

## A process approach to inferences of causation: empirical research from vaccine cases in the USA

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In law, inferences of causation are sometimes made through a structured process in which multiple participants play various roles, and make decisions concerning various logical components of the overall inference (such as legal rules, policy objectives, presumptions, evidence, burdens of proof and findings of fact). This article illustrates such a process using empirical research into compensation decisions in the USA for injuries allegedly caused by vaccinations. Empirical research into actual legal processes is essential, in order to discover how various players approach their sub-tasks of decision-making. It also provides insights for areas outside of law, such as non-monotonic logic, cognitive science, sociology and artificial intelligence.

*Keywords:* causation; inference; vaccine; compensation; factfinding; decision-making; legal rule; legal policy; presumption; burden of proof; evidence.

### 1. Introduction

In law, inferences of causation are sometimes made through a structured process in which multiple participants play various roles, and make decisions concerning various logical components of the overall inference. This article illustrates such a process using empirical research into compensation decisions in the USA for injuries allegedly caused by vaccinations. The issue of whether a particular vaccination caused an injury is decided through a process involving numerous decision-makers acting on various logical constituents of the causal inference. The major decision-makers include the U.S. Congress, the Secretary of the Department of Health and Human Services (HHS), the Supreme Court of the USA, the U.S. Court of Appeals for the Federal Circuit, the U.S. Court of Federal Claims and special masters attached to the Court of Federal Claims. The major logical constituents are legal rules, policy objectives, presumptions, evidentiary elements and findings of fact. The participants have different roles to play with respect to different logical constituents. For example, Congress establishes the statutory legal rules that are fundamental to the process, while administrative agencies can create additional rules, and reviewing courts interpret and elaborate all of those rules. Special masters function as factfinders by assessing the evidence in particular cases and making findings of fact on causation, while the Court of Federal Claims provides a first level of review of those findings. This article examines the dynamic elements of this decision-making process. A major thesis of the article is that empirical research into actual legal processes is essential, in order to discover how various players approach their sub-tasks of decision-making.

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The focal point of this article is at the intersection of several important topics, each having its own extensive literature. There is the traditional type of legal commentary on the U.S. vaccine compensation system, with particular focus on the adequacy of the legal rules and policies about determinations of causation.<sup>1</sup> With respect to analysing the issue of causation in law generally, there are both qualitative logical models of the concept of cause<sup>2</sup> and probabilistic or computational models of causal inference.<sup>3</sup> This article has, however, a distinct perspective. The approach taken here is (a) to empirically examine a large number of legal decision documents that report inferences about causation, and which explain the reasoning supporting those inferences on the basis of evidence in the legal record<sup>4</sup>; (b) to examine how the legal process divides up inferential roles among different institutions and (c) to formulate testable hypotheses about interactions among those roles and institutions, from the standpoint of making accurate and efficient causal inferences.

## 2. Methodology

This article is based upon empirical research by Hofstra Law's Research Laboratory for Law, Logic and Technology (LLT Lab, [www.LLTLab.org](http://www.LLTLab.org)) into the logical structure of the causal reasoning found in reported vaccine-injury compensation decisions. The Vaccine Injury Compensation Program (VICP) is a hybrid administrative-judicial system in the USA for providing compensation to persons who have sustained vaccine-related injuries.<sup>5</sup> Compensation awards are paid out of the Vaccine Injury Compensation Trust Fund, which is funded by an excise tax on each dose of covered vaccine.<sup>6</sup> Petitioners seeking compensation file claims against the Fund in the Court of Federal Claims. Petitions contested by the Secretary of HHS 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. Contested VICP cases often involve complex issues of fact, which require taking into account medical, scientific and other expert evidence along with the non-expert evidence. Moreover, the

<sup>1</sup> See, e.g. Laura A. Binski, *Balancing Policy Tensions of the Vaccine Act in Light of the Omnibus Autism Proceeding: Are Petitioners Getting a Fair Shot at Compensation?*, 39 *HOFSTRA LAW REVIEW* 683–721 (2011); Betsy J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 *HARVARD JOURNAL ON LEGISLATION* 343–414 (2011); James B. Currier, *Too Sick, Too Soon?: The Causation Burden Under the National Vaccine Injury Compensation Program Following De Bazan v. Secretary of Health & Human Services*, 19 *FEDERAL CIRCUIT BAR JOURNAL* 229–252 (2009); Katherine E. Strong, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 *GEORGE WASHINGTON LAW REVIEW* 426–459 (2007).

<sup>2</sup> See, e.g. American Law Institute, *RESTATEMENT OF THE LAW THIRD, TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM* §§ 26–27 (2010) (suggesting as a 'useful model for understanding factual causation' in law a set consisting of all the necessary conditions for the occurrence of a harm); Richard W. Wright, *Causation, Responsibility, Risk, Probability, Naked Statistics, and Proof: Pruning the Bramble Bush by Clarifying the Concepts*, 73 *IOWA LAW REVIEW* 1001–1077 (1988) (arguing for the 'Necessary Element of a Sufficient Set' (NESS) model 'as the only plausible definition of causation' in law).

<sup>3</sup> See, e.g. Tyler J. VanderWeele and Nancy Staudt, *Causal Diagrams for Empirical Legal Research: A Methodology for Identifying Causation, Avoiding Bias and Interpreting Results*, 10 *LAW, PROBABILITY AND RISK* 329–354 (2011); Judea Pearl, *Causality: Models, Reasoning, and Inference* (Cambridge: Cambridge University Press, 2000); Glenn Shafer, *The Art of Causal Conjecture* (Cambridge, Massachusetts: The MIT Press, 1996).

<sup>4</sup> For another empirical study of causation determinations in vaccine cases, see Whitney S. Waldenberg and Sarah E. Wallace, *When Science is Silent: Examining Compensation of Vaccine-Related Injuries When Scientific Evidence of Causation is Inconclusive*, 42 *WAKE FOREST LAW REVIEW* 303–331 (2007).

<sup>5</sup> Vern R. Walker, *Designing Factfinding for Cross-Border Healthcare*, 3 *OPINIO JURIS IN COMPARATIONE*, paper n. 1, 1–40 (2009); see generally *supra* n 1.

<sup>6</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 U.S. Department of Health and Human Services, Health Resources and Services Administration, *Vaccine Injury Compensation Trust Fund*, <http://www.hrsa.gov/vaccinecompensation/index.html> (accessed 3 April 2013).

special masters carefully document their evidence assessment and fact finding in their decisions, which must include ‘findings of fact and conclusions of law’.

The methodology of the LLT Lab incorporates the major aspects of empirical research in the sciences. In general, in order to study actual inferences about causation, a representative sample of legal decisions is selected. For each decision in the sample, data are generated on the structure of the reasoning reported, using a methodology whose reliability and validity can be assessed. Both qualitative and quantitative analyses of the data can then be performed, searching for types and patterns of reasoning that are more likely to occur under specifiable circumstances. Hypotheses can then be formulated and tested against the data, and theories developed to explain the findings. Finally, such descriptive analysis can also provide input to normative critiques, in which the adequacy of the reasoning found in the cases can be subjected to critical review. The remainder of this section of the article discusses the data-generation phase of this methodology in more detail.

The initial study sample of the decisions selected for the LLT Lab Vaccine/Injury Project (V/IP) consists of decisions filed by special masters between 29 July 2005 and 1 May 2007. The sample start date is the date of the Federal Circuit decision in the lead case of *Althen v. Secretary of HHS*, 418 F.3d 1274 (Fed. Cir. 2005), which established a 3-condition test of causation-in-fact. The sample end date is the date of the Federal Circuit decision in *Walther v. Secretary of HHS*, 485 F.3d 1146 (Fed. Cir. 2007). The study sample consists of every decision filed by a special master during this time frame, in which the special master applied the 3-condition test of causation-in-fact (a total of 35 decisions).<sup>7</sup> As will be explained below, this test states conditions for proving (in certain complex cases) whether vaccinations have caused injuries. This study sample was selected not only for its societal importance but also for its nuanced decisions applying complex yet stable legal rules concerning proof of causation.

The data of the study consist of ‘logic models’—one model for each decision in the study sample. A logic model represents the integrated reasoning on causation resulting from all of the players in the process. These logic models are divided into two major parts: the governing system of legal rules and the factfinder’s assessment of the evidence in the case. In creating these logic models, the Lab utilizes the Default-Logic Framework as the formal methodology,<sup>8</sup> and uses the Legal Apprentice<sup>TM</sup> software from Apprentice Systems, Inc., as the working environment in which the models are created.<sup>9</sup>

The governing system of legal rules is represented as an inverted ‘rule tree’. The top node of the tree is the ultimate issue to be proved by the claimant, and each level of each branch extending downward from the top node states the logical conditions for proving the immediately higher proposition. Inferences proceed upward. The higher levels of each case model consist of 30 propositional nodes in the rule tree, representing the conditions established by the legal rules. At each level of a branch, multiple propositions are connected together and to the next higher level by one of four logical connectives:

- ‘AND’ (the conclusion is true if, but only if, all connected conditions are true);
- ‘OR’ (the conclusion is true if, but only if, at least one of the connected conditions is true);

<sup>7</sup> The decisions are listed at: [http://lltlab.org/index.php/site/LLT\\_Lab\\_VIP-Features\\_post/vip\\_sample\\_of\\_decisions](http://lltlab.org/index.php/site/LLT_Lab_VIP-Features_post/vip_sample_of_decisions) (accessed 3 April 2013).

<sup>8</sup> Vern R. Walker, A Default-Logic Paradigm for Legal Fact-Finding, 47 *JURIMETRICS* 193–243 (2007); Vern R. Walker, Visualizing the Dynamics around the Rule-evidence Interface in Legal Reasoning, 6 *LAW, PROBABILITY AND RISK* 5–22 (2007); Vern R. Walker, Emergent Reasoning Structures in Law, in G. Trajkovski and S. G. Collins (eds), *Handbook of Research on Agent-Based Societies: Social and Cultural Interactions*, 305–324 (Information Science Reference: Hershey, New York, 2009).

<sup>9</sup> The software automatically creates XML-formatted files of the logic models, which is a standard format used in Internet-based programmes. The LLT Lab also makes HTML versions of these logic models available to the public on its website, [www.LLTLab.org](http://www.LLTLab.org) (accessed 3 April 2013).

- ‘UNLESS’ (if the defeating condition is true, then the conclusion is false, even if the main *prima facie* conditions are true) and
- ‘RULE FACTORS’ (the factfinder must take the listed conditions into account when making a finding, but the rule specifies no algorithm for assigning a truth-value to the conclusion as a function of the truth-values of those conditions).

Every proposition in a rule tree has one of three truth-values: ‘true’/‘undecided’/‘false’. The single ultimate issue at the top is dependent for its truth or falsehood upon combinations of the rule conditions that terminate the branches at the bottom (the ‘terminal’ or ‘leaf’ propositions).

When any particular vaccine-compensation proceeding begins, all propositions in the rule tree are ‘undecided’. The petitioner and the Secretary of Health and Human Services then stipulate some propositions as true or false, with the remainder forming a set of contested issues. The parties then produce the evidence on those contested issues that forms the legal record and try to prove their case by persuading the special master (as factfinder) to make favourable findings of fact on the contested terminal rule conditions. The special master’s role as factfinder is deciding which evidence is relevant to which issues of fact, evaluating the plausibility of the evidence, organizing the evidence and making reasonable inferences, and making findings of fact. Often this requires deciding between two conflicting expert opinions or integrating expert and non-expert evidence into a single line of reasoning. When the factfinder makes findings of fact about the terminal propositions at the ends of the branches, the tree’s logical connectives propagate those values upward, determining the values of propositions throughout the tree, and ultimately the truth-value of the issue at the top (in vaccine cases, either awarding compensation or not).

In modelling the reported reasoning in any particular vaccine decision, Lab researchers first select the rule tree that contains the legal rules governing the case.<sup>10</sup> They then extract from the decision all assertions that the special master reported as being relevant to the three conditions of causation. Such assertions may be statements made by testifying witnesses, statements contained in medical records, or statements of the special master herself (e.g. describing an evidentiary exhibit or a witness’s demeanor). The LLT Lab represents both evidence and findings as ‘evidentiary assertions’, which possess plausibility values on an ordinal scale with seven values: ‘highly plausible’/‘very plausible’/‘slightly plausible’/‘undecided’/‘slightly implausible’/‘very implausible’/‘highly implausible’. In deciding a case, the special master explicitly or implicitly organizes these assertions, assigns them degrees of plausibility, and uses them to support her findings of fact.

In creating the case model for a particular decision, Lab researchers first attach the findings of fact to the appropriate propositions in the rule tree, and then attach to those findings the special master’s reasoning, organizing the extracted evidentiary assertions into logical structures using ‘plausibility connectives’. Plausibility connectives are similar to logical connectives, but operate on seven plausibility-values:

- ‘MIN’, the plausibility counterpart to AND (the conclusion takes as its value the lowest plausibility-value possessed by any of its conditions);

<sup>10</sup> Over time, appellate decisions might elaborate the set of legal rules by interpreting the meaning of key concepts, by establishing accepted lines of proof, or by carving out exceptions. The 3-condition causation rules of *Althen*, however, remained substantially unchanged throughout the study sample.

- ‘MAX’, the plausibility counterpart to OR (the conclusion takes as its value the highest plausibility-value possessed by any of its conditions);
- ‘REBUT’, the plausibility counterpart to UNLESS (if the rebutting assertion is plausible to any degree, then the conclusion takes the degree of implausibility that is inverse to the degree of plausibility of the rebutting (defeating) assertion<sup>11</sup>) and
- ‘EVIDENCE FACTORS’, the plausibility counterpart to RULE FACTORS (the factfinder took the connected assertions into account when making a finding, but the decision provides no algorithm for assigning a plausibility-value to the conclusion as a function of the plausibility-values of those conditions).

Finally, researchers assign plausibility-values to the terminal, or leaf, assertions in the model, as well as to sets of evidence factors, so that the plausibility-values and truth-values throughout the model reflect the evaluation of the factfinder. As a result, each case model for a decision in the study sample captures the essential reasoning of the factfinder that supports a finding for or against causation.

### 3. The rule structure for causal inference

#### 3.1 *The statutory and regulatory framework on causation*

Applying this methodology to the vaccine compensation decisions requires constructing a rule tree that accurately represents the system of legal rules governing inferences of causation in particular decisions. The process of creating legal rules began when the U.S. Congress, the legislative branch of the U.S. government, established the basic legal rules for causal inference in the National Childhood Vaccine Injury Act of 1986, which established the VICP.<sup>12</sup> Congress was responding in part to an increase in litigation over vaccine-related injuries, which helped cause prices of vaccines to increase and vaccine manufacturers to leave the market.<sup>13</sup> The legislative history of the statute states as a goal the establishment of ‘a Federal “no-fault” compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity’.<sup>14</sup> Congress intended the VICP to be ‘fair, simple, and easy to administer’, and hoped that ‘a more stable childhood vaccine market will evolve’.<sup>15</sup> At this foundational level for the programme, Congress tried to set a politically acceptable balance of the competing policy objectives by establishing the basic procedural and substantive legal rules that would govern the VICP.

Critical to a fair and efficient compensation system is the issue of causation: a claimant should receive compensation if, but only if, the vaccine received did in fact cause the injury. If compensation is paid when the vaccine did not causally contribute to the injury, then the VICP would pay out money for injuries that are unrelated to vaccines, and money raised by vaccine taxes and targeted for vaccine-related injuries would be diverted to other uses. If compensation is not paid when the vaccine did in fact causally contribute to the injury, then the claimant would unfairly be without a remedy, part of the costs of societal vaccination would be externalized to a few unfortunate individuals, and people who could benefit from vaccination might under-utilize vaccines. Congress balanced

<sup>11</sup> For example, if the rebutting defeater is ‘highly plausible’, then the conclusion is ‘highly implausible’; but if the defeater is only ‘slightly plausible’, then the conclusion is only ‘slightly implausible’.

<sup>12</sup> Pub. L. No. 99-660, Title III, 100 Stat. 3755 (1986) (codified at 42 U.S.C. §§ 300aa-10 to 300aa-34 (2012)).

<sup>13</sup> H.R. Rep. 99-908, 1986 U.S.C.C.A.N. 6344, 6345-46 (26 September 1986).

<sup>14</sup> *Ibid* at 6344.

<sup>15</sup> *Ibid* at 6348.

its multiple policy objectives by providing two alternative sets of rules for proving that a vaccine caused an injury: ‘on-Table causation’ (or merely ‘Table causation’) and ‘off-Table causation’.<sup>16</sup>

The inference of ‘Table causation’ utilizes a Vaccine Injury Table that lists (a) covered vaccines, (b) recognized adverse reactions that might result from the administration of particular vaccines and (c) recognized time periods in which the first symptom or manifestation of onset must occur after vaccine administration.<sup>17</sup> If the claimant (the petitioner) can prove, by a preponderance of the evidence, that she received a listed vaccine, that she sustained or had significantly aggravated an injury or condition listed on the Table for that vaccine, and that the first symptom or manifestation of that injury or condition occurred within the listed time period, then there is a presumption of causation.<sup>18</sup> This presumption is rebutted if the injury was in fact due to factors unrelated to the administration of the vaccine.<sup>19</sup> Congress recognized that such a presumption ‘may provide compensation to some children whose illness is not, in fact, vaccine-related’,<sup>20</sup> but obviously considered this risk worth the trade-off for more efficient administration and more predictable recovery. Thus, the rule creating a statutory presumption of Table causation strikes a balance in favour of compensating petitioners in broad categories of situations.

Congress also authorized the Secretary of the Department of Health and Human Services to administratively amend the Table by incorporating new vaccines, reactions or time periods.<sup>21</sup> In 1995, for example, the Secretary amended the Table by deleting ‘residual seizure disorder (‘RSD’) from the list of compensable table injuries related to DPT vaccine and significantly narrow[ing] the definition of “encephalopathy”’,<sup>22</sup>

If the claimant’s injury is not listed on the Table, or if the first symptom or manifestation of onset or significant aggravation occurred outside the time period listed on the Table,<sup>23</sup> then an inference of ‘off-Table causation’ is still possible. A claimant is entitled to compensation if she can ‘demonstrate by a preponderance of the evidence’ that her injury or condition ‘was caused by a vaccine’.<sup>24</sup> But even if a claimant makes a *prima facie* showing of causation in an off-Table case, her proof may still be rebutted if the injury was in fact ‘due to factors unrelated to the administration of the vaccine’.<sup>25</sup> Congress, however, did not provide further substantive rules for proving off-Table causation, apparently leaving the elaboration of those rules of inference to the courts.<sup>26</sup>

Figure 1 shows a graphical depiction of that portion of the LLT Lab’s rule tree that represents the legal rules of causation in Table and off-Table cases, as those rules are established by the vaccine statute (discussed above) and the case law (discussed below). The causation requirement can be

<sup>16</sup> See *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (describing the two ways as ‘a statutorily-prescribed presumption of causation’ in the case of a ‘Table injury’, and ‘causation in fact’ in the case of an ‘off-Table injury’).

<sup>17</sup> 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), 300aa-14 (2012); 42 C.F.R. § 100.3 (2011).

<sup>18</sup> 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), 300aa-13(a)(1) (2012); *Bruesewitz v. Wyeth*, 131 S. Ct. 1068, 1073–1074 (2011); *Althen*, 418 F.3d at 1278.

<sup>19</sup> See 42 U.S.C. § 300aa-13(a)(1)(B) (2012); *Bruesewitz*, 131 S. Ct. at 1074.

<sup>20</sup> H.R. Rep. 99-908, 1986 U.S.C.C.A.N. 6344, 6359 (26 September 1986).

<sup>21</sup> 42 U.S.C. § 300aa-14(c), (e) (2012); H.R. Rep. 99-908, 1986 U.S.C.C.A.N. 6344, 6359 (26 September 1986); *Terran v. Secretary of Health and Human Services*, 195 F.3d 1302, 1311-14 (Fed. Cir. 1999).

<sup>22</sup> *Terran*, 195 F.3d at 1308; Department of Health and Human Services, 60 Fed.Reg. 7678-01 (8 February 1995) (final rule); see 42 C.F.R. § 100.3 (2011).

<sup>23</sup> 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1) (2012).

<sup>24</sup> *Ibid.*

<sup>25</sup> See 42 U.S.C. § 300aa-13(a)(1)(B) (2012); *Althen*, 418 F.3d at 1278.

<sup>26</sup> See *Shyface v. Secretary of Health and Human Services*, 165 F.3d 1344, 1350-51 (Fed. Cir. 1999).

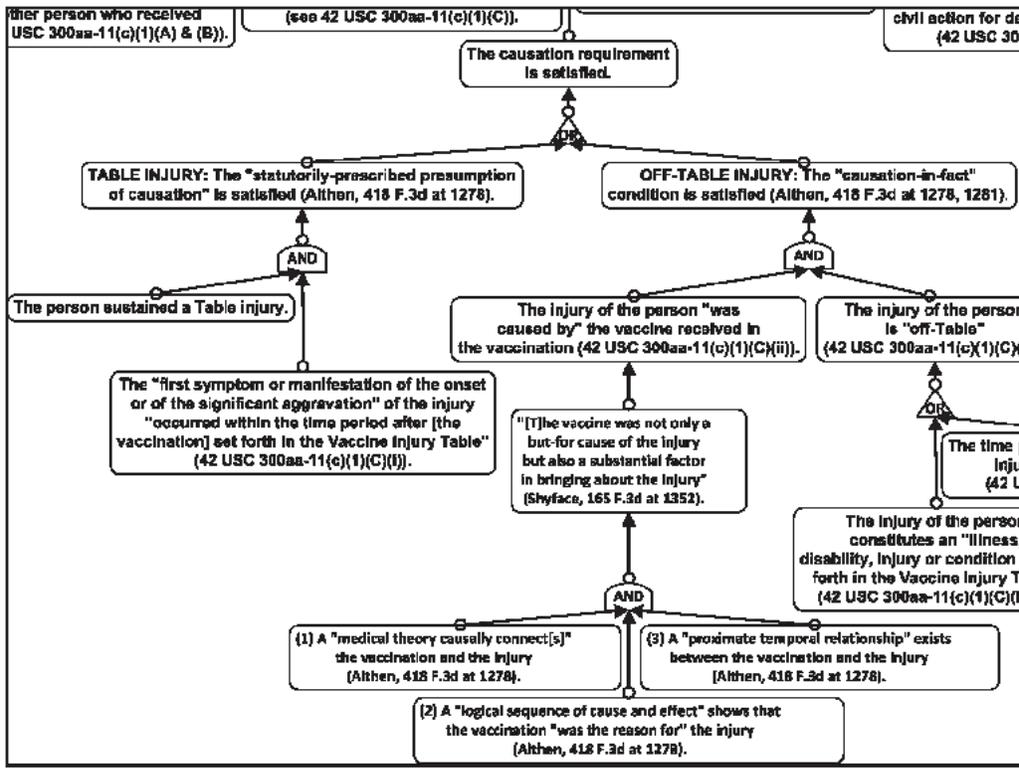


FIG. 1. Portion of the LLT Lab rule tree representing, in a graphical format, the legal rules governing the inference of causation in vaccine-compensation cases.

satisfied by proving either that the ‘statutorily-prescribed presumption of causation’ is satisfied (Table cases) or that the ‘causation-in-fact’ condition is satisfied (off-Table cases).

### 3.2 Judicial elaboration of substantive legal rules on causation

Courts often implement statutory provisions by elaborating more specific rules about the meaning of legal concepts and more explicit conditions for proving higher-level rule conditions. Courts are guided in this elaboration (and justify their elaborations) by reference to the legislatively established policy objectives, as well as to more general policy objectives. One important issue became the meaning and proof of ‘causation’ in off-Table cases. In the case of *Shyface v. Secretary of Health and Human Services*,<sup>27</sup> the Court decided that implicit in Congress’s purpose is ‘[n]ational uniformity in administration’.<sup>28</sup> This means that the legal rules determining the meaning and methods of proof of causation should be national rules, not the rules of tort law that can vary from state to state. The Court then held that a ‘uniform approach, one which implements the statutory purpose, is that of the Restatement

<sup>27</sup> 165 F.3d 1344 (Fed. Cir. 1999).

<sup>28</sup> *Shyface*, 165 F.3d at 1351.

(Second) of Torts'.<sup>29</sup> Following the Restatement, the court adopted the rule that a 'prima facie entitlement to compensation according to the non-Table method would require the petitioner to prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury'.<sup>30</sup> In a legal context, a 'but-for' causal event is any necessary condition for an occurrence (the occurrence would not have occurred in the absence of the causal event), while a 'substantial factor' plays what reasonable people would consider to be a significant or appreciable causal role.<sup>31</sup>

In 2005, the case of *Althen v. Secretary of Health and Human Services*<sup>32</sup> codified three substantive conditions (sub-issues or 'prongs' to be proved) for an inference of causation in off-Table cases. Firstly, the petitioner must establish, by a preponderance of the evidence, that 'a medical theory causally connect[s] the vaccination and the injury'.<sup>33</sup> Secondly, the petitioner must demonstrate 'a logical sequence of cause and effect showing that the vaccination was the reason for the injury'.<sup>34</sup> Thirdly, the petitioner must show that there existed 'a proximate temporal relationship between vaccination and injury'.<sup>35</sup> Figure 1 includes that portion of the LLT Lab's rule tree that represents the additional legal rules of causation codified by *Althen* (see the bottom level of conditions in the diagram).

The first condition of the *Althen* causation test requires the petitioner to prove 'general causation'—i.e. that the type of vaccine can cause the type of injury.<sup>36</sup> This proposition is normally supported by medical or scientific evidence and explanation, without depending on the truth or falsehood of actual causation in the particular case. In contrast, the second and third conditions require the petitioner to prove 'specific causation'—i.e. that the vaccination received in the particular case actually caused the particular injury.<sup>37</sup> This proof normally involves showing that the model of general causation established in Condition 1 actually explains the evidence of events in the particular case.

### 3.3 Judicial elaboration of process legal rules on causation

Courts may also elaborate legal rules that govern the decisional process itself, in addition to the substantive issues to be decided. For example, the vaccine statute requires, as a condition of the petitioner's prevailing on compensation, a finding, 'on the record as a whole, . . . that there is not a preponderance of the evidence that the . . . injury [or] condition . . . is due to factors unrelated to the administration of the vaccine'.<sup>38</sup> The statute does not, however, explicitly assign the burden of proof on this issue to any particular party—that is, does not select which party must introduce sufficient

<sup>29</sup> *Ibid* at 1351–1352.

<sup>30</sup> *Ibid* at 1352.

<sup>31</sup> See *Ibid*.

<sup>32</sup> 418 F.3d 1274 (Fed. Cir. 2005).

<sup>33</sup> *Althen*, 418 F.3d at 1278. This substantive condition derived from *Grant v. Secretary of Health and Human Services*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); see *Shyface*, 165 F.3d at 1353.

<sup>34</sup> *Ibid*.

<sup>35</sup> *Althen*, 418 F.3d at 1278.

<sup>36</sup> E.g. *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706, 714 (Texas 1997) (defining 'general causation' as 'whether a substance is capable of causing a particular injury or condition in the general population'); American Law Institute, RESTATEMENT OF THE LAW THIRD, TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 26, Com. g (2010).

<sup>37</sup> See, e.g. Michael D. Green, D. Michal Freedman and Leon Gordis, Reference Guide on Epidemiology in *Reference Manual on Scientific Evidence*, 333, 396 (2nd edn, 2000) (defining 'specific causation'); American Law Institute, RESTATEMENT OF THE LAW THIRD, TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 26, Com. g (2010).

<sup>38</sup> 42 U.S.C. § 300aa-13(a)(1)(B) (2012).

evidence into the legal record for a finding in its favour on this issue, or which party will lose if the weight of the evidence produced is in equipoise (not having a preponderance for either party). The Court in *Knudsen v. Secretary of the Department of Health and Human Services*<sup>39</sup> resolved these questions by deciding that it is the government that has the burden of rebutting a petitioner's *prima facie* proof of off-Table causation by showing 'that the injury was in fact caused by factors unrelated to the vaccine'.<sup>40</sup>

#### 4. Evidence assessment and inferences of causation in particular cases

In VICP cases, special masters attached to the Court of Federal Claims have the role of making the factual inferences under the three conditions of *Althen*.<sup>41</sup> If a party to the case seeks review of the decision of the special master by the Court, then the reviewing judges of the Court can set aside those findings of fact only if the special master's findings are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law'.<sup>42</sup>

As shown in [Table 1](#), out of the 35 cases in the study sample, 14 were decided for petitioners, while 21 were decided for the government. In order for a decision to be made in favour of a petitioner, the petitioner would have to prevail on all three conditions of the *Althen* test of causation. Failure on any one or more of those conditions, however, means failure for the petitioner's case. [Table 1](#) therefore also shows, out of the 21 cases decided against petitioners, the frequency with which each of those three conditions was determined to be true or false, or was left undecided by the special master. In all but one of the cases decided against the petitioner, there was a finding that *Althen* Condition 2 was not satisfied, while the truth-values of the other two *Althen* conditions varied.<sup>43</sup>

##### 4.1 Examples from *Althen* Condition 1, involving vaccines with attenuated viruses

The first condition of the *Althen* causation test requires the petitioner to prove that 'a medical theory causally connect[s] the vaccination and the injury'. This requires proof of 'general causation'—i.e. that the type of vaccine can cause the type of injury.<sup>44</sup> Some vaccines, such as the measles, mumps and rubella (MMR) and varicella vaccines, contain live but 'attenuated' microbes.<sup>45</sup> An empirical study of *Althen* Condition 1 in decisions involving such vaccines supports a number of conclusions about fact finding under the VICP.

First, due to the policy objectives behind the VICP, the level of legal proof required is quite low by scientific standards. In *Mulvaney v. Secretary of the Department of Health and Human Services*,<sup>46</sup>

<sup>39</sup> 35 F.3d at 543 (Fed. Cir. 1994).

<sup>40</sup> 35 F.3d at 547–551; *Althen*, 418 F.3d at 1278.

<sup>41</sup> 42 U.S.C. § 300aa-12(d)(3)(A) (2012).

<sup>42</sup> 42 U.S.C. § 300aa-12(e)(2)(B) (2012).

<sup>43</sup> One caveat is that, once a special master finds against the petitioner on Condition 2, it is sometimes difficult to determine from the text of the decision whether the special master has also made a definitive ruling on Conditions 1 and 3. Therefore, the frequencies for Conditions 1 and 3 in these types of cases might vary slightly, depending upon one's interpretation of the text.

<sup>44</sup> See *supra* n 36.

<sup>45</sup> See, e.g. National Institute of Allergy and Infectious Diseases, Department of Health and Human Services, 'Types of Vaccines' (stating that such vaccines 'contain a version of the living microbe that has been weakened in the lab so it can't cause disease'), found at: <http://www.niaid.nih.gov/topics/vaccines/understanding/pages/typesvaccines.aspx> (accessed 3 April 2013); Advisory Committee on Immunization Practices (ACIP), 'General Recommendations on Immunization', Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report* 60(2): 3–61 (28 January 2011).

<sup>46</sup> Office of Special Masters, Court of Federal Claims, No. 05-556V, 2006 WL 2438454 (26 July 2006).

TABLE 1 *Frequencies of case outcomes in the VIP study sample, with frequencies of truth-values on Althen causation conditions for cases decided against petitioner*

Case outcomes	True	Undecided	False
For petitioner (14)			
Against petitioner (21)			
<i>Althen</i> Condition number 1	4	6	11
<i>Althen</i> Condition number 2	0	1	20
<i>Althen</i> Condition number 3	1	10	10

petitioners alleged that their son's MMR vaccination (containing three live, attenuated viruses) was a substantial factor in causing opsoclonus-myoclonus syndrome (OMS), a syndrome of movements of the eyes and trunk. Special Master Millman ultimately decided this off-Table case for the petitioners. The Special Master considered it sufficient for the petitioner's case that there was 'medical probability rather than certainty', which meant 'biologic credibility or plausibility rather than exact biologic mechanism'. Requiring proof of a specific mechanism 'would be inconsistent with the purpose and nature of the vaccine compensation program'. Similarly, although medical science might prefer (or perhaps even insist upon) epidemiologic evidence before concluding that a particular type of vaccine can cause a particular type of harm, such evidence is not required for compensation under the VICP. The Special Master noted the Federal Circuit's statement that 'requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in *Althen*'. She also noted that 'the Federal Circuit in *Knudsen* ruled for petitioners even when epidemiologic evidence directly opposed causation from a vaccine'.

It is one thing, however, to recognize that the policies behind the VICP might lead to a more relaxed level of proof than scientists would require, but it is quite another thing to formulate what that more relaxed legal standard is or should be. Although scientific proof of the specific biological mechanism of causation is not required, what kind of account of a plausible mechanism is or should be required? Although a full-blown epidemiological study is not required, what kind of scientific support is needed? Although general acceptance in the scientific or medical communities is not required, is merely an opinion by a single medical expert sufficient? And should such questions be resolved by means of legal rules (adopted by the rule-making legal institutions) or left to factfinding in particular cases? It is not the task of this article to answer these questions, for each of them merits lengthy analysis. The purpose of this article is to suggest the kinds of questions raised, once the causal inference is decomposed into logical components, and different inferential roles are assigned to different institutions within a process approach to inference.

A second conclusion is that the policy objectives of the VICP can positively affect the causal inferences that special masters make. In *Casey v. Secretary of Health and Human Services*,<sup>47</sup> the petitioner alleged that her varicella vaccination (containing a live, attenuated virus) caused encephalomyeloradiculoneuropathy, an autoimmune reaction affecting her central and peripheral nervous systems. With respect to *Althen* Condition 1, Special Master Sweeney found that the petitioner had provided sufficient proof of a medical theory of causation, and ultimately decided the case for the

<sup>47</sup> Office of Special Masters, Court of Federal Claims, No. 97-612V, 2005 WL 3597263 (12 December 2005).

petitioner. The supporting reasoning was that ‘it is reasonable to assume that the virus can multiply once inside the body’. The (unstated) presumption was that *if* the vaccine contains a live but attenuated virus, *and if* a wild virus of the same type as the virus contained in the vaccine can cause certain negative effects on the nervous system, *then* the vaccine can cause those negative effects on the nervous system, at least in a few susceptible individuals. This presumption is rebuttable, but not merely by contending that such a reaction would occur very rarely. The presumption does not appear to be based on evidence of a mechanism that scientists would consider adequate. Nor is it based on probabilistic reasoning and epidemiologic evidence, for even if there were data associating the vaccine and the effect, the effect would happen very rarely. The rationale appears in the following sentence from the *Casey* decision: ‘It is precisely because individuals experience adverse reactions to safe vaccines on rare occasions that Congress created the Vaccine Program’. Special masters, responding to Congress’s goal to ‘stabilize the vaccine market and facilitate compensation’,<sup>48</sup> and under the direction of the Court of Appeals for the Federal Circuit that in the system created by Congress ‘close calls regarding causation are resolved in favor of injured claimants’,<sup>49</sup> make what seem to them to be reasonable inferences that favour the petitioner, and *de facto* create what seem to them to be reasonable presumptions for assessing certain types of evidence.

#### 4.2 Example from *Althen* Conditions 2 and 3, involving molecular mimicry theory

The second condition of the *Althen* test of causation requires the petitioner to prove ‘a logical sequence of cause and effect showing that the vaccination was the reason for the injury’, and the third condition requires a showing that there existed ‘a proximate temporal relationship between vaccination and injury’. These conditions in effect require proof of ‘specific causation’—i.e. that the vaccination received in the particular case actually caused the particular injury.<sup>50</sup> An empirical study of decisions involving the theory of molecular mimicry investigates the interplay between proving *Althen* Condition 1 and proving *Althen* Conditions 2 and 3. ‘Molecular mimicry’ is a theory that a vaccine can sometimes cause the body to attack its own tissue, and it is sometimes put forward by petitioners’ experts to satisfy the requirement of *Althen* Condition 1.

One hypothesis from this research is that special masters who accept a weaker medical theory for *Althen* Condition 1 may look more closely at the evidence in the particular petitioner’s case under Conditions 2 and 3, and scrutinize carefully how well the particular events and conditions track the general theory. In *Scott v. Secretary of the Department of Health and Human Services*,<sup>51</sup> for example, the petitioner alleged that an MMR vaccination that she received caused ‘an immune reaction . . . characterized by non-specific auto antibodies, including low levels of double-stranded DNA antibodies and also circulating anticoagulant’. Her condition had been variously diagnosed as multiple sclerosis (MS), antiphospholipid antibody syndrome (APS), systemic lupus erythematosus (SLE) and vasculitis. The Special Master found that the theory of molecular mimicry put forward by the petitioner’s expert ‘provided a sufficient basis to establish the first condition of the *Althen* test, a biologically plausible mechanism’. But the petitioner lost on *Althen* Condition 2 for a number of reasons, including that the antibodies produced in the petitioner had significant differences in nature and persistency from those most frequently found in viral- or vaccine-associated APS. In addition, the

<sup>48</sup> *Bruesewitz*, 131 S. Ct. at 1073.

<sup>49</sup> *Althen*, 418 F.3d at 1280.

<sup>50</sup> See *supra* n 37.

<sup>51</sup> Office of Special Masters, Court of Federal Claims, No. 03-2211V, 2006 WL 2559776 (21 August 2006).

petitioner also failed to convince the Special Master that she satisfied *Althen* Condition 3 (a ‘proximate temporal relationship’ between the vaccination and the injury).

This example illustrates the task of formulating and testing hypotheses about evidentiary reasoning, given an empirical approach to actual decisions. Some hypotheses about proof of causation in VICP cases involve within-branch or intra-branch reasoning. For example, what is the likelihood of success on *Althen* Condition 1 if the petitioner proffers a molecular mimicry theory, or has documented case reports directly on point, or has received a vaccine containing a live but attenuated virus? Other hypotheses are about between-branch or inter-branch associations, such as the example in the previous paragraph. In general, a broad range of investigations is possible once there is a standardized method for representing the supporting reasoning for findings of fact.

## 5. Discussion of the structure of the process

This section summarizes the major logical constituents of the causation inference in vaccine cases, as well as the major decision-makers, from the perspective of generalizing from the specific process of these cases to inference processes generally. This discussion then leads to some reflections on the advantages and disadvantages of a process approach to inference.

### 5.1 *Legal rules*

In the vaccine compensation process, legal rules play a central role in inferences of causation. Legal rules are essential means for achieving the rule of law, because they make the justification of governmental action more transparent, as well as help ensure that similar cases are decided similarly.<sup>52</sup> Rules binding on vaccine decisions issued by special masters can be created by Congress through statutes, by the Secretary through amendments to the Vaccine Injury Table, and by the appellate courts in deciding cases. Court of Federal Claims decisions do not create legal rules binding on other decisions of the same court on other claims,<sup>53</sup> nor do decisions by special masters create rules binding on other special masters.<sup>54</sup> Thus, the process can ensure that the governmental institutions that have rule-creating authority have the experience and competence to balance competing epistemic and non-epistemic policies<sup>55</sup> and to cast that balance in the form of legal concepts embedded in legal rules.

### 5.2 *Policy objectives*

Congress establishes the specific policy objectives of the VICP. Numerous participants are responsible for implementing Congressional objectives in their activities, including the Secretary (as party respondent in the adjudication of a particular claim), the reviewing courts, and the special masters (when

<sup>52</sup> Vern R. Walker, *Discovering the Logic of Legal Reasoning*, 35 *HOFSTRA LAW REVIEW* 1687, 1690–1696 (2007); Vern R. Walker, *A Default-Logic Paradigm for Legal Fact-Finding*, 47 *JURIMETRICS* 193, 198–207 (2007).

<sup>53</sup> *West Coast General Corp. v. Dalton*, 39 F.3d 312, 315 (Fed. Cir. 1994) (‘Court of Federal Claims decisions, while persuasive, do not set binding precedent for separate and distinct cases in that court’.); *Ains, Inc. v. United States*, 365 F.3d 1333, 1336 n. 1 (Fed. Cir. 2004) (‘CFC holdings, like those of federal district courts, are instructive but not precedential, and do not bind future court rulings’).

<sup>54</sup> *Graves v. Secretary of the Department of Health and Human Services*, 101 Fed. Cl. 310, 332 (Ct.Fed.Cl. 2011) (‘Special masters are not bound by decisions of other special masters’).

<sup>55</sup> Vern R. Walker, *Epistemic and Non-epistemic Aspects of the Factfinding Process in Law*, 3(1) *AMERICAN PHILOSOPHICAL ASSOCIATION NEWSLETTER ON LAW AND PHILOSOPHY* 132–136 (2003).

issuing findings of fact and conclusions of law in particular cases). The Secretary and the appellate courts can also implement more generic policies (such as administrative efficiency). The structure of the process ensures that only certain participants have policymaking authority outright, while the presence of discretion in implementing and balancing policies means that other participants can determine the influence of those policies in particular cases.

### 5.3 Findings of fact

In vaccine compensation cases, it is the responsibility of the special master to assess the evidence and to issue a decision, which involves making ‘findings of fact and conclusions of law’.<sup>56</sup> The Court of Federal Claims may reject those findings of fact only if they are ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law’.<sup>57</sup> If the Court of Federal Claims does set aside any finding of fact made by a special master, then it may either ‘issue its own findings of fact’ or ‘remand the petition to the special master for further action in accordance with the court’s direction’.<sup>58</sup> Over the course of many cases, the Court of Appeals for the Federal Circuit has developed more specific rules about the review of findings of fact, such as the rule that ‘the special master’s unique position to see the witnesses and hear their testimony’ makes the special master’s credibility findings ‘virtually unreviewable on appeal’.<sup>59</sup> Once again, the division into logical constituents and division of decision-making authority allows factfinders to develop special competences for the task of factfinding.

### 5.4 Legal presumptions

Presumptions provide an important bridge between legal rules, policy objectives and findings of fact. In general, presumptions have the form: ‘C is presumed to be true (or plausible) if both A and B are true (or plausible), unless there is a greater weight of evidence in the particular case for not-C’, where C is the issue to be decided, and A and B are evidentiary propositions. The vaccine cases exhibit two kinds of legal presumptions dealing with causation. Firstly, there are presumptions that are authoritatively established as legal rules, such as the statutory presumptions of causation listed in the Vaccine Injury Table. Such rules assist the petitioner in proving her case and impose constraints on factfinders in assessing the evidence. Secondly, there are presumptive patterns of evidence assessment that are not binding, but which reoccur in similar cases. Such patterns provide *de facto* guidance to future litigants and factfinders. Both types of presumptions help achieve the fundamental policy objective of the rule of law—that similar cases should be decided similarly.

### 5.5 Burdens of proof

There are two quite different legal concepts that are together confusingly called ‘burden of proof’. One concept, called the ‘burden of production’, imposes upon some particular party, with respect to some particular issue, the burden of developing evidence (witness testimony, documents) and introducing it into the legal record in the case.<sup>60</sup> If that party fails to produce the minimum amount or quality of

<sup>56</sup> 42 U.S.C. § 300aa-12(d)(3)(A)(i) (2012).

<sup>57</sup> 42 U.S.C. § 300aa-12(e)(2)(B) (2012); *Stotts v. Secretary of the Department of Health and Human Services*, 23 Cl. Ct. 352, 358–62 (1991).

<sup>58</sup> 42 U.S.C. § 300aa-12(e)(2)(B), (C) (2012).

<sup>59</sup> *Porter v. Secretary of Health and Human Services*, 663 F.3d 1242, 1251 (Fed. Cir. 2011).

<sup>60</sup> Fleming James, Jr., Geoffrey C. Hazard, Jr. and John Leubsdorf, *Civil Procedure* § 7.12 (4th edn, Little, Brown and Co. 1992).

evidence that is ‘legally sufficient’ (i.e. the minimum evidence that a reasonable factfinder would need in order to find in favour of that party on that issue), then that party should lose on that issue under the rules (‘as a matter of law’).<sup>61</sup> The presiding judge (as distinct from the factfinder) decides whether a party has satisfied its burden of production, and therefore whether the factfinder should be allowed to assess the evidence and reach a finding.<sup>62</sup> This also means that a reviewing court decides the sufficiency-of-evidence issue *de novo*, without deference to the lower tribunal.

There are many examples of legal sufficiency rules within the VICP cases. Some rules state that certain types of evidence are *insufficient* to support a finding, thus giving the opposing party a basis for a ruling against the proponent of the proposition.<sup>63</sup> Other rules might positively state what kinds of evidence are legally sufficient, thus giving the proponent of the proposition a defence against an argument that the available evidence is insufficient.<sup>64</sup> In both situations, such rules give reviewing courts the means to take a factual issue away from the factfinder (and in particular, from the special master).

In contrast with ‘burden of production’, the second concept (‘burden of persuasion’) pertains to weighing the probative value of the evidence (not just its minimal sufficiency), and is decided by the factfinder (not by the presiding judge).<sup>65</sup> Under the preponderance standard of proof applicable in the VICP cases<sup>66</sup> (which is also the standard applicable generally in the U.S. civil litigation<sup>67</sup>), the factfinder must make a finding in the direction in which the ‘greater weight of the evidence’ or its ‘convincing force’ points (i.e. either for or against the proposition to be proved).<sup>68</sup> Under this standard, a finding should mean that the factfinder has determined the proposition to be ‘more probably true than false’.<sup>69</sup> The party who bears the burden of persuasion must lose on that factual issue, if the factfinder determines that the weight of the evidence on that issue is in equipoise.

Rules regarding the burden of persuasion and the standard of proof provide guidance to factfinders in assessing the evidence, and provide some leverage to reviewing courts in overseeing the results of factfinding. For example, the Federal Circuit has determined that Congress intended the VICP to be a system ‘in which close calls regarding causation are [to be] resolved in favor of injured claimants’.<sup>70</sup> Some special masters have interpreted this as meaning that ‘50% and a feather’ is enough weight of evidence to warrant a finding,<sup>71</sup> and the Federal Circuit has upheld findings made under

<sup>61</sup> *Ibid* at § 7.15.

<sup>62</sup> See *Ibid* at § 7.19.

<sup>63</sup> E.g. *Grant v. Secretary of Health and Human Services*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (determining that, in establishing causation-in-fact in off-Table vaccine cases, a temporal association of the onset of injury with the vaccination is, by itself, insufficient evidence of causation; nor is it sufficient to establish a mere similarity between a petitioner’s injury and an injury listed on the Vaccine Injury Table).

<sup>64</sup> *Knudsen v. Secretary of Health and Human Services*, 35 F.3d 543, 549 (Fed. Cir. 1994) (holding that ‘causation [in fact] can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms’).

<sup>65</sup> James, Hazard and Leubsdorf, *supra* n 60 at § 7.13.

<sup>66</sup> 42 U.S.C. § 300aa-13(a)(1) (2006).

<sup>67</sup> James, Hazard and Leubsdorf, *supra* n 60 at § 7.5.

<sup>68</sup> Vern R. Walker, Preponderance, Probability and Warranted Factfinding, 62 *BROOKLYN L. REV.* 1075, 1076 (1996); James, Hazard and Leubsdorf, *supra* n 60 at § 7.14.

<sup>69</sup> Walker, *supra* n 68 at 1076.

<sup>70</sup> *Althen*, 418 F.3d at 1280.

<sup>71</sup> E.g. *Colon v. Secretary of Health and Human Services*, 2007 U.S. Claims LEXIS 13, at \*47 (2007) (stating that ‘[u]nder the Vaccine Act, a petitioner is not required to prove his case by medical certainty but only by a preponderance of the evidence, which this Court has described as 50% and a feather’).

this understanding.<sup>72</sup> The Federal Circuit has also stated that ‘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’.<sup>73</sup> Thus, circumstantial evidence is expected and often legally sufficient.

The set of process rules that constrain the factfinder’s discretion (rules about burden of production, sufficiency of evidence, burden of persuasion, and standard of proof) mean that evidence assessment is decomposed into a set of logical components, which in turn result in allocating different aspects of evidence assessment to the court (as ‘issues of law’) and to the factfinder (as ‘issues of fact’).

### 5.6 *Differentiated inference tasks and institutional competence*

Separating the logical constituents of an inference (legal rules, policy objectives, findings of fact, presumptions, burdens of proof) allows the structuring of a process for making the inference. One aspect of the process approach to inference is that different participants can then perform different tasks within a single process. This approach has several advantages. First, different institutions can be designed to have the particular competences needed for performing the particular tasks assigned. For example, the political nature of Congress is best fitted for negotiating the trade-offs needed in balancing competing policy objectives; the experience of appellate court judges is best fitted for elaborating systems of legal rules; and the experience of special masters with a high number of vaccine cases is best fitted for determining the credibility of the expert witnesses encountered in such cases. The distinction between ‘issues of law’ (to be decided *de novo* by reviewing courts) and ‘issues of fact’ (to be judicially reviewed under a deferential standard) is designed to ensure that particular institutions with particular competences play a suitable role with regard to the inference process, and do not encroach upon the decisional role of another institution. Secondly, such institutions can collectively provide a structure with internal ‘checks and balances’ on the different participants. For example, reviewing courts can ensure that special masters understand and correctly apply the legal rules, while special masters can ensure that the peculiar evidence in each particular case receives individual treatment under those rules. Thirdly, the structured process can incorporate a large number of participants without unduly sacrificing efficiency, which has the potential to increase not only accuracy of decision-making, but also public confidence in the decisions made.

There are also disadvantages in the process approach to inference. One is inefficiency, because implementing a process tends to consume more resources (in time and the various other costs of participation) than inference without a process. Another is unfairness with respect to access, if the very existence of the process is a disincentive against some people engaging in it (e.g. those who cannot afford to wait or to pay for participation). A related disadvantage is that inferences of causation must be important enough to society (or to private parties) to warrant the expense of the process, and questions of causation that are not sufficiently important do not warrant a process approach.

<sup>72</sup> See *Pafford v. Secretary of Health and Human Services*, 451 F.3d 1352, 1360, 1361 (Fed. Cir. 2006) (upholding the decision of the special master; but the dissent stated that ‘the Special Master “painstakingly looked for the feather in Petitioners’ argument that would tip the scales” as to causation in fact’, that the special master did not find such additional evidence, and that ‘[t]he majority holds that this was proper’).

<sup>73</sup> *Althen*, 418 F.3d at 1280.

### 5.7 *The necessity for empirical research*

The LLT Lab's logic model for a particular legal decision represents the entire reasoning supporting the ultimate conclusion. It consists of both the applicable rule tree and the supporting reasoning, including the evidence in the legal record and the reasoning from that evidence to the findings of fact. But, as the vaccine cases illustrate, the rule tree results from a balancing of competing policy objectives, and the factfinding often does as well. One implication of understanding this structure and the process from which it results is that empirical research is necessary in order to discover how various participants in the process are in fact using their discretion to strike particular balances of those policy objectives as they go about their particular tasks in the process. Understanding an area of law in which complex issues arise involving a variety of evidence, such as in the vaccine cases, requires a methodology that extends down through the factfinding and provides a neutral framework through which different kinds of cases, in different legal areas or systems, can be compared.<sup>74</sup>

## 6. Conclusion

In law, inferences of causation are sometimes made through a structured process in which multiple participants play various roles, and make decisions concerning various logical components of the overall inference (such as legal rules, policy objectives, presumptions, evidence, burdens of proof, and findings of fact). Empirical research into actual legal processes is essential, in order to discover how various players approach their sub-tasks of decision-making. Such research into the law's process approach to inferences of causation not only provides data for hypothesis testing and theory refinement, but also has value for areas outside of law. The dynamic interaction among the logical components (such as between policy objectives and default presumptions, or between policy objectives and legal rules) might provide insights for non-monotonic logic and artificial intelligence. Moreover, the structure of the legal process itself, and the allocation of decision-making roles within that process, might help frame interesting questions about process elements (such as burdens and standards of proof), and might provide useful heuristics and hypotheses for such disciplines as sociology, cognitive science, and artificial intelligence. This is particularly important for inferences about difficult but socially important concepts, such as causation. The empirical methodology of the LLT Lab allows a deep and comparative analysis of such process approaches to such inferences. Moreover, the logic models that result from this methodology are in a form that is useful for quantitative analysis and computational uses.<sup>75</sup>

<sup>74</sup> See, e.g. Giovanni Comandé, *Legal Comparison and Measures: It's Logic to go Beyond Numerical Comparative Law. Studi in onore di Aldo Frignani, Nuovi orizzonti del diritto comparato europeo e transnazionale* 173–202 (2011) (using the default-logic framework to compare the rule trees for medical malpractice liability in the USA and in Italy, and thereby illustrating 'research that is much more effective both in detecting variances and similarities as well as placing specific phenomena within the context of a legal system').

<sup>75</sup> See, e.g. Vern R. Walker, Nathaniel Carie, Courtney C. DeWitt and Eric Lesh, *A Framework for the Extraction and Modeling of Fact-Finding Reasoning from Legal Decisions: Lessons from the Vaccine/Injury Project Corpus*, 19 *ARTIFICIAL INTELLIGENCE & LAW* 291–331 (2011).

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