

## Representing the use of rule-based presumptions in legal decision documents

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This article discusses rule-based presumptions that are authoritatively established, as distinct from other types of presumptions that are generalization-based or policy-based. It first introduces some legal distinctions that are used to define presumptions in law, and then presents extended examples of legal presumptions drawn from the statute and case law governing compensation for vaccine-related injuries in the USA. It proposes a formal method of representing rule-based legal presumptions that utilizes a three-valued, default logic. Finally, it uses the vaccine-injury compensation cases and the concept of legal presumption to explore difficulties in determining the burdens of production and persuasion, the meaning of legal terms in propositions to be proved and the inferences to be drawn from them.

*Keywords:* Presumptions; factfinding; legal decision documents; vaccine compensation; evidence law; burden of proof; burden of production; burden of persuasion.

### 1. Introduction

This article addresses the problem of formally representing the use of rule-based presumptions, as that use appears in judicial or administrative legal decisions. The article first summarizes (in Section 2) some standard legal terminology and distinctions that are relevant to understanding presumptions, and then defines (in Section 3) ‘rule-based’ presumptions. Section 4 introduces the statutory system in the USA for adjudicating compensation claims that are based on injuries allegedly caused by covered vaccines, under which at least one method of proving causation clearly involves invoking a presumption. In contrast, a second method of proving causation in such cases presents difficulties for the concept of presumption. Section 5 presents a formal representation for the use of rule-based presumptions in legal decisions, and Section 6 explores and resolves the difficulties with the second method of proving causation in vaccine cases, and argues that it also involves a legal presumption.

### 2. Basic Terminology and Distinctions

This article concerns legal presumptions in civil or administrative cases in which the standard of proof is preponderance of the evidence, and therefore excludes consideration of presumptions that reflect due process requirements in criminal cases.

Ordinary dictionary definitions of ‘presumption’ include ‘a belief or assumption based on reasonable evidence’ (Collins English Dictionary, 2003) or ‘belief on reasonable grounds or probable evidence’ (Random House Kernerman Webster’s College Dictionary, 2010). In law, the term has taken on a more specialized meaning, such as ‘an inference permitted as to the existence of one fact from proof

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of the existence of other facts' (Random House Kernerman Webster's College Dictionary, 2010), and 'a rule of law, statutory or judicial, by which finding of a basic fact gives rise to existence of presumed fact, until presumption is rebutted' (Black's Law Dictionary, 1979, citing *Van Wart v. Cook*, Okl.App., 557 P.2d 1161, 1163).

### 2.1 Formal Structure of a Presumption: First Approximation

The formal logical structure of a legal presumption, therefore, is that it is a logical conditional: 'if  $p$ , then  $q$ ', where the antecedent  $p$  is often called the 'basic fact' and the consequent  $q$  is often called the 'presumed fact'. Of course, this is the formal logical structure of any inference, and a presumption is an inference of a certain sort. We can say generally that a presumption is an inference of the form 'if  $p$ , then  $q$ , unless not- $q$ ', which means that if  $p$  is proven to be true, then  $q$  is inferred to be true by default (in the absence of further evidence), unless  $q$  is in fact not true (based on other evidence). I will call the negation not- $q$  the 'defeater proposition' for the presumption. Moreover, the definition assumes that  $p$  is not equivalent to  $q$ , nor does  $p$  entail  $q$ —for in those cases the inference is tautological and we would not consider it a presumption. Formally, we can say that the basic logical structure of a presumption in law is: 'if  $p$  is proved to be true, then  $q$  is presumed to be true, unless not- $q$  . . .'. What wording goes in this final ellipsis about non- $q$  depends upon our theory of a 'presumption' in a legal context, which will be discussed in the remainder of this section.

### 2.2 Burdens of Production and Persuasion, Issues of Law and of Fact

Legal practice makes use of the distinction between: (1) a party's having a burden of producing such evidence as is sufficient to enable a reasonable factfinder to find an issue of fact in favour of that party (the 'burden of production' to come forward with 'sufficient evidence'); and (2) a party's having the burden of persuading the factfinder by a preponderance of the relevant evidence, which entails the party's losing on that issue if the probative value of the evidence is in equipoise (the 'burden of persuasion' by the 'more likely than not' standard) (Hazard *et al.*, 2011, pp. 458–64; Mueller and Kirkpatrick, 2003, pp. 101–09; Wright *et al.*, 2013, § 5122).

Whether or not a party has satisfied its burden of production is an issue of law to be decided by the presiding judge, while the question of whether a party has satisfied its burden of persuasion is an issue of fact to be decided by the factfinder<sup>1</sup> (Hazard *et al.*, 2011, pp. 458–61, 472–78). In systems or proceedings where the same individual plays the roles of presiding official and factfinder (e.g. administrative adjudications, bench trials), the distinction between issues of law and issues of fact is still maintained, since different questions may still be governed by different procedural rules and may trigger different standards of review (Hazard *et al.*, 2011, p. 459).

### 2.3 Probative Value of Evidence

This article presupposes that the probative value of the totality of evidence relevant to any particular issue of fact in a case can be graded into three categories. First, the evidence might be so inadequate as to be legally insufficient as a matter of law—i.e., it fails to satisfy the party's burden of production

<sup>1</sup> The article addresses presumptions within adjudicatory systems that recognize a clear distinction between issues of law and issues of fact. Presiding judges or other presiding officials decide issues of law, and appellate courts generally use a *de novo* standard of review, without deference to the conclusions of law of the tribunal of first instance. Factfinders decide issues of fact, and reviewing judges generally give findings of fact a very deferential standard of review (Hazard *et al.*, 2011, pp. 476–78).

(Hazard *et al.*, 2011, p. 478). In effect, the court rules that, given only this evidence, no reasonable factfinder could find for the party with the burden of production. I will call this ‘legally insufficient evidence’, or simply ‘insufficient evidence’. Second, the evidence might be legally sufficient, and some reasonable factfinder could decide the issue for the party with the burden of persuasion, but a reasonable factfinder might also decide against that party. In this situation, the evidence must be presented to the factfinder for assessment and findings of fact. I will call this ‘sufficient but inconclusive evidence’. Third, the evidence might be so cogent and compelling as to be conclusive, in the sense that any reasonable factfinder would decide in favour of one party, so that giving the issue to the factfinder is unnecessary. Courts sometimes say that they can decide issues supported by such evidence ‘as a matter of law’, without involving the discretion of the factfinder. I will call this ‘conclusive evidence’ (Wright *et al.*, 2013, § 5122).

For every factual issue in a legal case, the party with the burden of production tries to produce sufficient evidence for the factfinder to decide the issue, even if that evidence is only inconclusive. It would be better, of course, to produce conclusive evidence, which presents no need to take a chance on a factfinder’s decision.

#### 2.4 *Theories of Presumptions in Law*

These distinctions (between the burden of production and the burden of persuasion, between issues of law and issues of fact, and among the different grades of probative evidence) lead to a range of theories of presumptions in law, within which there are three principal theories.

Under the first, traditional theory, a legal presumption shifts the burden of production (and only a burden of production) with respect to the negation of the presumed fact to the opponent: ‘if the proponent proves *p* to be true, then *q* is presumed to be true, unless the opponent has produced sufficient evidence for a reasonable factfinder to find not-*q*.’ Under this traditional interpretation, the presumption itself ‘disappears’ from the case (does no more inferential work) once the presiding judge decides that the party opposing the presumption has produced sufficient evidence for a reasonable factfinder to find that *q* is not true. Once the presumption disappears, the factfinder is to choose between *q* and not-*q* solely on the basis of the relevant evidence in the legal record of the case. Thayer and Wigmore espoused this theory of legal presumptions (Giannelli, 2009, pp. 58–59; Wright *et al.*, 2013, § 5122.1).

The theory at the other extreme is that the presumption continues to do inferential work in a case even after the opponent produces sufficient evidence, and the presumption places upon the opponent a burden of persuasion with respect to not-*q*, as well as a burden of production. Formally, ‘if the proponent proves *p* to be true, then *q* is presumed to be true, unless the opponent proves not-*q* to be true’. Under this theory, even after the opponent produces sufficient evidence of not-*q*, the presumption continues to have effect until such time as the factfinder decides that not-*q* is true. (In cases where the evidence of not-*q* is conclusive, the judge may find not-*q* ‘as a matter of law’.) This interpretation is normally identified with Morgan and McCormick, as a ‘reform view’ that considered the traditional view to give too little inferential effect to presumptions (Mueller and Kirkpatrick, 2003, p. 111; Wright *et al.*, 2013, § 5122.1).

There are various theories intermediate to these two extremes (Giannelli, 2009, p. 60; Wright *et al.*, 2013, § 5122.1), such as leaving the burden of persuasion about *q* with the proponent, but letting the case go to the jury on the basis of evidence that is legally sufficient to prove *p* (the basic facts) and giving an instruction to the jury (when the factfinder is a jury) that structures a legally permissible

inference for them without using the word ‘presumption’. For example, the jury could be instructed along these lines: ‘if you find *p* to be true, by a preponderance of the evidence, then you may also find *q* to be true, but the burden of persuading you as to *q* remains on the proponent of the inference’ (a statement of a permissive inference). This appears to be the default rule in civil proceedings in US federal courts under Federal Rule of Evidence 301. See Federal Rule of Evidence 301 and its Conference Committee Report (Wright *et al.*, 2013, §§ 5121, 5122.2).

Of course, when the factfinder is the judge (in a bench trial) or an administrative law judge (in an administrative adjudication), such an instruction is unnecessary, and the continuing inferential effect of a presumption is more difficult to formulate.

What is clear is that defining what a presumption is in law is tied to the procedural options with respect to assigning burdens of production and persuasion on the constituent factual issues.

### 3. Rule-based Presumptions

This article discusses presumptions that are ‘rule-based’, as contrasted with presumptions that are generalization-based or policy-based. A rule-based presumption is one established by legal authority as a rule binding upon some participant in the legal process.

As applied to the distinctions in Section 2, a rule-based presumption about the burden of production is a rule binding on presiding officials when they make rulings on motions addressing the sufficiency of evidence. A presumption can provide a blueprint and a guarantee for evidence production: If the party with the burden of production produces sufficient evidence for a reasonable factfinder to find the antecedent conditions (basic facts) of the presumption in that party’s favour, then the presumption might guarantee (as a matter of law) that the party has produced sufficient evidence to satisfy its burden of production on the consequent condition (presumed fact). In such a situation, the presumption is a rule binding on the official presiding at the hearing (e.g. the judge) when she makes her decision about whether the party has failed to produce sufficient evidence (e.g. in ruling on a motion to dismiss a claim).

A rule-based presumption about the burden of persuasion is a rule binding on the factfinder when the factfinder weighs the probative value of the evidence and arrives at a finding. If a party has the burden of persuasion, then unless the factfinder weighs the probative value of the evidence in favour of that party, that party must lose on the issue (as a matter of law). In this situation, the presumption is a rule binding on the factfinder in deciding the merits of the case on the evidence.

Both types of rules must be established by legal institutions that have the authority to adopt binding rules—e.g. the legislature and the executive (adopting rules in statutes), administrative agencies (adopting rules in administrative regulations) and appellate courts (adopting rules in case decisions). Whether or not the presiding official or the factfinder has complied with the binding rule might itself provide an issue of law to be decided in a particular case.

There are several grounds or policies that might justify adopting a presumption (Giannelli, 2009, p. 57; Mueller and Kirkpatrick, 2003, pp. 113–17; Wright *et al.*, 2013, § 5122.1). One is a desire to assist one party in proving the presumed fact *q* in situations where evidence is normally lacking—e.g. a presumption that someone missing without tidings, for some fixed period of time, is dead (Mueller and Kirkpatrick, 2003, p. 117). Another justification might be that the opposing party has better access to the evidence—e.g. a presumption that if goods were turned over to a bailee in good condition and were returned in damaged condition, then the bailee’s negligence caused the damage (Mueller and Kirkpatrick, 2003, p. 110). Or the adopting authority might be codifying what it determines to be

the normal probabilities in the situation, so as to obviate the need to waste trial resources on attempting alternative modes of proof—e.g. a presumption that if someone with black lung disease worked in a coal mine for at least 10 years, then the disease came from mining (Mueller and Kirkpatrick, 2003, p. 114). As the previous example suggests, presumptions may also be adopted to further substantive policies—e.g. a presumption that if there was a marriage ceremony, or if a man and woman lived as spouses and considered themselves to be married, then there is a valid marriage that continues in force (Mueller and Kirkpatrick, 2003, p. 117).

Not all presumptions found in legal decisions, however, are rule-based. Factfinders, who by definition have no authority to adopt legal rules that are binding on anyone, might adopt presumptions for themselves that are based on generalizations or probabilities. This is particularly evident when repeat factfinders who decide multiple cases involving similar issues (e.g. judges or special masters) use the same default inferences for assessing the evidence. They might also adopt presumptions for themselves that are based on legal policies or principles relevant to the area of law, regardless of the statistics or probabilities involved. This article addresses only rule-based presumptions that legal authorities have adopted as binding.

#### 4. Statutory Example of a Rule-based Presumption

This section presents an example of a rule-based presumption in the USA taken from the National Childhood Vaccine Injury Act of 1986 ('Vaccine Act'), which established the Vaccine Injury Compensation Program (VICP), Pub. L. No. 99-660, Title III, 100 Stat. 3755 (1986) (codified at 42 U.S.C. §§ 300aa-10–300aa-34 (2012)). It first outlines the adjudicatory system established by the statute, and then sets forth the statutory language concerning causation. It then discusses the statutory presumption of causation, and contrasts it with an alternative statutory method of proving causation.

##### 4.1 *The Statutory System of Adjudication*

If a person has sustained an injury caused by a vaccine covered by the VICP, then the programme provides compensation out of the Vaccine Injury Compensation Trust Fund, which is funded by an excise tax on each dose of covered vaccine<sup>2</sup> (Walker, 2009, p. 8). Petitioners seeking compensation file claims against the Fund in the Court of Federal Claims. In the case of claims that are contested by the government, the issues of fact are decided by one of eight special masters in the Office of Special Masters, which Congress established for this purpose within the Court of Federal Claims (Walker, 2009, pp. 8–11; Walker *et al.*, 2013, pp. 2–3).

In contested cases, the critical issue is often causation: whether the vaccination caused the injury or adverse condition alleged by the petitioner. The statute establishes substantive legal rules governing the issue of causation, and the Supreme Court of the United States and the U.S. Court of Appeals for the Federal Circuit have jurisdiction to interpret those statutory provisions, and thereby to establish binding rules for adjudications under the Vaccine Act. Court of Federal Claims decisions do not create legal rules binding on other decisions of the same court on other claims, nor do decisions by special masters create rules binding on other special masters (Walker *et al.*, 2013, pp. 5–9, 12).

<sup>2</sup> The Vaccine Injury Compensation Trust Fund is established under 26 U.S.C. § 9510 (2012), and payment of compensation from that Fund is authorized by 42 U.S.C. § 300aa-15(i)(2) (2012). See also US Department of Health and Human Services, Health Resources and Services Administration, Vaccine Injury Compensation Trust Fund, [http://www.hrsa.gov/vaccinecompensation/VIC\\_Trust\\_Fund.htm](http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm).

Special masters deciding contested issues of fact follow rules of procedure designed to ‘provide for a less-adversarial, expeditious, and informal proceeding’ (§ 300aa-12(d)(2)) and are not bound by the Federal Rules of Evidence (see *id.*, Vaccine Rule 8(b)(1): ‘In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties’). ‘The special master’s role is to apply the law. Questions of law regarding the interpretation or implementation of the Vaccine Act are matters for the courts.’ *Althen v. Sec. of Health & Human Serv.*, 418 F.3d 1274, 1280 (Fed.Cir. 2005). The statute requires special masters to issue decisions that ‘include findings of fact and conclusions of law’ (§ 300aa-12(d)(3)(A)).

Section 300aa-12(e)(2) of the statute gives jurisdiction to the Court of Federal Claims to: (A) uphold the findings and conclusions of the special master and sustain the special master’s decision; (B) ‘set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law’; or (C) remand the petition to the special master for further action.

With respect to findings of fact, under § 300aa-12(e)(2)(B), the Court of Federal Claims ‘review[s] the special master’s factual findings under the arbitrary and capricious standard’. *Althen*, 418 F.3d at 1278. ‘To the extent that the Court of Federal Claims adopts factual findings made by the special master, [the Federal Circuit] accord[s] them the same deference as the Court of Federal Claims and review[s] them under the arbitrary and capricious standard as provided in the statute.’ *De Bazan v. Sec. of Health & Human Serv.*, 539 F.3d 1347, 1350–51 (Fed.Cir. 2008).

On the other hand, when ‘the Court of Federal Claims makes its own factual findings either in the first instance or when it has found the special master’s findings arbitrary and capricious, [the Federal Circuit] review[s] those findings for clear error’. *De Bazan*, 539 F.3d at 1351.

With respect to conclusions of law, the Court of Federal Claims reviews the conclusions of law reached by special masters *de novo*, without any deference, *Dobrydneva v. Sec. of Health & Human Serv.*, 94 Fed.Cl. 134, 143 (2010), and the Federal Circuit reviews ‘legal determinations of the Court of Federal Claims *de novo*’. *De Bazan*, 539 F.3d at 1350.

#### 4.2 Vaccine Act Language about Causation

Section 300aa-13 of Title 42 of the US Code provides the general rule governing the award of compensation under the VICP. The primary substantive subsection is shown in [Table 1](#).

This subsection requires that compensation be paid to a petitioner if the factfinder makes two findings: (A) that the petitioner has demonstrated by a preponderance of the evidence that the required allegations in the petition are true, and (B) that ‘there is not a preponderance of the evidence’ in the legal record that the injury ‘is due to factors unrelated to’ the vaccination. The statute places the burden of persuasion (and by implication the burden of production) with respect to (A) on the petitioner, but is silent as to which party bears a burden of production or persuasion with respect to (B). Indeed, (B) is a rather unusual rule condition, because it requires a positive finding about a lack of preponderant evidence.

In defining the *prima facie* case of a petition, § 300aa-13(a)(1)(A) refers to ‘the matters required in the petition by section 300aa-11(c)(1)’. This latter subsection sets forth various issues of fact that the petition for compensation must address, and which the petitioner must therefore prove by a preponderance of the evidence. Of particular interest here is the allegation and demonstration of causation, § 300aa-11(c)(1)(C), set out in [Table 2](#).

TABLE 1 *The general compensation rule for vaccine-injury compensation cases, 42 U.S.C. § 300aa-13(a)*

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- (1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—
- (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and
  - (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

- (2) For purposes of paragraph (1), the term ‘factors unrelated to the administration of the vaccine’—
- (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
  - (B) may, as documented by the petitioner’s evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner’s illness, disability, injury, condition or death.
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TABLE 2 *The causation rule for vaccine-injury compensation cases, 42 U.S.C. § 300aa-11(c)(1)(C)*


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A petition for compensation under the Program for a vaccine-related injury or death shall contain—

- (1) . . . an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died— . . .
  - (C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or
  - (ii)(I) sustained, or had significantly aggravated, any illness, disability, injury or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or
  - (II) sustained, or had significantly aggravated, any illness, disability, injury or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A), . . .
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This subsection provides for two alternative methods of proving that the vaccination caused the injury. The first method, set forth in (1)(C)(i) in Table 2, refers to a Vaccine Injury Table, which was originally established by the Vaccine Act itself, 42 U.S.C. § 300aa-14, and was subsequently amended administratively, 42 C.F.R. § 100.3. The Table lists (a) covered vaccines, (b) recognized injuries that might result from the administration of particular vaccines and (c) recognized time periods in which the first symptom or manifestation of onset or of the significant aggravation of such injuries must occur after vaccine administration. See 42 C.F.R. § 100.3. Under this method of proof, the statute requires the petitioner to prove, basically, (1) that the injury was ‘set forth in the Vaccine Injury Table in

association with the vaccine’ and (2) that ‘the first symptom or manifestation of the onset or of the significant aggravation’ of the injury ‘occurred within the time period after vaccine administration’ set forth in the Table. As the courts will hold (see Section 4.3 below), this creates a statutory presumption of causation in the particular case.

The second method of proving causation, see (1)(C)(ii) in Table 2, is available if the petitioner cannot prove either (I) that the injury was set forth in the Table or (II) that the first symptom or manifestation of the onset or of the significant aggravation of the injury occurred within the time period in the Table. In either of these situations, called ‘off-Table’ or ‘non-Table’ cases, the petitioner must prove that the injury ‘was caused by’ the vaccine. The courts refer to this as ‘causation in fact’ (see Section 4.4 below). With respect to the meaning of ‘caused’ in this subsection, or how to prove causation through this second method, the statute is silent. See *Shyface v. Sec. of Health & Human Serv.*, 165 F.3d 1344, 1350–51 (Fed.Cir. 1999).

#### 4.3 *The Statutory Presumption of Causation: Table Cases*

This section discusses the judicial case law interpreting the first method of proving causation, as set forth in the Vaccine Act, 42 U.S.C. § 300aa-11(c)(1)(C)(i), in combination with the dual findings required under § 300aa-13(a)(1).

The Supreme Court has summarized this first method of proof:

A claimant who meets certain other conditions not relevant here makes out a prima facie case by showing that she (or someone for whom she brings a claim) ‘sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a] vaccine . . . or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.’ 42 U.S.C. § 300aa-11(c)(1)(C)(i). Thus, the rule of prima facie proof turns the old maxim on its head by providing that if the *post hoc* event happens fast, *ergo propter hoc*.

*Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995). ‘The Vaccine Table, in effect, determines by law that the temporal association of certain injuries with the vaccination suffices to show causation.’ *Grant v. Sec. of Dept. of Health & Human Serv.*, 956 F.2d 1144, 1147 (Fed.Cir. 1992). The courts have labelled this ‘a statutorily-prescribed presumption of causation’, *Althen*, 418 F.3d at 1278.

With regard to proving that a vaccination caused a ‘significant aggravation’ of a pre-existing condition, the court in *Whitecotton* articulated a four-step test for Table cases: ‘the special master must: (1) assess the person’s condition prior to administration of the vaccine, (2) assess the person’s current condition, and (3) determine if the person’s current condition constitutes a “significant aggravation” of the person’s condition prior to vaccination within the meaning of the statute. If the special master concludes that the person has suffered a significant aggravation, the special master must . . . (4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the Table.’ *Whitecotton v. Sec. of Health & Human Serv.*, 81 F.3d 1099, 1107 (Fed.Cir. 1996).

The courts have interpreted § 300aa-13(a)(1)(B) as imposing upon the government, as the respondent in vaccine cases, a burden of production and persuasion with respect to a defence. The Supreme Court has stated that ‘[t]he Secretary of Health and Human Services may rebut a prima facie case by

proving that the injury or death was in fact caused by “factors unrelated to the administration of the vaccine . . .” § 300aa–13(a)(1)(B). If the Secretary fails to rebut, the claimant is entitled to compensation. 42 U.S.C. § 300aa–13(a)(1) (1988 ed. and Supp. V). *Whitcotton*, 514 U.S. at 270–271. As the Federal Circuit has held:

In a ‘table’ case, the petitioner has an initial burden to prove an injury listed in the Vaccine Injury Table within the prescribed time period . . . . Upon satisfying this initial burden, the petitioner earns a presumption of causation. At that point, the burden shifts to the respondent to prove that a factor unrelated to the vaccination actually caused the illness, disability, injury, or condition.

*Pafford v. Sec. of Health & Human Serv.*, 451 F.3d 1352, 1355 (Fed.Cir. 2006). ‘[I]f a petitioner has . . . obtained the benefit of a presumption, and the government cannot prove actual alternative causation for whatever reason, then the petitioner is entitled to compensation.’ *Knudsen v. Sec. of Dept. of Health & Human Serv.*, 35 F.3d 543, 547 (Fed.Cir. 1994).

Moreover, the statute places some constraints on proving the defence. In the *Knudsen* case, the petitioners successfully established a Table presumption of causation based on an encephalopathy following receipt of DTP vaccine. The government tried to establish that a viral infection unrelated to the vaccine in fact caused the encephalopathy. As the court noted, ‘[a]ccording to the statute, however, “any idiopathic, unexplained, unknown, hypothetical, or undocumented cause, factor, injury, illness, or condition” may *not* be considered a “factor [] unrelated to the administration of the vaccine” and therefore cannot defeat a petitioner’s right to recovery’. *Id.* at 547–48 (citing the Vaccine Act at § 300aa-13(a)(2)). The court held that ‘[i]f the evidence [on alternative causation] is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded’. *Id.* at 550.

#### 4.4 *The Althen Conditions for Causation-in-Fact: Off-Table Cases*

This section discusses the judicial case law interpreting the second method of proving causation, as set forth in the Vaccine Act, 42 U.S.C. § 300aa-11(c)(1)(C)(ii), in combination with the dual findings required under § 300aa-13(a)(1). As the Federal Circuit in *Shyface* noted, ‘the statute does not elaborate on the requirement of causation in the proof of a non-Table case’ under § 300aa-11(c)(1)(C)(ii), *Shyface*, 165 F.3d at 1350–51, nor does it provide guidance on how to prove that the injury ‘was caused by’ the vaccine in cases that do not qualify for the statutory Table presumption.

In *Shyface*, the Federal Circuit rejected the argument that in off-Table (‘non-Table’) cases the special masters and courts should apply ‘the law of the state in which the tort claim could have been brought’. *Shyface*, 165 F.3d at 1351. The court then held that ‘[n]ational uniformity in administration is implicit in the statutory scheme’, and that ‘[a] uniform approach, one which implements the statutory purpose, is that of the Restatement (Second) of Torts’. *Id.* Following the Restatement, the court held that the petitioner must prove ‘that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury’. *Id.* at 1352. It is not sufficient if the vaccine has an ‘insignificant effect’, but the vaccine need not be the ‘sole cause’, or even the ‘predominant cause’ of the injury. *Id.* Citing *Grant*, the court held that ‘in order to show that the vaccine was a substantial factor in bringing about the injury, the petitioner *must show* “a medical theory causally connecting the vaccination and the injury”, [and] [t]here *must be* a “logical sequence of cause and effect showing that the vaccination was the reason for the injury”’. *Id.* at 1352–53 (emphasis added). As *Grant* had

stated: ‘To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury. . . . Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.’ *Grant*, 956 F.2d at 1148 (citing *Hasler v. U.S.*, 718 F.2d 202, 205–6 (6th Cir. 1983) (*Hasler* being a Federal Tort Claims Act case involving the swine flu vaccine, applying Michigan tort law and predating the VICP).

The Federal Circuit in the *Althen* case codified and perhaps expanded the petitioner’s *prima facie* case in an off-Table, causation-in-fact case:

Concisely stated, [the petitioner’s] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If [the petitioner] satisfies this burden, she is ‘entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine’.

*Althen*, 418 F.3d at 1278 (citing *Knudsen*, 35 F.3d at 547).

The Federal Circuit explained in *Capizzano* that *Althen*’s first prong can be satisfied by the finding that the vaccine ‘can cause’ the injury. *Capizzano v. Sec. of Health & Human Serv.*, 440 F.3d 1317, 1326 (Fed.Cir. 2006). The first prong of *Althen* can be interpreted as the issue of general causation: whether the vaccine at issue can cause the type of injury alleged. See *Pafford*, 451 F.3d at 1356–57.

With respect to *Althen*’s second prong, the Federal Circuit explained in *Pafford* that ‘the second prong of the Special Master’s test in this case [i.e., “that the vaccine actually caused the alleged symptoms in her particular case”] restates correctly that the petitioner must show that the vaccine was the “but for” cause of the harm according to *Shyface*, or in other words, that the vaccine was the “reason for the injury” as stated in the second prong of the *Althen* test’. *Pafford*, 451 F.3d at 1357. Moreover, *Capizzano* was a case where there was no dispute that the *Althen* first and third prongs were satisfied (a medical theory causally connecting the vaccination and the injury, and a proximate temporal relationship between the vaccination and the injury), and the court held that

if close temporal proximity, combined with the finding that hepatitis B vaccine can cause RA [rheumatoid arthritis], demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then medical opinions to this effect are quite probative. . . . [M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether ‘a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’.

*Capizzano*, 440 F.3d at 1326.

The Federal Circuit recognizes that proving causation in fact in a vaccine case cannot require scientific or medical proof of causation:

Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of

cause and effect is ‘logical’ and legally probable, not medically or scientifically certain. . . . Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.

*Knudsen*, 35 F.3d at 548–49. The preponderance standard in the Vaccine Act envisions the use of circumstantial evidence by the petitioner in proving a *prima facie* case. ‘[T]he system created by Congress [is one] in which close calls regarding causation are resolved in favor of injured claimants’, and ‘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*, 418 F.3d at 1279–80.

Given the location in the statute of the provision establishing the defence of alternative causation (‘factors unrelated to’ the vaccination), see [Table 1](#), this defence also applies to proving the *Althen* conditions for causation. ‘[I]f a petitioner has proved actual causation . . . , and the government cannot prove actual alternative causation for whatever reason, then the petitioner is entitled to compensation.’ *Knudsen*, 35 F.3d at 547. This raises the question whether the *Althen* conditions as a method of proving causation in fact, in combination with the government’s defence of proving alternative causation, can fairly be called a ‘presumption’. This is discussed in Section 6, after the discussion in Section 5 about formally representing the use of these causation rules in vaccine cases.

## 5. Formally Representing the Use of a Rule-based Presumption in a Legal Decision Document

This section presents a formal representation for rule-based presumptions as they are used in legal decisions. It utilizes a three-valued, default-logic framework ([Walker, 2007](#), pp. 198–207; [Walker et al., 2013](#), pp. 2–5). Legal rules (including presumptions) are conditional in form (‘if . . . , then . . . ’), and multiple antecedent propositions (conditions) can be connected to each other and to the conclusion by the logical connectives ‘AND’ and ‘OR’. The connective AND means that the conclusion is true if, but only if, all of the connected conditions are true. The connective OR means that the conclusion is true if, but only if, at least one of the connected conditions is true.

Propositions functioning as conditions or conclusions have one of three truth-values: True/Undecided/False. When a legal case begins, every proposition within the rules is undecided, and opposing parties produce evidence and attempt to persuade the factfinder that any given proposition is either true or false. In a given case, the factfinder might decide, by a preponderance of the evidence, that some propositions are true and that others are false, while other propositions remain undecided. Thus, in a three-valued system, the truth of proposition *q* entails that its negation not-*q* is false, and the truth of not-*q* entails that *q* is false, but *q* and not-*q* can both remain undecided throughout the case.

A third logical connective needed to represent presumptions is ‘UNLESS’, which connects a defeater proposition (as condition) to a conclusion. If the defeater proposition is true, then the conclusion is false, even if the main *prima facie* conditions for that conclusion are true. In law, such defeater propositions often represent an affirmative defence or an exception to the general rule.

As discussed in Section 2.1, rule-based presumptions in law have the form ‘if *p*, then *q*, unless not-*q*’, where *p* does not entail *q*. The next two subsections use this formal structure to represent rule-based presumptions in vaccine cases.

### 5.1 Representing the Use of the Statutorily-Prescribed Presumption of Causation

The courts have regularly referred to the first (Table) method of proving causation in vaccine cases as a ‘statutorily-prescribed presumption’. *Althen*, 418 F.3d at 1278. In the traditional presumption terminology of Section 2, the ‘basic facts’ of the presumption are (1) that the person who is the subject of the petition ‘sustained, or had significantly aggravated’, an injury set forth in the Vaccine Injury Table in association with the vaccine (or the person died), and (2) that ‘the first symptom or manifestation of the onset or of the significant aggravation’ of that injury (or the death) occurred within the time period after vaccine administration set forth in the Vaccine Injury Table. The ‘presumed fact’ is that the vaccination caused the injury. The defeater proposition (the defence) is that the injury was ‘due to factors unrelated to the administration of the vaccine’. This presumption is triggered by the petitioner’s proving, by a preponderance of the evidence, that the basic facts are true, which in turn requires the factfinder to infer that the presumed fact is true, unless the government proves by a preponderance of the evidence that the defeater proposition is true—in which case the factfinder must conclude that the presumed fact is false. Figure 1 shows a formal representation of this presumption.

It seems clear from the wording of the statute and from the case law that proving the basic facts of this statutory presumption of causation shifts both a burden of production and a burden of persuasion to the government with respect to the defeating proposition. If there is insufficient evidence in the record to support a finding that the injury was due to factors unrelated to the vaccination, then compensation must be awarded. See § 300aa-13(a)(1). Likewise, if there is sufficient but inconclusive evidence in the record on this issue, but the factfinder does not find a preponderance of evidence for this defeating proposition, then compensation must be awarded. *Id.* Thus, the statute prescribes a strong presumption, of the type favoured by Morgan. (See Section 2.4 above.)

### 5.2 Representing the Use of the *Althen* Conditions for Causation in Fact

The Federal Circuit in *Althen* established a *prima facie* case for the second (off-Table) method of proving causation in vaccine cases. In the traditional presumption terminology of Section 2, the ‘basic facts’ that the petitioner must prove are: (1) that a medical theory causally connects the vaccination and the injury; (2) that a logical sequence of cause and effect shows that the vaccination was the reason for the injury; and (3) that a proximate temporal relationship exists between the vaccination and the injury. *Althen*, 418 F.3d at 1278. The ‘presumed fact’ is that the vaccination caused the injury. The defeater proposition (the defence) is the same as for Table cases: that the injury was ‘due to factors unrelated to the administration of the vaccine’. Figure 2 shows a formal representation of this presumption.

It is clear that proving the three *Althen* prongs to be true by a preponderance of the evidence shifts both a burden of production and a burden of persuasion to the government with respect to the defeating proposition. *Knudsen*, 35 F.3d at 547. Thus, if the *Althen prima facie* case triggers a presumption, then it is a strong type of presumption. The question arises, however, whether proving the *Althen* conditions can fairly be said to trigger a presumption at all. That is, if the elements of the *prima facie* case, taken together, prove that the injury ‘was caused by’ the vaccine, in the language of § 300aa-11(c)(1)(C)(ii), then does not this entail that the injury was not ‘due to factors unrelated to’ the vaccination, in the language of § 300aa-13(a)(1)(B)? Is the requirement that *p* not entail *q* satisfied? The next Section addresses this question.

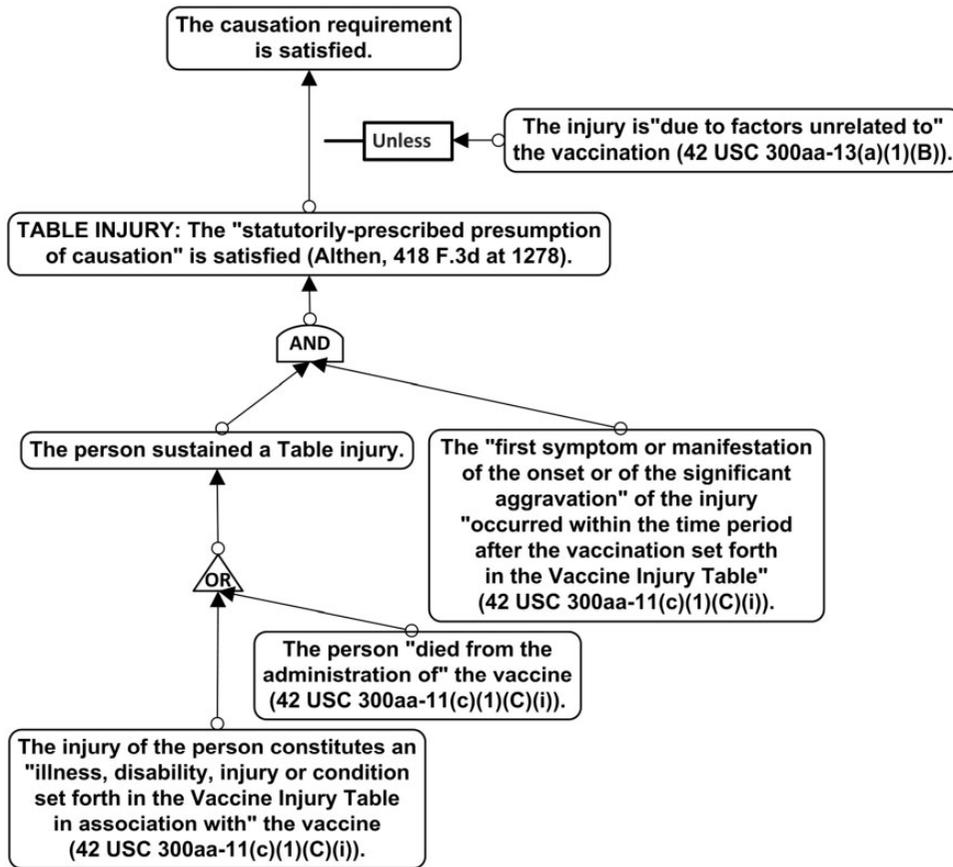


FIG. 1. Partial rule tree for vaccine decisions, showing the statutory presumption of causation and the rebutting defeater (defence).

## 6. Does *Althen* Create a Presumption?

As discussed in Section 2, a presumption has the form 'if  $p$ , then  $q$ , unless not- $q$ ', where  $p$  does not entail  $q$ . On the one hand, the elements of the *Althen prima facie* case shown in Fig. 2, together with the defence of alternative causation, would seem to have the form of a presumption. On the other hand, it might be argued that proving the three *Althen* prongs would entail that the defeater proposition not- $q$  is not true, and that the presumed fact  $q$  must be true, so that this is not a true presumption.

In fact, this puzzle about the semantics of these four propositions, and about the logical relation between the three *Althen* prongs and the defeating proposition, has caused great difficulty in vaccine cases. The burden of production and persuasion for the *Althen prima facie* case is on the petitioner, but the burden of production and persuasion on the defeating proposition is on the government. But in vaccine cases it is often the case that there is some evidence of another potential cause of the injury, other than the vaccine. Which party, therefore, has the burden to prove or disprove the causal role of

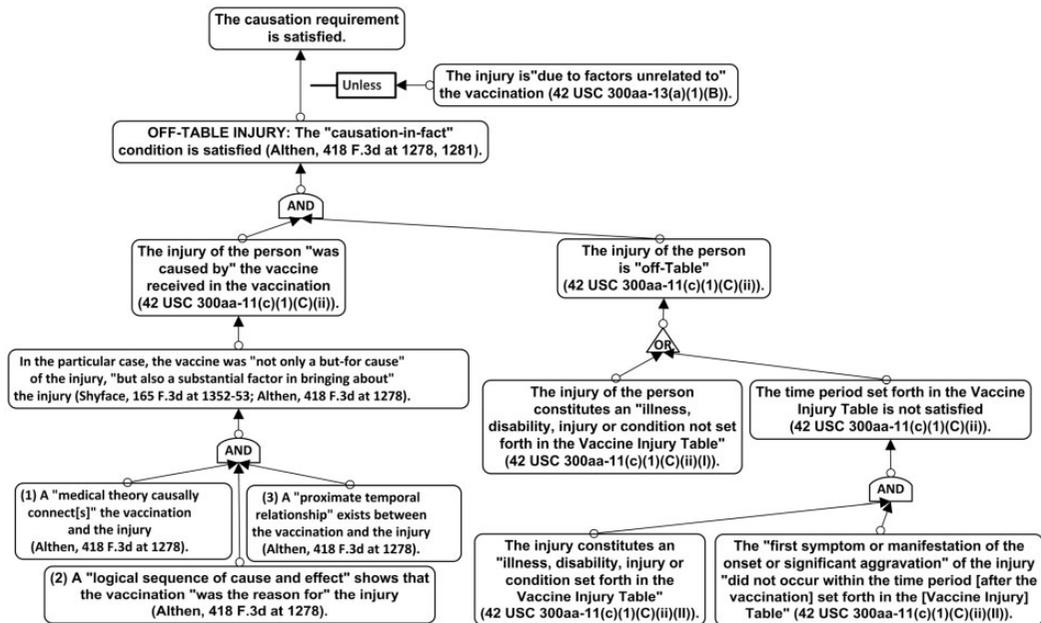


FIG. 2. Partial rule tree for vaccine decisions, showing the three causation conditions of *Althen* and the rebutting defeater (defence).

potential alternative causes? Can the government insist that the petitioner rule out all potential causes other than the vaccination? Allocating this burden can be critical in a case where too little is known about the causation of the injuries involved.

This problem can also be seen as a puzzle from the standpoint of statutory interpretation. A positive finding on the *prima facie* case (that the injury was ‘caused by’ the vaccination) would seem to entail a negative finding on the alternative-causation defeater. And a negative finding on the *prima facie* case seems to entail a positive finding on the alternative-causation defeater. See *De Bazan*, 539 F.3d at 1353 (‘It is certainly true that a finding that the administration of the vaccine was not a cause-in-fact of an injury necessarily implies that some other cause resulted in the injury, assuming the injury itself is proven.’). The third possibility—that the *prima facie* case remains undecided—also results in the petitioner losing, even though the alternative-causation defeater also remains undecided. In sum, this means that in cases involving off-Table causation in fact, the statutory requirement of a second finding is completely gratuitous and plays no role, which is unacceptable under accepted canons of statutory interpretation. See *Walther v. Sec. of Health & Human Serv.*, 485 F.3d 1146, 1150 (Fed.Cir. 2007) (stating that ‘placing the alternative causation burden on the petitioner would essentially write § 300aa-13(a)(1)(B) out of the statute’, making the provision ‘redundant or largely superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative’, and drawing the latter quote from *Colautti v. Franklin*, 439 U.S. 379, 392 (1979)).

It seems to be the case that proving *Althen* prongs 1 and 3 alone does not entail that the vaccination caused the injury or that the injury is not due to any factor unrelated to the vaccination. The trouble

arises with also proving *Althen* prong 2: establishing ‘a logical sequence of cause and effect showing that the vaccination was the reason for the injury’ in the particular case. As the court in *Capizzano* noted: ‘A claimant could satisfy the first and third prongs [of *Althen*] without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.’ *Capizzano*, 440 F.3d at 1327.

There are two possible scenarios involving multiple potential causes in vaccine cases, where the *Althen prima facie* case would not seem to entail the negation of the alternative-causation defeater. The first is when the vaccine and the alternate potential cause(s) might combine to bring about the injury, where each is a but-for cause but each alone is insufficient to cause the injury. This was the petitioner’s contention in *Shyface*, where the petitioner’s expert testified that the DPT vaccination was a but-for cause of the death, as was an *Escherichia coli* infection, and that it was the combination of the two that caused the death. *Shyface*, 165 F.3d at 1346. The court held that the petitioner did not have to prove that the vaccine was the predominant factor, only that it was a substantial factor (not an insignificant factor). See *id.* at 1352. In such a situation, the government’s defence could be that the *E. coli* infection had ‘no known relation to the vaccine involved’ and was the agent ‘principally responsible for causing’ the injury. See § 300aa–13(a)(2)(B).

On this first scenario, the court in *Walther* also discussed the possibilities: ‘The Restatement distinguishes between forces that combine to produce a harm, and forces that independently caused a harm. When a case involves multiple causes acting in concert . . . , we recognized in *Shyface* that a petitioner need not show the asserted vaccine was the predominant cause, but must show that it was substantial.’ *Walther*, 485 F.3d at 1151 note 4. The court added a caveat, however: ‘Where multiple causes act in concert to cause the injury, proof that the particular vaccine was a substantial factor may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine.’ *Id.* The court in *De Bazan* also discussed this scenario: ‘While a failure of proof that the vaccine was the cause of the petitioner’s injury suggests that some other cause was responsible, that is not equivalent to having proven by preponderant evidence that a *particular* agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor). This latter showing is the government’s burden once the petitioner has met her burden.’ *De Bazan*, 539 F.3d at 1354.

The second scenario is one in which the vaccine and the alternate potential cause(s) might be independently sufficient to bring about the injury. The *Walther* case presented such a situation, in which the courts were required to differentiate between the *Althen prima facie* case and the government’s defence. *Walther* was a captain in the U.S. Army at the time of her vaccinations. On 31 July 1997 she was vaccinated with tetanus-diphtheria (‘Td’), yellow fever, typhoid and meningitis vaccines, and on August 6 she received a rabies vaccination. *Walther*, 485 F.3d at 1146–47. On August 7 and 8 she experienced trembling in her left hand, weakness and fatigue, which led to a condition diagnosed as post-vaccinal acute disseminated encephalomyelitis (‘ADEM’). *Id.* at 1147. Of the vaccines that *Walther* received, Td was the only one listed in the Table and therefore the only one for which she could receive compensation under the VICP. *Id.* at 1149. Moreover, ADEM is not an injury listed in the Table for the Td vaccine, so *Walther* was required to prove causation in fact. *Id.*

In *Walther*, the government conceded that the petitioner satisfied the first and third prongs of *Althen*. *Id.* at 1148. The Federal Circuit held that ‘[w]hile our recent decision in *Pafford* held that a petitioner as a practical matter may be required to eliminate potential alternative causes where the petitioner’s other evidence on causation is insufficient . . . , we conclude that the Vaccine Act does not require the

petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a *prima facie* case'. *Id.* at 1149–50. '[T]he petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm. On the other hand, a petitioner is certainly permitted to use evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a *prima facie* case, as was true in *Pafford*.' *Id.* at 1151.

As the Federal Circuit stated in *De Bazan*: 'So long as the petitioner has satisfied all three prongs of the *Althen* test, she bears no burden to rule out possible alternative causes.' *De Bazan*, 539 F.3d at 1352. 'As we explained in *Walther*, we have held that a petitioner may *instead* [of proving the *Althen* prongs] rule out possible alternative causes to prove causation-in-fact when evidence as to the *Althen* requirements is insufficient.' *Id.* at 1352 note 3.

In either of these two scenarios, where multiple potential causes (including the vaccination) either act in combination or independently to bring about the injury, there may be an inferential gap between the *Althen prima facie* case and the alternative-causation defeater. '[S]uccessfully proving the elements of the *Althen* test establishes that the medical evidence indicating that the vaccine may have caused the petitioner's injury is strong enough to infer causation-in-fact *absent proof that some other factor was the actual cause*. The government then must provide that proof by identifying a particular such factor (or factors) and presenting sufficient evidence to establish that it was the sole substantial factor in bringing about the injury.' *De Bazan*, 539 F.3d at 1354 (emphasis in original).

The court in *De Bazan* pointed out that while 'the petitioner's case-in-chief concerns the medical evidence relating to the possible role the *vaccine* had in causing her injury', 'the government's burden, in contrast, concerns "factors unrelated to the administration of the vaccine described in the petition"'. *De Bazan*, 539 F.3d at 1353–54. The logical subjects of the evidence are different: the petitioner's evidence must tie the vaccine causally to the injury, while the defence must identify some other particular cause unrelated to the vaccine and tie it causally to the injury so as to defeat the petitioner's evidence. 'Thus, the government may defeat a petitioner's claim with a theory of viral infection so long as it proves that there was in fact a viral infection, and that the viral infection "in the particular case [was] . . . principally responsible for *causing* the petitioner's illness, disability, injury, condition, or death"'. *Knudsen*, 35 F.3d at 549 (citing and adding emphasis to § 300aa-13(a)(2)).

This suggests that proving the three *Althen* prongs is not equivalent to, and does not entail, disproving the alternative-causation defeater, at least where alternative potential causes are present. And if this is true, then 'was caused by' in the *prima facie* case established by § 300aa-11(c)(1)(C)(ii) is not synonymous with 'is due to' in the defence established by § 300aa-13(a)(1)(B). Therefore, the three *Althen* prongs function as a presumption.

## 7. Conclusion

This article has used the statutory language of the Vaccine Act to explore and illustrate the concept of a rule-based presumption in law. The statutorily created method of proving causation by means of the Vaccine Injury Table clearly exhibits the formal characteristics of a strong legal presumption. In contrast, the judicially adopted interpretation of the second statutory method of proving causation, the *Althen prima facie* case, at first appears not to qualify as a legal presumption, because proving the *prima facie* elements seems to entail the disproof of the defeater proposition. Upon closer examination, however, the courts have identified types of common instances where this entailment does not hold. At

least in these instances, therefore, *Althen* creates a legal presumption. This, moreover, is not mere terminology. The question whether a rule-based inference is a legal presumption can lead to critical questions about burdens of production and persuasion, the meaning of legal terms in propositions to be proved, and the inferences to be drawn from them.

## ACKNOWLEDGMENTS

My thanks to the organizers of the ICAIL 2013 Workshop on Formal Argument and Evidential Inference for inviting me to present this article. I also gratefully acknowledge the generous support of the Maurice A. Deane School of Law at Hofstra University for this research and for the Research Laboratory for Law, Logic and Technology.

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