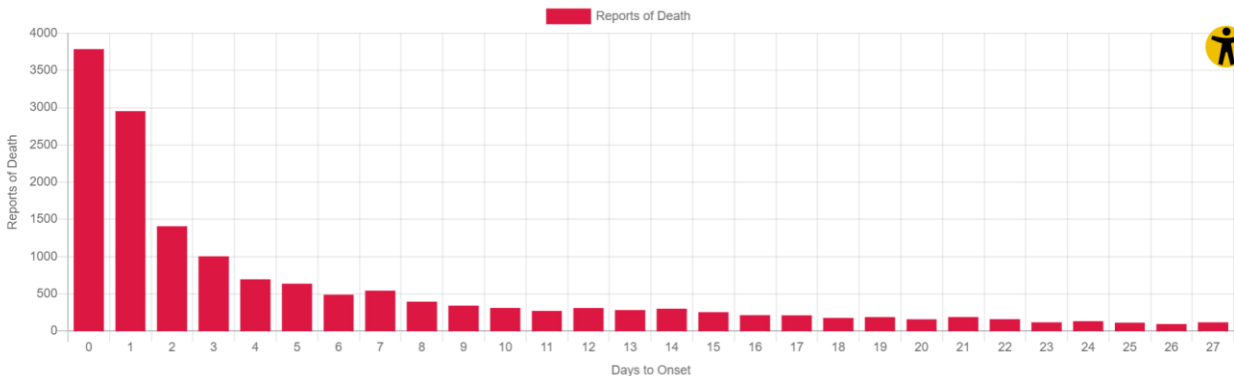


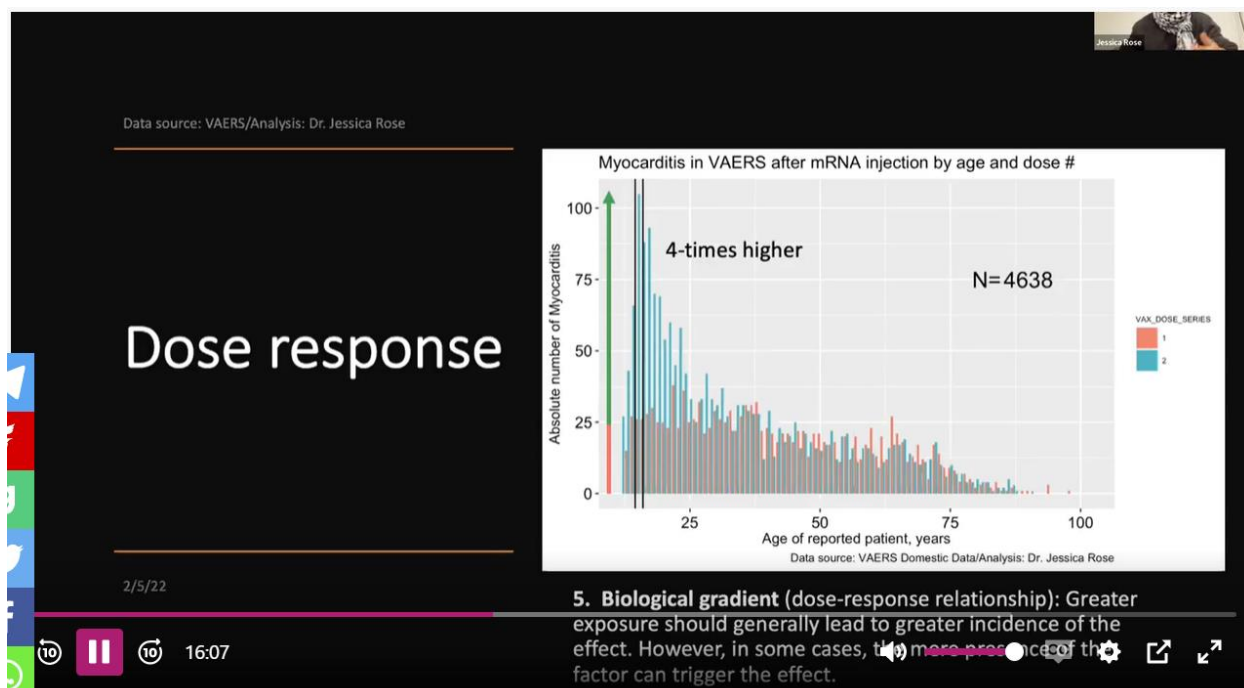
Figure 9.2 Time series plot — Percentage of reported neurological AEs by time elapsed between injection date and adverse event



Another way to illustrate temporality is found on the OPENVAERS website which shows 80% of all deaths occurring within the first week after vaccination: (<https://openvaers.com/covid-data>)



CRITERIA 5: DOSE RESPONSE: This data showed an increase rate of myocarditis relative to the number of injections given.



CRITERIA 6: PLAUSIBILITY: Both the spike protein and the lipid nanoparticle are highly toxic (see later discussion) and provide a plausible explanation for these adverse events

Data source: VAERS/Analysis: Dr. Jessica Rose

Plausibility: Is it biologically plausible that A can cause B?

2/5/22

Dual mechanism of action

1. Spike proteins
2. Lipid Nano Particles

6. Plausibility: A plausible mechanism between cause and effect is helpful.

The lipid nano particle contains highly toxic cationic lipids:

Data source: VAERS/Analysis: Dr. Jessica Rose

Plausibility

2/5/22

ALC-0315 mRNA LNP formulation ALC-0159

Cationic/ionizable lipids
e.g., DOTMA, DOTAP / MC3, C12-200

- nucleic acids complexation
- membrane fusion

Structural helper lipids
e.g., DSPC, DPPC

- bilayer support

Cholesterol

- integrity
- endosomal release

"Stealth" PEG lipids
e.g., DSPE-PEG, DMPE-PEG

- hydrophilic surface
- steric hindrance

lipid bilayer structure inverted hexagonal structure

SARS

LNPs

CRITERIA 7: COHERENCE: There is coherence between the epidemiological data and the clinical trial lab data.


Data source: VAERS/Analysis: Dr. Jessica Rose

Coherence: Does it make sense that 'A' can cause 'B'?

2/5/22

7. **Coherence:** Coherence between epidemiological and laboratory findings increases the likelihood of an effect. However, Hill noted that "... lack of such [laboratory] evidence cannot nullify the epidemiological effect on associations".

Moderna clinical trial lab data
vs.
Epidemiological – VAERS



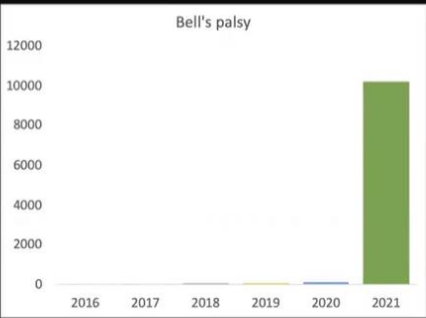
Data source: VAERS/Analysis: Dr. Jessica Rose

Coherence

2/5/22

Adverse events n (%)	Placebo	mRNA-1273	Rate ratio	Total
Overall	N=15162	N=15184		N=30346
Facial paralysis	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
218-65 yrs	N=11411	N=11415		N=22826
Facial paralysis	3 (<0.1)	5 (<0.1) ^a	-	8 (<0.1)
≥65 yrs	N=3751	N=3769		N=7520
Facial paralysis	0	3 (<0.1) ^a	-	3 (<0.1)
Serious				
Facial paralysis	0	1 (<0.1)		1 (<0.1)

Treatment-emergent adverse event (TEAE) defined as any event not present before exposure to study vaccination or any event already present that worsened in intensity or frequency after exposure. Percentages are based on the number of safety set participants. The rate ratio was calculated as the ratio of the percentage of participants who reported the event in mRNA-1273 divided by that in placebo; 95% CI was calculated using the Miettinen and Nurminen method. ^a All severe (grade 3) male, 56 yrs, white, SARS-CoV-2 negative, not treatment-related, recovering/resolved, concomitant meds, follow-up time 2nd dose=179 days. ^b All severe (grade 3-4) female, 67 yrs, white, SAE criteria, not treatment-related, recovered/resolved, concomitant meds, follow-up time 2nd dose=172 days and 2) male, 73 yrs, white, not treatment-related, recovered/resolved, concomitant meds, follow-up time 2nd dose=172 days. MedDRA version 23.0. Data-cutoff date: March 26, 2021.



Moderna trial

VAERS



7

Data source: VAERS/Analysis: Dr. Jessica Rose

Experiment: Is A causing B disease etiology?

2/5/22

The claim is that a RCT is the best way to determine if causal relationships exist -> testing if drug works with minimal bias.

8. Experiment: "Occasionally it is possible to appeal to experimental evidence"

Jessica Rose

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8

Data source: VAERS/Analysis: Dr. Jessica Rose

Experiment

2/5/22

VAERS AE data for 2021 - non-COVID vs. COVID reports

Category	Value
non_COVID	2631
COVID	798460

VAERS death AE data for 2021 - non-COVID vs. COVID reports

Category	Value
non_COVID	36
COVID	12635

Jessica Rose

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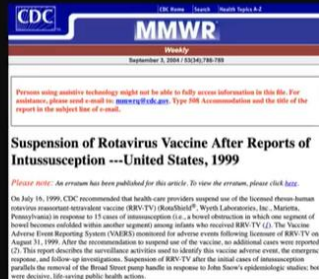
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Data source: VAERS/Analysis: Dr. Jessica Rose

Analogy

2/5/22

Rotavirus vaccine and intussusception



9. **Analogy:** The use of analogies or similarities between the observed association and any other associations.

Data source: VAERS/Analysis: Dr. Jessica Rose

Reversibility: If A stops, does B stop?

2/5/22

Not even the placebo group did well in Moderna trials. What did they use? Saline or LNPs without mRNA payload?

Table S24. Bell's Palsy in Overall Safety Set and By Age Group

Adverse events n (%)	Placebo	mRNA-1273	Rate ratio	Total
Overall	N=15162	N=15184		N=30346
Facial paralysis	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
≥18-<65 yrs	N=11411	N=11415		N=22826
Facial paralysis	3 (<0.1)	5 (<0.1)*	-	8 (<0.1)
≥65 yrs	N=3751	N=3769		N=7520
Facial paralysis	0	3 (<0.1)†	-	3 (<0.1)
Serious	0	1 (<0.1)		1 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)

Treatment-emergent adverse event (TEAE) defined as any event not present before exposure to study vaccination or any event already present that worsened in intensity or frequency after exposure. Percentages are based on the number of safety set participants. The rate ratio was calculated as the ratio of the percentage of participants who reported the event in mRNA-1273 divided by that in placebo. 95% CI was calculated using the Miettinen and Nurminen method. *1 AE severe (grade 3): male, 56 yrs, white, SARS-CoV-2 negative, not treatment-related, recovering/resolving, concomitant meds, follow-up time 2nd dose=179 days. †2 AE severe (grade 3): 1) female, 67 yrs, white, SAE criteria, not treatment-related, recovered/resolved, concomitant meds, follow-up time 2nd dose=172 days and 2) male, 73 yrs, white, not treatment-related, recovered/resolved, concomitant meds, follow-up time 2nd dose=172 days. MedDRA version 23.0. Data-cutoff date: March 26, 2021.

We won't know if these products are UNSAFE until we STOP giving them to people. THAT'S JUST THE WAY IT GOES.

10. **Reversibility:** If the cause is deleted then the effect should disappear as well.