

# Scientific causation in populational health cases: an alternative for non-communicable diseases

**This white paper advocates for a new theory of causation in mass tort law to address health harms such as non-communicable diseases (NCDs) caused by the consumption of unhealthy products produced by profit-driven transnational corporations. Traditional tort law struggles with the complex causation issues inherent in NCDs, often resulting from prolonged exposure to harmful products, as it focuses on individual causation which scientific research does not typically provide. This has shielded industries from liability, as legal practitioners rely on unprincipled standards of proof based on belief rather than scientific evidence. The paper proposes integrating epidemiological methodologies into legal standards of evidence to better establish causation in mass tort cases. By adopting these scientific approaches, the legal system can better fulfill its role in compensating and deterring harms caused by unhealthy products. This could benefit from both substantial and procedural changes in law, including a collective approach to tort claims, to effectively address the growing burden of NCDs. Although epidemiology may not provide indisputable evidence in every case, its methodologies should be fully utilized when available to enhance the accuracy and fairness of causation determinations in tort law.**

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## INTRODUCTION

The diseases that harm our populations the most have changed in the past centuries. If the rise of injuries and accidents marked the 19<sup>th</sup> century<sup>1</sup> and, in the transition to the 20<sup>th</sup> century, societies faced and gained a greater understanding of communicable diseases,<sup>2 3</sup> the ultra-connected and globalized world of the 21<sup>st</sup> century ironically presented us with the growing challenge of non-communicable

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- 1 LAWRENCE M. FRIEDMAN, *A HISTORY OF AMERICAN LAW* 467 (Fourth edition ed. 2019). (“Every legal system tries to redress harm done by one person to another. The industrial revolution added an appalling increase in dimension. It manufactured injury and sudden death, along with profits and the products of machines.”)
  - 2 Anthony S. Fauci & David M. Morens, *The Perpetual Challenge of Infectious Diseases*, 366 *NEW ENGLAND JOURNAL OF MEDICINE* 454-461 (2012). (“In the late 1800s, the realization that identifiable microbes caused specific diseases led to pathogen-specific medical diagnosis.”)
  - 3 Communicable diseases harmed us before that century and, as the COVID-19 pandemic demonstrated, clearly still do. However, communicable diseases are not the primary concern in terms of disease prevalence nowadays, as will be explained below.

diseases.<sup>4</sup> The problems of previous centuries are now intertwined. However, regarding overall prevalence, non-communicable diseases are now the primary concern. For instance, in a recent study<sup>5</sup> spanning from 1980 to 2016 and involving data collection from 195 countries, the findings revealed that injuries constituted a mere 8.43% of all fatalities. In contrast, communicable diseases accounted for 19.3%, while non-communicable diseases were responsible for a significant 72.3% of deaths.<sup>6</sup> Therefore, our current times present the culmination of an epidemiological transition,<sup>7</sup> demanding new answers from sciences and institutions.

In the public health arena, prevention is the fundamental goal from the health<sup>8</sup> and economic perspectives.<sup>9</sup> Injuries are generally the consequence of accidents, unintended and unexpected,<sup>10</sup> and are prevented with safety measures.<sup>11</sup> Communicable diseases are caused by pathogens<sup>12</sup> and are addressed by tackling well-understood mechanisms<sup>13</sup> and vectors.<sup>14</sup> In turn, non-communicable diseases are a far more complicated matter, mainly because of the characteristics of such diseases. They represent changes in our way of thinking about vectors of disease, causation,<sup>15</sup> and the extent of damages.<sup>16 17</sup>

The vectors of non-communicable diseases are arguably the transnational corporations that produce harmful consumer products,<sup>18</sup> pointed out by some authors as the cause of the current “industrial epidemics.”<sup>19</sup> Unlike the vectors of communicable diseases, usually identified as viruses or bacteria carried out through water or air,<sup>20</sup> transnational corporations make profit-driven decisions that produce consumer

- 4 The term “non-communicable diseases” refers to illnesses like cancer, diabetes, and cardiovascular diseases. They are multi-factored and proven consequences of the consumption of unhealthy foods and beverages, tobacco use, physical inactivity, and the harmful use of alcohol. Also, they are characterized as a group of conditions that are not mainly caused by an acute infection, are not passed from person to person, result in long-term health consequences, and often create a need for long-term treatment and care. Noncommunicable Diseases—PAHO/WHO | Pan American Health Organization, <https://www.paho.org/en/topics/noncommunicable-diseases> (last visited Jun 7, 2023); World Health Organization, *Noncommunicable diseases*, 2022, <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases> (last visited Mar 31, 2023).2023
- 5 Mohsen Naghavi et al., *Global, regional, and national age-sex specific mortality for 264 causes of death, 1980–2016: a systematic analysis for the Global Burden of Disease Study 2016*, 390 *THE LANCET* 1151–1210 (2017).
- 6 Such findings have been ever since confirmed by several other studies. See e. g. Gregory A Roth et al., *Global, regional, and national age-sex specific mortality for 282 causes of death in 195 countries and territories, 1980–2017: a systematic analysis for the Global Burden of Disease Study 2017*, 392 *THE LANCET* 1736–1788 (2018); Daniele Piovani, Georgios K. Nikolopoulos & Stefanos Bonovas, *Non-Communicable Diseases: The Invisible Epidemic*, 11 *JOURNAL OF CLINICAL MEDICINE* 5939 (2022)
- 7 M.H. Wahdan, *The epidemiological transition*, 2 *MHJ-EASTERN MEDITERRANEAN HEALTH JOURNAL* 8–20 (1996); *Id.*; George A. Atiim & Susan J. Elliott, *The Global Epidemiologic Transition: Noncommunicable Diseases and Emerging Health Risk of Allergic Disease in Sub-Saharan Africa*, 43 *HEALTH EDUCATION & BEHAVIOR* 375–555 (2016).
- 8 Charles Alessi & Elaine Rashbrook, *Public health and prevention: acting to make longer lives healthier*, 20 *WORKING WITH OLDER PEOPLE* 110–120 (2016).
- 9 See e. g. Steven Simoens, *Public health and prevention in Europe: is it cost-effective?*, 2 *JOURNAL OF PHARMACEUTICAL HEALTH SERVICES RESEARCH* 151–155 (2011).
- 10 G. EDWARD. WHITE, *TORT LAW IN AMERICA: AN INTELLECTUAL HISTORY* (1980); Donald G. Gifford, *Technological Triggers to Tort Revolutions: Steam Locomotives, Autonomous Vehicles, and Accident Compensation*, 11 *JOURNAL OF TORT LAW* 71–143 (2018); John Fabian Witt, *Toward a New History of American Accident Law: Classical Tort Law and the Cooperative First-Party Insurance Movement*, 114 *HARVARD LAW REVIEW* 690–841 (2001).
- 11 See e. g. *INTERNATIONAL JOURNAL OF INJURY CONTROL AND SAFETY PROMOTION*, (2005).
- 12 DAVID D. CELENTANO, M. SZKLO & LEON GORDIS, *GORDIS EPIDEMIOLOGY* (6th edition ed. 2019). (“[Communicable] [d]iseases can be transmitted directly or indirectly. For example, a disease can be transmitted from person to person (direct transmission) by means of direct contact (as in the case of sexually transmitted infections). Indirect transmission can occur through a common vehicle such as a contaminated air or water supply or by a vector such as the mosquito”)
- 13 Fauci and Morens, *supra* note 2 at 454. (“Not only are some infectious diseases transmissible to others, a unique characteristic among human diseases, but their transmission mechanisms are relatively few (including inoculation and airborne and waterborne transmission), well understood, and comparatively easy to study, both experimentally and in the field. In addition, such transmission is generally amenable to medical and public health interventions”)
- 14 On a broad definition, a vector is an organism (vertebrate or invertebrate) that functions as a carrier of an infectious agent between organisms of a different species Anthony James Wilson et al., *What is a vector?*, 372 *PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY B: BIOLOGICAL SCIENCES* 20160085 (2017).
- 15 The present work will use the expressions ‘causation’ and ‘causality’ but does not intend any systematic distinction. Some authors define causality as what relates to the causal agent whereas causation is what relates to the effect. See Anselm Winfried Müller, *Understanding causation*, 199 *SYNTHESE (DORDRECHT)* 12121–12153, 12121 (2021).
- 16 Among several other differences. However, those three are the main factors relevant to the focus of the present work.
- 17 The word “damages” is usually used in the text as the mere plural of “damage,” to describe the overall consequences of the consumption of unhealthy foods and beverages, and it often deviates from its traditional legal meaning.
- 18 Rob Moodie et al., *Profits and pandemics: prevention of harmful effects of tobacco, alcohol, and ultra-processed food and drink industries*, 381 *THE LANCET* 670–679 (2013). (“In industrial epidemics, the vectors of spread are not biological agents, but transnational corporations. Unlike infectious disease epidemics, however, these corporate disease vectors implement sophisticated campaigns to undermine public health interventions.”)
- 19 See e. g. Martin O’Flaherty & Maria Guzman, *Keeping Public Health Clean: Food Policy Barriers and Opportunities in the Era of the Industrial Epidemics*, 3 *AIMS PUBLIC HEALTH* 228–234 (2016); Moodie et al., *supra* note 18.
- 20 See generally Fauci and Morens, *supra* note 2.

goods that, nowadays, knowingly cause health damages.<sup>21</sup> Considering these are agents who cause damages and can be held liable for their actions,<sup>22</sup> it is clear that the battle against non-communicable diseases has to involve regulation, social accountability, and liability.<sup>23</sup>

Therefore, tort law, a field that revolves around obligations and upholds a noninjury principle,<sup>24</sup> has a new role to play. Such a role consists of identifying harms and providing compensation<sup>25</sup> and deterrence.<sup>26 27</sup> In other words, with conscious profit-driven vectors, prevention is also accomplished by deterrence, and with non-communicable diseases, there is room to consider tort law and its objectives.<sup>28</sup>

Nevertheless, while the vectors of non-communicable diseases make possible discussions about the use of tort law, certain facets stemming from these ailments complicate the straightforward utilization of this legal framework to address the resulting damages. Communicable diseases are typically caused by single agents, and their identification points to a corresponding health measure (vector control, vaccination, treatment).<sup>29</sup> In contrast, non-communicable diseases are usually the result of multiple interacting risk co-factors,<sup>30</sup> mainly consumed during long latency periods,<sup>31</sup> and can affect diffuse parts of populations.<sup>32 33</sup> Therefore, the application of tort law is a possibility, but it also faces known challenges that have made it historically challenging to hold corporations accountable for their actions.<sup>34</sup>

At the core of such difficulties, when dealing with non-communicable diseases, is the issue of causation–

21 See generally Ilona Kickbusch, Luke Allen & Christian Franz, *The commercial determinants of health*, 4 THE LANCET GLOBAL HEALTH e895–e896 (2016).

22 Nicolas Bueno & Claire Bright, *Implementing Human Rights Due Diligence Through Corporate Civil Liability*, 69 INTERNATIONAL AND COMPARATIVE LAW QUARTERLY 789–818 (2020); GWYNNE SKINNER, RACHEL E. CHAMBERS & SARAH McGRATH, TRANSNATIONAL CORPORATIONS AND HUMAN RIGHTS: OVERCOMING BARRIERS TO JUDICIAL REMEDY (2020); SIMON. BAUGHEN, HUMAN RIGHTS AND CORPORATE WRONGS CLOSING THE GOVERNANCE GAP (2015).

23 See Generally Benjamin Wood et al., *Behind the ‘creative destruction’ of human diets: An analysis of the structure and market dynamics of the ultra processed food manufacturing industry and implications for public health*, JOURNAL OF AGRARIAN CHANGE (2023), <https://onlinelibrary.wiley.com/doi/10.1111/joac.12545> (last visited May 17, 2023); See J. S. Vernick, *Role of Litigation in Preventing Product-related Injuries*, 25 EPIDEMIOLOGIC REVIEWS 90–98, 90 (2003). (“A primary purpose of litigation is indeed to assess and assign liability for injury causation, and litigation can result in the compensation of the injured party. However, litigation can serve as a powerful tool for prevention as well. It has long been argued that transferring the cost of injuries through litigation, from the damaged person to the person or corporation who could have but did not prevent the injury, creates a motivation to invest in prevention rather than to pay the penalty of neglect. The conceptual basis by which litigation, actual or threatened, can foster injury prevention involves the direct link that lawsuits create between faulty products or risky behaviors and the imposition of liability for damages. Civil litigation for private wrongs (much of which is called “tort” litigation), rather than criminal prosecution for wrongs committed against society, has as its primary desired outcome a judgment involving money. For obvious reasons, the desire to avoid paying monetary damages can be a powerful motivation.”)

24 John C. P. Goldberg, *Tort Law at The Founding*, FLORIDA STATE UNIVERSITY LAW REVIEW 85–105, 85 (2011) (“[T]hat is, duties to conduct oneself in certain ways toward certain persons so as to avoid injuring them”).

25 And with compensation, provide a sense of interpersonal justice. See Diego M. Papayannis, *The Morality of Compensation through Tort Law*, 36 RATIO JURIS 3–25 (2023).

26 TORT LAW AND ECONOMICS, (Michael Faure ed., 2009). (“In engaging with activities, people create externalities, that is, the probability that others will suffer losses as a result of this activity. Tort law is regarded as an instrument that can provide behavioral incentives to the actors, so that they internalize these externalities. In other words, due to the threat of being held liable, actors incorporate the possible losses of others in their decision on how much care to take, and how often to engage in the activity”).

27 For a more in-depth analysis of both theories and how they relate, see Mark A Geistfeld, *The coherence of compensation-deterrence theory in tort law*, 61 THE DE PAUL LAW REVIEW 383– (2012); and Gary T Schwartz, *Mixed theories of tort law: affirming both deterrence and corrective justice*, 75 TEXAS LAW REVIEW 1801–1801 (1997).

28 WENDY E. PARMET, POPULATIONS, PUBLIC HEALTH, AND THE LAW 220 (2009). (“Put most simply, tort law is the field of civil (noncriminal) law that determines the rights and responsibilities that individuals and organizations, including corporations, owe one another. In contrast to the law of contracts, in which rights and responsibilities flow primarily from private agreements, in tort law responsibilities arise from and are shaped by social, especially legal, norms.”)

29 Fauci and Morens, *supra* note 2 at 454.

30 *Id.* at 454.

31 Piovani, Nikolopoulos, and Bonovas, *supra* note 6. (“NCDs, also known as chronic diseases, are characterized by non-contagious nature, multiple risk factors, a long latency period, a prolonged temporal course, functional impairment or disability, and incurability (i.e., a complete cure is rarely achieved”).

32 Antonio Gidi, *Class Actions in Brazil: A Model for Civil Law Countries*, 51 THE AMERICAN JOURNAL OF COMPARATIVE LAW 311, 350 (2003). Diffuse damages can be defined as damage to “a transindividual and indivisible right that belongs to a group of indeterminate people not previously connected, who are linked only by the factual circumstances of the specific instance.”

33 World Economic Forum, *The Global Economic Burden of Non-communicable Diseases* 12 (2011), [https://www.weforum.org/reports/global-economic-burden-non-communicable-diseases/?DAG=3&gclid=CjwKCAjwwb6lBhBJEiwAbuVUSuSIT750sfYzayDVG4LB8iWAsuqC1tr522LJoNtrqGpz7AdUPGaqcRoCinsQAvD\\_BwE](https://www.weforum.org/reports/global-economic-burden-non-communicable-diseases/?DAG=3&gclid=CjwKCAjwwb6lBhBJEiwAbuVUSuSIT750sfYzayDVG4LB8iWAsuqC1tr522LJoNtrqGpz7AdUPGaqcRoCinsQAvD_BwE) (last visited Jul 13, 2023). (“The business community is also concerned about the rising costs of health and life insurance and about the impact of NCDs on the size and purchasing power of its customer base”. (...) “Worries focus on the impact of NCDs on workforce productivity via absenteeism, presenteeism (that is, a worker being present, but unable to effectively do the work), the loss of critical skills, and the need to promote employees prematurely when more experienced employees die or can no longer work”).

34 See generally Glen Wright, *Risky Business: Enterprise Liability, Corporate Groups and Torts*, 8 JOURNAL OF EUROPEAN TORT LAW 54–77 (2017).

particularly proving the causal link between exposure and disease.<sup>35</sup> Here, the main obstacle is proof of a causal link between countless exposures to unhealthy products over the years and decades and its effects on consumers and other parts of society,<sup>36</sup> characterized as mass torts.<sup>37</sup> This paper explores the hypothesis that just as science unraveled the path to causation in communicable diseases,<sup>38</sup> it can help legal systems address causation between the consumption of unhealthy goods and non-communicable diseases, especially when dealing with damages derived from unhealthy products at the population level. In exploring this hypothesis, the present paper specifically considers the use of scientific knowledge to address the issue of uncertain causation,<sup>39</sup> primarily focusing on populations and possible solutions that epidemiology can provide for health damages derived from product consumption. The question is whether scientific knowledge can motivate a shift on the current here-called “causation paradox” in product liability, where several products, undoubtedly, are identified as causes of non-communicable diseases, but none of their manufacturers can be held liable due to uncertain causation.<sup>40</sup> The paper explores this question by focusing on the common law system.

The initial premise is that science and law are becoming more intertwined every day,<sup>41</sup> and scientific knowledge is no longer considered a privilege of some but rather a right in itself and a tool for realizing several other entitlements.<sup>42</sup> Moreover, not only does scientific knowledge heavily influence regulatory frameworks,<sup>43</sup> but it also features in more and more judicial procedures,<sup>44</sup> impacting tort law.<sup>45</sup> As a result, studies about the role of science as evidence, and that of judges as its doorkeepers, have become ever more meaningful.<sup>46</sup>

Another premise is the idea that causation is more than a legal concept. It is something that, among others, physics, philosophers, and legal and medical practitioners have studied and struggled to define.<sup>47</sup> Since law is only one of the disciplines that study such matter, the answer to the proof of causation in complex

- 35 Using the example of toxic torts, but describing the same challenges, see Steve C Gold, *When certainty dissolves into probability: a legal vision of toxic causation for the post-genomic era*, 70 WASHINGTON AND LEE LAW REVIEW 237-, 244 (2013). (“A fundamental difficulty in proving such a claim is that exposure and disease usually do not correlate perfectly: some people get sick without exposure, and some people receive exposure without getting sick.”)
- 36 Economics of noncommunicable diseases in the Americas, REVISTA PANAMERICANA DE SALUD PÚBLICA (2018), <http://iris.paho.org/xmlui/handle/123456789/49537> (last visited Jul 13, 2023). (“Global evidence indicates that the high health burden of NCDs translates into significant economic and social costs that threaten to diminish the quality of life of millions of individuals, impoverish families, jeopardize universal health coverage, and increase health disparities within and between countries.”)
- 37 RICHARD A. NAGAREDA, MASS TORTS IN A WORLD OF SETTLEMENT (2007). (“Mass torts are the by-products of industrialization, with its systematized processes for production and sale on an unprecedented scale. As in any complex process, there is a potential for error, however inadvertent. The scale of production and sale simply expands the adverse effects of any error.”)
- 38 Fauci and Morens, *supra* note 2 at 457. (“In this effort, we still follow the familiar pathway that was set down in the late 1800s for the identification and characterization, both clinical and epidemiologic, of the causative agent; the characterization of the human immune response to the pathogen; and the development of pathogen-specific diagnostic tests, treatment strategies, and public health prevention strategies such as vaccinations.”)
- 39 See e. g. Sandy Steel & David Ibbotson, *MORE GRIEF ON UNCERTAIN CAUSATION IN TORT*, 70 THE CAMBRIDGE LAW JOURNAL 451-468 (2011); See also ARIEL PORAT & ALEX STEIN, TORT LIABILITY UNDER UNCERTAINTY (2001), <https://oxford.universitypressscholarship.com/view/10.1093/acprof:oso/9780198267973.001.0001/acprof-9780198267973> (last visited Feb 8, 2022); See UNCERTAIN CAUSATION IN TORT LAW, (M. Martín-Casals & Diego M. Papayannis eds., 2015). (“Sometimes, claimants are unable to show that the substance to which they were exposed caused their loss, even when there is a strong statistical association between the exposure to the suspected substance and the kind of loss that claimants have suffered. That is, there is uncertainty at the general causation level. In some other cases, however, while general causation is scientifically established, there are problems in the proof of specific causation, because what is specifically unknown is whether a particular defendant harmed a particular victim. Moreover, on some other occasions it happens that a group of defendants impose risk on the victim, but it is impossible to determine who among them harmed the victim or, when it is known that more than one defendant contributed to the harm, it is the magnitude of each contribution that is still unknown.”)
- 40 Gold, *supra* note 35.
- 41 See WILLIAM G. TOWN & JUDITH N. CURRANO, SCIENCE AND THE LAW: ANALYTICAL DATA IN SUPPORT OF REGULATION IN HEALTH, FOOD, AND THE ENVIRONMENT (2014); FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (1994).
- 42 See Marcos Orellana, *Right to science in the context of toxic substances*, <https://undocs.org/A/HRC/48/61>; United Nations, *Universal Declaration of Human Rights* Art. 27 (1948); United Nations, *International Covenant on Economic, Social and Cultural Rights* Art. 15 (1966), <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights>; Organization of American States., *Charter of the Organization of American States* Art. 38 (1951), <http://www.oas.org/dil/1948%20charter%20of%20the%20organization%20of%20american%20states.pdf>; Organization of the American States, *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights* Art. 14 (1999), <https://www.refworld.org/docid/3ae6b3b90.html>.
- 43 Roland Cormier, Tyler Tunney & Manon Mallet, *Framing the science for technical measures used in regulatory frameworks to effectively implement government policy*, 9 FRONTIERS IN MARINE SCIENCE (2022).
- 44 ROBIN. FELDMAN, THE ROLE OF SCIENCE IN LAW (2009).
- 45 Dawis Phillip A., *The Role of Scientific and Statistical Evidence in Assessing Causality Perspectives on Causation*, in PERSPECTIVES ON CAUSATION 133-148 (Richard Goldberg ed., Kindle Edition ed. 2011).
- 46 See Stephanie Domitrovich, *Judges as Gatekeepers of Science and the Law: The Importance of Judicial Education*, 56 THE JUDGES’ JOURNAL 1-39 (2017); see also MICHELE TARUFFO, LA PRUEBA DE LOS HECHOS 333-334 (2 ed. 2003).
- 47 Jaegwon Kim, *Laws, Causation, and Explanation in the Special Sciences*, 27 HISTORY AND PHILOSOPHY OF THE LIFE SCIENCES 325-338 (2005); Cristina Puente Águeda, *Causality in Science*, 1 PENSAMIENTO MATEMÁTICO, 3 (2011). (“Causation plays a different role when analyzed from different fields. In legal ambiances it is a matter of conduct and result, while in science, such as physics it is the result of empirical experiments and evidence.”)

damages derived from product consumption may lie outside our closed legal boundaries.

Importantly, the present paper does not intend to propose how judges should assess the quality of scientific knowledge.<sup>48</sup> Science can take several forms and enter courtrooms no matter the quality of the methodology. The judiciary's role in separating "good science" and "junk science" is a relevant and controversial topic,<sup>49</sup> but one that is beyond this paper's scope.<sup>50</sup> In this regard, it suffices to say that the law usually does not provide precise guidance about how scientific knowledge should be approached,<sup>51</sup> and this topic is still being debated on several corners of the world.<sup>52</sup> Here, I assume that scientific knowledge is methodologically sound and a consequence of a peer-review process that conveys a solid communal and available understanding of its time.

The paper will start by examining the current role of science in tort law and its use in establishing factual and legal causation. It will develop the concept of causation from a legal perspective, exploring how tort law has shaped the use of scientific knowledge in connection with an individualized assessment of cause-and-effect. This section will explain how this narrow approach can be problematic when considering mass damages linked to non-communicable diseases that are derived from product consumption, pointing out that the law currently requires from science a standard of proof that science is simply not designed to produce. Moreover, this section will argue that this might as well be one of the causes of the lack of deterrence and compensation in tort cases regarding non-communicable diseases.

The following section will look at how causation is addressed by medicine and epidemiology. It will explain the methodology used primarily by epidemiology to assess cause-and-consequence linking product consumption to certain diseases, using an established scientific methodology aimed at collective evaluations. This section will also explain how this methodology was explicitly developed to address the challenges of biological chains of events and multi-factored diseases such as non-communicable diseases. It will describe how epidemiology uses concepts including relative risk and attributable fraction to reach conclusions about the association between risk factors and health harms, and argue that this can inform a revised concept of causation from the legal perspective.

The next section will contemplate the current use of scientific knowledge by law and develop how the scientific methods of epidemiology could aid tort law in achieving the principle of noninjury, providing an alternative path for causation in the case of product consumption and non-communicable diseases that can effectively promote compensation and deterrence. The section will consider the differences between the standards of proof of epidemiology and law, as well as the outcomes that these standards have so far provided. It will also propose a new standard of proof in cases regarding damages to population health—one that does not evaluate epidemiology through legal standards but instead makes methodologically sound epidemiology standards have legal consequences. Finally, the section will describe the main steps that law would need to take to make epidemiology a viable tool for tort law in such cases, examining how a collective approach to the matter could partially solve the existing issues with uncertain causation.

Final considerations will address the proposal's potential, challenges, and limitations.

48 Domitrovich, *supra* note 46.

49 See Thomas O McGarity, *Our science is sound science and their science is junk science: Science-based strategies for avoiding accountability and responsibility for risk-producing products and activities*, 52 U. KAN. L. REV. 897 (2003).

50 To better understand this issue, see JORDI FERRER BELTRÁN, *MANUAL DE RAZONAMIENTO PROBATORIO* 188 (2022), <https://www.scjn.gob.mx/derechos-humanos/sites/default/files/Publicaciones/archivos/2022-05/Manual%20de%20razonamiento%20probatorio.pdf> (last visited Mar 27, 2023); also see *generally* CARMEN VÁZQUEZ ROJAS, *DE LA PRUEBA CIENTÍFICA A LA PRUEBA PERICIAL* (2015).

51 Juan Manoel Alcoceba Gil, *Scientific Standards as Admissibility Requirements for Scientific Evidence*, 4 REV. BRAS. DE DIREITO PROCESSUAL PENAL 215-242, 226 (2018).

52 See e. g. Carmen Vásquez-Rojas, *Sobre la cientificidad de la prueba científica en el proceso judicial*, 24 ANUARIO DE PSICOLOGÍA JURÍDICA 65-73 (2014); Gil, *supra* note 51; FEDERAL JUDICIAL CENTER, *supra* note 41.

# 1. CAUSATION IN TORT LAW

In every science, causation is a complex concept,<sup>53</sup> and it is no different in law. Like several other disciplines, law has developed concepts of causation with its goals and methods.<sup>54</sup> In tort law, causation mainly focuses on individual damage, and particularly on proving that the defendant caused harm to the claimant, entitling them to some form of reparation.<sup>55</sup>

Legal frameworks typically evaluate causation in a two-step process.<sup>56</sup> The first step is to assess factual causation. This comprehends evaluating a cause-and-consequence relationship in the scope of a factual occurrence.<sup>57</sup> Therefore, the legal study of causation starts with an empiric assessment of a fact and its role in a given situation,<sup>58</sup> in the search for cause-and-consequence relationships that can have legal consequences.<sup>59</sup> The facts enter the judicial procedure as an affirmed objective reality customarily observed, tested, or concluded by another field of science,<sup>60</sup> shaped as evidence.<sup>61</sup> To some extent, it can be said that every assumption about a fact is a consequence of a scientific discovery<sup>62</sup> since facts are only facts because there is a high degree of scientific consensus about their validity and recurrence.<sup>63</sup> The clearer and more tested a given hypothesis is, the less scientific it appears to be, coming across instead as common knowledge—but there is always a (sometimes historic) scientific background.<sup>64</sup>

In our current world, science has a fundamental role in discovering facts related to a claim's controversial points.<sup>65</sup> For the plaintiff, a successful tort claim starts with a factual assessment based on a scientific hypothesis that the defendant is not able to refute.<sup>66</sup> Therefore, the facts that enter a judicial procedure result from an understanding that other sciences have established.<sup>67</sup> In tort law, these scientific facts are mainly a cause-and-consequence relationship that can have legal implications,<sup>68</sup> pointing to harm and the cause of such harm.

53 See generally James Woodward, *Causation in science*, in THE OXFORD HANDBOOK OF PHILOSOPHY OF SCIENCE 163–184 (2016).

54 Kim, *supra* note 47; Leen De Vreese, *Epidemiology and causation*, 12 MEDICINE, HEALTH CARE, AND PHILOSOPHY 345–353, 347 (2009). (“That a certain concept of cause is useful for a certain scientific discipline means that it is useful from a certain point of view, namely a point of view that reflects the interests and goals of the discipline.”)

55 Steel and Ibbetson, *supra* note 39 at 467. (“[T]he traditional, individualist model of tort law dictates that a particular defendant must be shown to have caused harm to a particular claimant in order to come under a duty to compensate”).

56 See generally Ernest J. Weinrib, *A Step Forward in Factual Causation*, 38 MODERN LAW REVIEW 518–534, 518 (1975).

57 *Id.* at 518. (“Tort lawyers traditionally distinguish between two meanings of the word “cause.” Under the rubric of cause in fact, the focus is a historical one, and attention is directed to the simple question of what happened, of whether the defendant’s conduct produced the injury.”)

58 Jane Stapleton, *Choosing What We Mean by Causation in the Law*, 73 MISSOURI LAW REVIEW 433–480, 444 (2008).

59 Richard W. Wright, *Causation in the law*, in ROUTLEDGE ENCYCLOPEDIA OF PHILOSOPHY (1 ed. 2016), <https://www.rep.routledge.com/articles/thematic/causation-in-the-law/v-1> (last visited Jan 12, 2023). (“The relevant purpose of the causal inquiry in law is the attribution of legal responsibility. Thus, in legal discourse, the phrase ‘the cause’ is an elliptical way of saying ‘the (legally responsible) cause.’”)

60 Stapleton, *supra* note 58 at 433–434. (“The world is out there, seamless and rolling along, manifesting what we call the physical laws of nature in complex confluence and combinations. (...) A well-known example is Newton’s First Law of Motion: in an isolated system, an object will maintain a constant velocity unless acted upon by an unbalanced force. We express this latter proposition as a “law” to indicate that it applies (or so it seems on the non-quantum scale) in our natural world.”)

61 Weinrib, *supra* note 56 at 518. (“The first meaning of the cause is considered to require a factual inquiry which is resolved by the production of evidence and the drawing of inferences from that evidence.”)

62 Michael S. Moore, *Causation and Responsibility*, 16 SOCIAL PHILOSOPHY AND POLICY 1–51 (1999). (“The conventional wisdom about the causation requirement in both criminal law and torts is that in reality it consists of two very different requirements. The first requirement is that of ‘cause-in-fact’. This is said to be the truly causal component of the law’s two requirements framed in causal terms, because this doctrine adopts what is thought of as the ‘scientific’ notion of causation. Whether cigarette smoking causes cancer, or whether the presence of hydrogen or helium caused an explosion, are factual questions to be resolved by the best science the courts can muster.”)

63 NATIONAL ACADEMY OF SCIENCES, *TEACHING ABOUT EVOLUTION AND THE NATURE OF SCIENCE* 5 (1998), <http://www.nap.edu/catalog/5787> (last visited Sep 22, 2023). (“[T]he word “fact” has a different meaning in science than it does in common usage. A scientific fact is an observation that has been confirmed over and over.”)

64 As an example, many liability cases use Newton’s laws of motion as an undisputed reality. See e. g. David Hamer, *‘Factual causation’ and ‘scope of liability’: What’s the difference?: ‘Factual causation’ and ‘scope of liability’*, 77 THE MODERN LAW REVIEW 155–188 (2014); Stapleton, *supra* note 58 at 433–434.

65 Carl F. Cranor, *The Science Veil over Tort Law Policy: How Should Scientific Evidence Be Utilized in Toxic Tort Law?*, 24 LAW AND PHILOSOPHY 139–210, 139 (2005). (“In the scientific and technological world in which we live, science provides one of the most reliable means for investigating empirical claims and producing comparatively objective evidence about them, which has resulted in “huge advances in human understanding ... over the ages.”)

66 See generally DANUTA MENDELSON & IAN FRECKELTON, *CAUSATION IN LAW AND MEDICINE* 40 (2002), <http://ebookcentral.proquest.com/lib/georgetown/detail.action?docID=4817421>.

67 In this sense, some authors refer that factual causation can be expressed by words like ‘actual causation’, ‘natural causation’, or ‘scientific causation’. See Richard W. Wright, *The NESS Account of Natural Causation: A Response to Criticisms*, in PERSPECTIVES ON CAUSATION (2011).

68 See generally Hamer, *supra* note 64.

However, not only empirical and scientific observations and evaluations play a part. Under tort law, beyond the assessment of facts, causation is embedded with a sense of accountability.<sup>69</sup> Hence, the law does not settle on factual causation, and here begins the second step. Values, morals, as well as economic and social goals also influence how legal systems understand and give power to causal relationships, with legal consequences.<sup>70</sup> When a factual causal relationship enters a lawsuit as evidence, our legal systems reshape its value, evaluating the so-called legal causation.<sup>71</sup> In this sense, law reshapes the meaning and the effect of factual causation, by either enhancing or diminishing its legal consequences. By doing so, it reframes scientific knowledge. More precisely, law does not reframe scientific concepts and conclusions, but rather their consequences in the legal environment. Therefore, depending on what law understands as legal causation, it can mold the practical effects of factual causation to deny<sup>72</sup> or impose<sup>73</sup> liability.<sup>74</sup> As a result, legal practitioners are always disputing what causation means and what consequences factual (scientific) knowledge should have in our society from a legal standpoint.<sup>75</sup>

The exercise of attributing legal meaning to science fits within a broader context. After all, legal systems reflect and respond to social pacts regarding the trade-offs that our society is willing to make to protect its interests.<sup>76</sup> One meaningful part of this is deciding when a wrongful act has occurred, when deterrence is needed, when reparation is due, and who is responsible for it.<sup>77</sup> Therefore, legal causation in tort law is a complex web of observation, science, values, and desires that legal systems use to steer society in the direction of political, economic, and sociological goals, under abstract understandings of right, wrong, permitted, and forbidden.<sup>78</sup>

Here, one point stands tall. Legal causation is an intentional choice towards an intended result, made possible because scientific knowledge enters lawsuits as evidence.<sup>79</sup> In the procedural and substantial assessment of facts (in legal terms, acceptance and evaluation of evidence), law assigns legal meaning and value to science, aiming at the solution of the case in question.<sup>80</sup> Scientific knowledge, therefore, enters a discussion that is essentially confined, designed not to evaluate science itself, but rather its capability to shape legal discussions. No matter how sound and undisputed on its own grounds, science loses the home-field advantage in the legal arena.

Regarding causation in tort law, the use of scientific knowledge can be problematic. The challenges faced by courts in using scientific knowledge are partly due to the epistemological focus of each field of knowledge. Although one of science's main objectives is to "discover and master the chain of causalities,"<sup>81</sup> the approach to this subject by tort law can be quite different. Science<sup>82</sup> is usually focused on creating a hypothesis,

69 Wright, *supra* note 59. ("Such responsibility may exist (e.g., under principles of distributive justice) even though the person in question was not a cause of the consequence.")

70 Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL LAW REVIEW 469-533, 471 (1988). ("Legal notions of causation, however, differ in important ways from scientific causal concepts.")

71 Thomas Byrne, *Legal causation*, 14 JURISPRUDENCE 55-75 (2023). See also Cornell Law School, *Legal Cause*, LEGAL INFORMATION INSTITUTE, [https://www.law.cornell.edu/wex/legal\\_cause](https://www.law.cornell.edu/wex/legal_cause) (last visited Sep 25, 2023). ("Legal cause involves examining the foreseeability of consequences, and whether a defendant should be held legally responsible for such consequences. The focus in the legal causation analysis is whether, as a matter of policy, the connection between the ultimate result and the act of the defendant is too remote or insubstantial to impose liability.")

72 For example, if the factual cause is too remote or accompanied by an exculpatory circumstance.

73 Like, to name two hypotheses, the cases of vicarious liability and causation by omission.

74 See generally H. L. A. HART & TONY HONORE, *CAUSATION IN THE LAW* (2nd ed ed. 1985); Byrne, *supra* note 71.

75 See generally Stapleton, *supra* note 58.

76 *Id.*

77 David G. Owen, *Philosophical Foundations of Fault in Tort Law*, in *THE PHILOSOPHICAL FOUNDATIONS OF TORT LAW* 201-228 (David G. Owen ed., 1 ed. 1997), <https://academic.oup.com/book/9398/chapter/156232939> (last visited Sep 27, 2023). ("The law of torts by definition concerns the law of 'wrongs'. With few exceptions, fault defines the core and borders of responsibility throughout this entire area of the law. While harm alone in some abstract sense may be viewed as a 'wrong' to the person suffering it, in most cases an actor fairly may be held accountable for making good the harm only if he was at fault in causing it, only if his choices that resulted in the harm fairly may be blamed. Choosing to deny another person's equal right to freedom is the most fundamental reason for such blame. While intentional harms generally are wrongful, an actor may properly choose to harm another in the exercise of his prior protective rights. In an imperfect and dynamic world, accidental harm is inevitably entailed in human freedom, such that conduct resulting in accidental harm may be considered faulty only if it results from a choice to violate another person's vested rights or the community's interests in utility. Based on philosophical foundations of this type, the law of torts rests comfortably on elemental notions of right and wrong, on principles of fault.")

78 Richard L. Abel, *A Critique of Torts*, 37 UCLA LAW REVIEW 785-831, 801 (1990). ("The decision to award compensation is inescapably political and unprincipled")

79 See generally David M. Benjamin, *Elements of causation in toxic tort litigation: Science and law must agree*, 14 THE JOURNAL OF LEGAL MEDICINE (CHICAGO. 1979) 153-165 (1993).

80 De Vreese, *supra* note 54 at 347.

81 United Nations Educational, Scientific and Cultural Organization (UNESCO), *Recommendation on Science and Scientific Researchers* (2017), <https://unesdoc.unesco.org/ark:/48223/pf0000260889.page=116>.

82 Here, science as a field of knowledge that uses methods for experimentation and repetition. BARRY GOWER, *SCIENTIFIC METHOD* (0 ed. 2012), <https://www.taylorfrancis.com/books/9781134806300> (last visited Nov 9, 2023).

and the failure to reject such a hypothesis confirms the scientific validity.<sup>83</sup> Tort law aims to determine responsibility for a past occurrence.<sup>84</sup> Therefore, while other fields of science are more focused on the “effects of causes,” tort law is more interested in the “causes of effects.” In this sense, scientific knowledge usually seeks to explain a prospective evaluation to discover “if ‘A’ will cause ‘B.’” Tort law, in turn, focuses mainly on a retrospective evaluation aimed at discovering “if ‘A’ was the cause of ‘B’ in a particular event.”<sup>85</sup> This opposite approach produces a (sometimes understood as) limited applicability of scientific knowledge<sup>86</sup> when addressing product liability, because factual (scientific) causation in tort law can be evaluated and considered general causation or individual causation.<sup>87</sup>

General causation is the analysis of the abstract capacity of an agent to cause the alleged harm.<sup>88</sup> This is the approach of “classical scientific methods,”<sup>89</sup> where a hypothetical effect is investigated, tested, and sometimes proven to be the consequence of a fact. Usually, this is where scientific knowledge stops, because science is interested in patterns.<sup>90</sup> Law requires an additional step, since, especially when it comes to causation in torts, patterns are not enough. To impose legal consequences, law systems use general causation as the foundation of a cause-and-consequence relationship, but also require individual causation.<sup>91</sup> Regarding product liability, individual causation demands proof that the agent, in a determined case, produced the harm that befell a specific individual and originated the tort claim.<sup>92</sup>

Here is where the friction starts to occur. In our current state of knowledge, there is an immense difference regarding individual causation between a direct cause-and-effect relationship with a physical explanation<sup>93</sup> and cases with a biological explanation,<sup>94</sup> as in non-communicable diseases. Law uses the concept of sufficient and necessary cause to determine liability,<sup>95</sup> and this is common in cases revolving around the general laws of physics.<sup>96</sup> The situation is quite different in cases involving a biological chain of events.<sup>97</sup> For example, a tort claim involving a simple traffic accident usually uses a straightforward application of tort concepts to promote compensation and deterrence. The same outcome is not seen in cases built around multi-factored diseases.<sup>98</sup> In these situations, while scientific knowledge can usually point to a clear cause-

83 MENDELSON AND FRECKELTON, *supra* note 66 at 40. (“Cause can never be unequivocally proven in a scientific sense. The scientific method involves creation of hypotheses, which are then tested and sometimes rejected. It is the failure of rejection of hypotheses that confirms scientific validity.”)

84 Ingeborg Puppe, *The Concept of Causation in the Law*, in CRITICAL ESSAYS ON “CAUSATION AND RESPONSIBILITY”, 68 (2013). (“The jurist employs the notion of causality to justify responsibility for something that has already happened”)

85 Phillip A., *supra* note 45 at 133.

86 Brennan, *supra* note 70 at 471.

87 See generally Donald G. Gifford, *The Challenge to the Individual Causation Requirement in Mass Products Torts*, WASHINGTON AND LEE LAW REVIEW 873 (2005).

88 FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE. 392 (2011). (“To consider the problem of general causation is to consider whether an agent (e.g., an exposure factor) is capable of causing disease, typically in a population”)

89 See generally GOWER, *supra* note 82.

90 MENDELSON AND FRECKELTON, *supra* note 66 at 40.

91 Also referred to as specific causation.

92 David Bernstein E., *Getting to Causation in Toxic Tort Cases*, 74 BROOKLIN LW REVIEW 51-74, 51. (“First, a plaintiff must show that the substance in question is capable of causing the injury in question. This is known as “general causation.” Second, a plaintiff must show that this substance caused *his* injury.”)

93 Brennan, *supra* note 70 at 471. (“[T]he causal concepts that derived from Newtonian physics are quite similar to those that inform the law, although they are no longer essential to science”)

94 See generally M Parascandola & D L Weed, *Causation in epidemiology*, 55 JOURNAL OF EPIDEMIOLOGY AND COMMUNITY HEALTH (1979) 905-912 (2001).

95 Such theory is divided into several sub-theories, which nonetheless require, in some way, analysis of “how” and “why” causal chains occur. See e. g. Tony Honoré, *Necessary and Sufficient Conditions in Tort Law*, in THE PHILOSOPHICAL FOUNDATIONS OF TORT LAW 363-386 (David G. Owen ed., 1 ed. 1997), <https://academic.oup.com/book/9398/chapter/156243912> (last visited Dec 1, 2023).

96 L R Karhausen, *Causation: the elusive grail of epidemiology*, 3 MEDICINE, HEALTH CARE, AND PHILOSOPHY 59-67, 63 (2000). (“Many of the discussions covering causation subscribe to the doctrine of the unity of science which construes scientific method as invariant as to its various objects. Physics - often seen as the crown of sciences - bulks large with those debates. Law-like statements are grounds for explanation; they answer questions about how and why some sort of event happened.”)

97 Kenneth J Rothman & Sander Greenland, *Causation and Causal Inference in Epidemiology*, 95 AMERICAN JOURNAL OF PUBLIC HEALTH (1971) S144-S150, 144 (2005). (“A “sufficient cause,” which means a complete causal mechanism, can be defined as a set of minimal conditions and events that inevitably produce disease; “minimal” implies that all of the conditions or events are necessary to that occurrence. [...] For biological effects, most and sometimes all of the components of a sufficient cause are unknown”)

98 PARMET, *supra* note 28 at 227-228. (“[I]n our increasingly complex environment, plaintiffs often face insurmountable problems in trying to prove causation. A hundred and fifty years ago, when the bread and butter tort case involved railroad accidents or other injuries that occurred quickly through physical contact, it was relatively simple to show that the defendant’s action caused the plaintiff’s injury. In a more complex world, in which toxic chemicals and other hazards are understood to have long-term diffuse and disparate effects over broad populations, and in which we understand that the determinants of disease and injury are almost always multifactorial, the relationship between the defendant’s action and any one plaintiff’s injury cannot be established merely on intuition or eyewitness testimony. Indeed, as discussed, the most potent determinants of a disease or injury are often those that are distal and incidental, observable only by comparing the incidence of a disease or injury in one population to that in another population which is not exposed to that variable. In such cases, it is often difficult, if not impossible, to establish the linkage that courts frequently demand between the plaintiff’s injury and the defendant’s activity.”)



and-consequence relationship between the agent (in this case, a given substance's properties) and the type of damage, it is uncommon to find an actual scientific proof of a specific cause-and-consequence relationship between such agent and a particular harm.<sup>99</sup>

Moreover, in tort law and product liability, the road to proving cause-and-consequence relationships with legal implications, starting with general causation and passing through individual causation, has yet another stop: meeting the required standard of proof.<sup>100</sup> Tort law establishes a standard of proof based on individual causation, which serves as guidance for legal systems in instructing judges and jurors on the level of confidence society expects them to employ when reaching factual conclusions.<sup>101</sup> Therefore, to prove individual causation, the evidence must meet the "burden of persuasion"<sup>102</sup> and convince the decision-maker that the argument in question should prevail.

However, the concept of standard of proof has problems of its own. Different cases and situations are assessed in legal systems using different evidentiary thresholds. The main ones are summarized by expressions like "preponderance of the evidence,"<sup>103</sup> "beyond reasonable doubt,"<sup>104</sup> or "clear and convincing evidence."<sup>105</sup> Tort law usually uses the first standard, "preponderance of the evidence."<sup>106</sup> Even though the standards can differ, one thing appears to be shared: the assessment of the standard of proof is qualitative,<sup>107</sup> not grounded on percentages or other precise guidance.<sup>108</sup> Law dictates that practitioners must simply apply the standard of proof without providing clear parameters of what those standards mean.<sup>109</sup> The consequence is a lack of boundaries and an unclear understanding of the required standards of proof in tort law cases related to meeting the preponderance of evidence threshold.<sup>110</sup> What settles a case in favor or against a plaintiff is a sense of belief of the judge or juror.<sup>111</sup> Therefore, scientific knowledge enters the judicial case, and the fulfillment of the standard of proof is decided based on usually vague appreciations (beliefs) that are not bound to the scientific methods upon which the evidence was produced. Hence, the legal answer for the

99 See generally Gifford, *supra* note 87.

100 David L Schwartz & Christopher B Seaman, *Standards of proof in civil litigation: an experiment from patent law*, 26 HARVARD JOURNAL OF LAW & TECHNOLOGY 458-434 (2013). The author quotes a definition from the United States Supreme Court that explains that the standard of proof is "[T]he degree of certainty by which the factfinder must be persuaded . . . to find in favor of the party bearing the burden of persuasion. In other words, the term 'standard of proof' specifies how difficult it will be for the party bearing the burden of persuasion to convince the jury of the facts in its favor."

101 *Id.* at 430. ("[Standards of proof] serve 'to instruct the factfinder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions.'" The various standards of proof reflect the legal system's judgment about the proper allocation of risk between litigants, as well as the relative importance of the issues at stake.")

102 Law Insider, *burden of persuasion*, LAW INSIDER DEFINITION, <https://www.lawinsider.com/dictionary/burden-of-persuasion> (last visited Oct 11, 2023). ("Burden of persuasion means the obligation of a party to meet the requirements of a rule of law that the fact be proved either by a preponderance of the evidence or by clear and convincing evidence or beyond a reasonable doubt, as the case may be.")

103 Alice Guerra, Barbara Luppi & Francesco Parisi, *Standards of Proof and Civil Litigation: A Game-Theoretic Analysis*, 19 THE B.E. JOURNAL OF THEORETICAL ECONOMICS, 2 (2018), <https://www.degruyter.com/document/doi/10.1515/bejte-2017-0005/html> (last visited Sep 29, 2023). ("In common law, the most commonly used standard of proof requires plaintiffs to prove their claim by the so-called 'preponderance of evidence' standard (or 'balance of probabilities'), which means 'to prove that something is more likely so than not so'. This is generally understood as implying a 50% threshold degree of certainty.")

104 Schwartz and Seaman, *supra* note 100 at 436. ("[P]roof beyond a reasonable doubt is constitutionally required for conviction in criminal cases. This standard has been described by the Court as the 'bedrock . . . principle whose enforcement lies at the foundation of the administration of our criminal law.'" In terms of allocation of risk, the beyond a reasonable doubt standard places almost all risk upon the government rather than the criminal defendant.")

105 *Id.* at 2. ("Higher than 50% evidence standards are also often adopted in civil litigation. For example, in some civil cases, more stringent standards are applied and one must adduce 'clear and convincing' proof. This standard is applied when settling cases involving withdrawal of life support in comatose patients, child custody, involuntary commitment, or in some administrative disciplinary proceedings for attorneys, physicians or other medical professionals.")

106 David Rosenberg, *The Casual Connection in Mass Exposure Cases: A Public Law Vision of the Tort System*, 97 HARVARD LAW REVIEW 849, 857 (1984). ("The tort system conventionally uses the preponderance-of-the-evidence rule to resolve causal connection questions. That rule imposes an all-or-nothing burden - normally on plaintiffs - to present proof from which the jury may 'find that the existence of the contested fact is more probable than its nonexistence'")

107 Louis Lasagna & Sheila R. Shulman, *Bendectin and the Language of Causation*, in PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 101-122, 112 (Kenneth R. Foster, David E. Bernstein, & Peter W. Huber eds., 1993). ("The evidence in such cases is qualitative, and resists precise measurement. . . . The precise extent of the causal connection is not specified when legal responsibility is imposed.")

108 See generally Richard W. Wright, *Proving Causation: Probability versus Belief*, in PERSPECTIVES ON CAUSATION (Richard Goldberg ed., 2011).

109 See e. g. Kevin M. Clermont, *Standards of Proof Revisited*, 33 VERMONT LAW REVIEW 469-488 (2009).

110 Schwartz and Seaman, *supra* note 100 at 438. The authors, quoting a study conducted to quantify the understanding of judges and jurors regarding the preponderance standard, demonstrated that there was a substantial disagreement regarding "the percentage likelihood needed to satisfy the preponderance standard. For the median judge, this standard was satisfied with a 54% probability (i.e., 5.4 on a 10-point scale). In contrast, the median juror believed that 75% probability was required (i.e., 7.5 on a 10-point scale) to satisfy the preponderance standard.")

111 Wright, *supra* note 108. ("In both systems, the plaintiff generally must provide evidence sufficient to convince the trier of fact of the truth of the facts at issue in the particular situation; a mere statistical probability, no matter how high, generally is insufficient. Moreover, in both systems, the required degree of belief varies in criminal actions and civil actions, given the different interests at stake in each action. For criminal actions, a very high degree of belief is required: no reasonable doubt can remain. For most issues in civil actions, however, the standard of persuasion is much lower: all that is required is the formation of a minimal personal belief (intimate conviction) by the trier of fact in the truth of the facts at issue.")

unknown is to require the same burdens of persuasion and proof of all plaintiffs, trying to extract evidence of individual causation in every case, based on what a jury or judge believes occurred in a given situation.<sup>112</sup> Law requires certainty, even if it is only a believed certainty.<sup>113</sup> An imprecise standard of proof subdues scientific knowledge and its conclusions in our legal systems.

The sum of this lack of boundaries regarding standards of proof, the requirement of individual causation, and multifactor diseases (with risk factors where the causation chain is already complex)<sup>114</sup> may explain our current difficulties in addressing liability in the industry epidemic era.<sup>115</sup> As stated before, the current reality presents our societies with the overwhelming burden of non-communicable diseases,<sup>116</sup> which harm not only individuals but populations as a collectivity.<sup>117</sup> As currently used, the legal and individual approaches to causation struggle to present an answer that can promote deterrence.<sup>118</sup> Despite scientific knowledge pointing to general causation, tort law seeks the holy grail of individual causation,<sup>119</sup> evaluated upon an abstract standard of proof.

Mass damages derived from product consumption and non-communicable diseases may call for a different solution.<sup>120</sup> If our current damages are a consequence of massified production and consumption, then the answer may lie on a different take on liability, focusing on mass torts<sup>121</sup> and expanding the horizon of what legal practitioners “choose” as causation.<sup>122</sup> As pointed out, values and economic and social goals permeate what legal systems understand as causation, and influence what legal practitioners choose and define as the evidentiary standard. The question here is whether law practitioners have the power to disregard the consequences of scientifically sound methods that can also provide an answer to the “causation paradox”<sup>123</sup> of product liability, in the name of their election to limit causation based on a set of objectives. Therefore, if general causation can be proved with scientifically sound methods, but individual causation remains a challenge (for science and the law), the way forward may lie in an alternative use of general causation and

112 *Id.* at 209. (“Of course, we rarely, if ever, will have knowledge of the multitude of necessary abstract elements in the causal laws underlying a possibly relevant causal generalisation, much less direct particularistic evidence of instantiation of each of those elements. Instead, instantiation of the unknown elements, and even some or many of the known elements, will have to be inferred circumstantially from particularistic evidence of instantiation of the network of causal relationships that encompasses the particular occasion, which fit coherently into a story of what happened on the particular occasion”)

113 Here, a certainty regarding the surpassing of the burden of persuasion and proof, but still a certainty. See e. g. Wright, *supra* note 108.

114 J Olsen, *What characterizes a useful concept of causation in epidemiology?*, 57 JOURNAL OF EPIDEMIOLOGY AND COMMUNITY HEALTH 86-88, 2 (2003). (“We operate with complex biological systems, with large variation in how exposures are taken up, metabolized, distributed, and eliminated.”)

115 Moodie et al., *supra* note 18.

116 Naghavi et al., *supra* note 5.

117 Economics of noncommunicable diseases in the Americas, *supra* note 36. (“Global evidence indicates that the high health burden of NCDs translates into significant economic and social costs that threaten to diminish the quality of life of millions of individuals, impoverish families, jeopardize universal health coverage, and increase health disparities within and between countries”); World Economic Forum, *supra* note 33 (“In addition to the tremendous demands that these diseases place on social welfare and health systems, they also cause decreased productivity in the workplace, prolonged disability and diminished resources within families”)

118 PROPORTIONAL LIABILITY: ANALYTICAL AND COMPARATIVE PERSPECTIVES, 5 (Yiśra’el Gil;ad et al. eds., 2013). (“The application of this rule of ‘all-or-nothing’ in cases of causal uncertainty leads to the outcome that Ds [defendants] are absolved from liability, and Ps [plaintiffs] are left with no redress, although it is established that D acted tortiously, and although it is established that D’s tortious conduct may have been the cause of P’s harm. Some courts, in some countries, in some kinds of cases, have found this ‘no-liability’ outcome undesirable.”)

119 Rosenberg, *supra* note 106 at 857-858. (“Under the “strong version” of the preponderance rule, even statistical correlations indicating that the probability of causation exceeds fifty percent provide an insufficient basis for liability; some “particularistic” proof of the causal connection is required. [...] The motive behind the system’s individualized focus seems fairly obvious. Imposing liability only upon the defendant whose tortious conduct actually caused the plaintiff’s harm is more than a rational means of controlling the occurrence of accidents. Individualized determination of the causal connection also comports with deeply rooted notions of moral responsibility and just compensation”)

120 *Id.* at 858. (“Yet the tort system cannot realize the aspiration to do individualized justice in mass exposure cases under the conventional approach to causality. The preponderance rule may be adequate for the set of sporadic accident cases in which causal indeterminacy arises randomly and always signifies a substantial chance that the defendant in fact harmed no one. But the rule is neither a rational nor a just means of resolving the systematic causal indeterminacy presented by mass exposure cases involving defendants whose tortious conduct has caused or will cause a statistically ascertainable increase in the incidence of a particular disease. Because long latency periods and the mysteries of disease etiology necessitate exclusive reliance on statistical evidence, the strong version of the preponderance rule requires the dismissal of all mass exposure claims. This same result would obtain in nearly all mass exposure cases in which the courts applied the weak version of the rule. The excess risk caused by exposure to a toxic agent frequently does not exceed the background risk; thus, a significant proportion of plaintiffs will be unable to prove that it is more probable than not that such exposure caused their disease.”)

121 Paul D Rheingold, *Mass Torts—Maturation of Law and Practice*, 37 PACE LAW REVIEW 617-641, 617 (2017). Mass torts as “product liability personal injury cases involving similar injuries from exposure to the same product and resulting in multiple claimants”.

122 Stapleton, *supra* note 58; Wright, *supra* note 108.

123 As stated before, a paradox where several products, undoubtedly, are pointed as causes of diseases, but none of them can be held liable due to uncertain causation.

the enforcement of collective rights, transforming an issue of individual damages into a matter of increased risk borne by entire populations.<sup>124</sup>

Additionally, causation is an epistemological construct employed by various sciences, enabling an exploration of the unknown and providing frameworks to define and address uncertainty.<sup>125</sup> If legal systems are struggling to provide compensation<sup>126</sup> and deterrence<sup>127</sup> for our current damages derived from the consumption of unhealthy goods,<sup>128</sup> scientific knowledge could have another role in tort law besides establishing the basis for factual (scientific) causation. Causation in health damages is a main concern of medicine and epidemiology, and their methodologies can perhaps aid tort law in fulfilling its objectives.

## 2. CAUSATION IN HEALTH<sup>129</sup>

As described, causation is the object of analysis of several sciences in the search for the unknown<sup>130</sup> and, as all scientific knowledge, it does not exist in isolation.<sup>131</sup> In medicine, causation is used in a forward-looking way to treat illnesses and, in retrospect, to seek explanations for diseases.<sup>132</sup> This model comes from observational studies and past experiences,<sup>133</sup> and is based on probabilities since the human body does not react evenly to treatments or illnesses.<sup>134</sup> Ever since ancient times, medicine has been anchored in scientific methods,<sup>135</sup> and these foundations have been reaffirmed in the evidence-based medicine (EBM) movement, which, beginning in the 1990s, promoted a better understanding of how medical evidence should be produced and evaluated.<sup>136</sup> EBM places a greater emphasis on evidence stemming from clinical research than on intuition and unstructured clinical experience. It centers its approach on the pathophysiological rationale as the foundation for clinical decision-making, diminishing dependence on subjective factors. Ultimately, it underscores the significance of empirical evidence in guiding medical practice.<sup>137</sup> In this sense, the EBM movement also reiterated the importance of epidemiology in the health field,<sup>138</sup> stressing the need for collective research and evaluation.

Therefore, epidemiology plays a crucial role in the study of causation in the health field, by providing a

- 124 Michele Taruffo, *Proving Complex Facts: The case of mass torts*, in *UNCERTAIN CAUSATION IN TORT LAW*, 168 (M. Martín-Casals & Diego M. Papayannis eds., 2015). (“It is usually said, actually, that the matter is of general causation when the case deals with the responsibility for increasing the risk of an illness or of any harmful effect, as it is usually determined by epidemiological research (for instance, in the case of smoke or of exposure to dangerous materials). The matter is of specific or individual causation when the case deals with the causes of particular damage suffered by a specific person: here the problem is not an increased risk of anything; it is the material causal connection between a particular fact and the individual damage suffered by a particular person”)
- 125 Brennan, *supra* note 70 at 470–471. (“In both legal and scientific reasoning, causation is an epistemological construct that allows one to investigate the unknown and to define and overcome uncertainty.”)
- 126 See generally Geistfeld, *supra* note 27.
- 127 See generally Schwartz, *supra* note 27.
- 128 See generally *UNCERTAIN CAUSATION IN TORT LAW*, *supra* note 39; Kevin D. Hall et al., *Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake*, 30 *CELL METABOLISM* 67–77.e3 (2019); Wood et al., *supra* note 23; Xiaojia Chen et al., *Consumption of ultra-processed foods and health outcomes: a systematic review of epidemiological studies*, 19 *NUTRITION JOURNAL* (2020), <https://nutritionj.biomedcentral.com/articles/10.1186/s12937-020-00604-1> (last visited Jul 19, 2023).
- 129 Health here as a view of causation focusing on medicine and epidemiology. See L R Karhausen, *Causation: the elusive grail of epidemiology*, 3 *MEDICINE, HEALTH CARE, AND PHILOSOPHY* 59–67, 59 (2000). (“Being a cause is a special characterization of some state of affairs characterized by change, i.e. an event, a fact, a state or a deed: in medicine and epidemiology, a cause makes a disease happen or not happen”)
- 130 Brennan, *supra* note 70 at 470–471.
- 131 MENDELSON AND FRECKELTON, *supra* note 66 at 39. (“Scientific knowledge does not exist in isolation. It is “framed” by current philosophical, cultural, religious, political and sociological ideas.”)
- 132 *Id.* at 5.
- 133 *Id.* at 52. (“The medical approach, especially in this era of Evidence Based Medicine (EBM), is to review the available evidence, graded according to its scientific level, and then to apply this to the case at hand.”)
- 134 *Id.* at 80.
- 135 *Id.* at 59. (“Many classical Greek concepts of medical epistemology and causation form part of modern medical and scientific thinking. In particular, Greek physicians developed a notion of rational aetiology, which involves correlation of disease to cause. The aetiology of a condition or disease would be arrived at through the process of diagnosis.”)
- 136 See generally JEREMY HOWICK, *THE PHILOSOPHY OF EVIDENCE BASED MEDICINE* (1 ed. 2011), <https://onlinelibrary.wiley.com/doi/book/10.1002/9781444342673> (last visited May 15, 2023).
- 137 *Id.* at 15. (“Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiological rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research”)
- 138 DAVID L. KATZ, *CLINICAL EPIDEMIOLOGY & EVIDENCE-BASED MEDICINE FUNDAMENTAL PRINCIPLES OF CLINICAL REASONING & RESEARCH XI* (2001). (“The science of applying the principles of population-based (epidemiologic) evidence to the management of individual patients has come to be known as clinical epidemiology. While epidemiology characterizes the impact of health related conditions on populations, clinical epidemiology applies such data to individual patient care.”)

practical framework for investigating the relationship between exposures and health outcomes.<sup>139</sup> Causation, for epidemiology, is one of the main reasons for the existence of such science,<sup>140</sup> since the study of the distribution and determinants of health-related events in populations<sup>141</sup> is its objective.<sup>142</sup> Also, by using methodologically sound criteria and techniques, epidemiology is recognized as an example of “science-based approach to causation.”<sup>143</sup>

In the past decades, with the rise of non-communicable diseases, epidemiology started to study the multifaceted nature of such illnesses when it came to causation.<sup>144</sup> However, to obtain results, epidemiology uses a methodology different from the law, which follows the path from general to individual causation, and then to the threshold of the standard of proof. In contrast, to establish causation, epidemiologists search for general causation<sup>145</sup> and use various study designs aimed at populations, such as randomized controlled trials, case-control studies, and cohort studies,<sup>146</sup> to investigate the relationship between exposure and health outcomes in populations. These studies allow epidemiologists to identify and quantify the measure of association<sup>147</sup> between the exposure and the outcome, as well as to identify potential confounding factors<sup>148</sup> that may influence this relationship.<sup>149</sup> By using a populational approach, epidemiology fills a scientific gap in relation to uncertain causation still faced by medicine<sup>150</sup> to determine the etiology of several diseases.<sup>151</sup> One of its main objects of study is non-communicable diseases.<sup>152</sup>

- 139 See generally CELENTANO, SZKLO, AND GORDIS, *supra* note 12; On the more practical role of epidemiology, see M Parascandola & D L Weed, *Causation in epidemiology*, 55 *JOURNAL OF EPIDEMIOLOGY AND COMMUNITY HEALTH* (1979) 905–912, 911 (2001). (“While philosophers are interested in general principles of causation, epidemiologists tend to be interested in particular examples of causal relations. Thus, philosophers seek definitions while epidemiologists construct causal models.”)
- 140 De Vreese, *supra* note 54 at 345. (“The notion of ‘cause’ is of central importance in the goals and practice of epidemiology”)
- 141 Anthony R. Mawson, *On not taking the world as you find it—epidemiology in its place*, 55 *JOURNAL OF CLINICAL EPIDEMIOLOGY* 1–4, 2 (2002). (“The true subject matter of epidemiologic practice and of textbooks of epidemiology is research design and methods for disentangling causes and effects. The definition [of epidemiology] may have evolved into the study of diseases in populations mainly because identifying and determining the importance of specific risk factors necessarily involves studying people in groups. Only by comparing people with and without the disease in terms of a history of exposure to a given factor, or by comparing disease rates among those who either have or have not been exposed to a factor of interest, can causes be elucidated. Epidemiology deals with groups of individuals because the methods for determining causality require it.”)
- 142 Mark Parascandola, *Causes, risks, and probabilities: Probabilistic concepts of causation in chronic disease epidemiology*, 53 *PREVENTIVE MEDICINE* 232–234 (2011).
- 143 De Vreese, *supra* note 54 at 346. (“The epidemiological literature on causation is not only of interest for epidemiologists, but also for philosophers of science because it exemplifies a science-based approach to causation.”)
- 144 *Id.* at 346. (“[T]he era of chronic disease epidemiology” (second half of the twentieth century) has given rise to theoretical writings on disease causation in which the need for ‘multicausal’ and ‘multilevel’ approaches to causation came to the foreground.”)
- 145 M Susser & E Susser, *Choosing a future for epidemiology: II. From black box to Chinese boxes and eco-epidemiology*, 86 *AMERICAN JOURNAL OF PUBLIC HEALTH* 674–677, 675 (1996). (“Like all the sciences, epidemiology seeks generalizing the concepts to explain causes of things”)
- 146 See LEON GORDIS, *EPIDEMIOLOGY* (4th ed ed. 2009); Swapna Munnangi & Sameh W. Boktor, *Epidemiology Of Study Design*, in *STATPEARLS* (2023), <http://www.ncbi.nlm.nih.gov/books/NBK470342/> (last visited Dec 2, 2023); F. Rivas-Ruiz, M. Expósito-Ruiz & S. Domínguez-Almendros, *Research designs in clinical epidemiology*, 40 *ALLERGOLOGIA ET IMMUNOPATHOLOGIA* 117–124 (2012).
- 147 Mark Gerard Haug, *measure of association*, *ENCYCLOPEDIA BRITANNICA*, <https://www.britannica.com/topic/measure-of-association> (last visited Oct 10, 2023). (Measure of association, in statistics, any of various factors or coefficients used to quantify a relationship between two or more variables. Measures of association are used in various fields of research but are especially common in the areas of epidemiology and psychology, where they frequently are used to quantify relationships between exposures and diseases or behaviors)
- 148 Theodore H. Tulchinsky & Elena A. Varavikova, *Measuring, Monitoring, and Evaluating the Health of a Population*, in *THE NEW PUBLIC HEALTH* 91–147, 116 (2014), <https://linkinghub.elsevier.com/retrieve/pii/B9780124157668000033> (last visited Oct 10, 2023). (“A confounding variable (confounder) is a factor other than the one being studied that is associated both with the disease (dependent variable) and with the factor being studied (independent variable). A confounding variable may distort or mask the effects of another variable on the disease in question”)
- 149 See e. g. Gulnar Azevedo E Silva et al., *The Fraction of Cancer Attributable to Ways of Life, Infections, Occupation, and Environmental Agents in Brazil in 2020*, 11 *PLOS ONE* e0148761–e0148761 (2016).
- 150 De Vreese, *supra* note 54 at 348. (“Studying disease causation in large groups makes us nevertheless able to answer the question of what causes diseases without knowing much about the precise biological and chemical mechanisms involved.”)
- 151 GORDIS, *supra* note 146 at 2; Parascandola and Weed, *supra* note 94 at 906. (“A small minority of epidemiologists maintain that the term “cause” should be limited to highly specific necessary conditions. The view that all causes must be necessary for their effects is traditionally associated with the germ theory of disease, wherein each disease—for example, tuberculosis—is caused by a specific infectious agent—for example, tubercle bacillus. Stehbens applies this model to all diseases, claiming that no particular disease has been proven to have more than one cause. Instead, says Stehbens, multi-causal models merely indicate gaps in scientific understanding, as scientists have not yet uncovered a sole, specific cause or adequately defined a disease outcome. [...] Support for this narrow definition of causation is ultimately a product of the lingering historical influence of scientific determinism. Since Galileo and Newton, classical physics has been rooted in a world view in which complex phenomena can always be reduced to simple, deterministic mechanisms. Strict determinism requires a one to one correspondence between cause and effect; the same cause invariably leads to the same effect, with no role for chance or stochastic variation.”)
- 152 See e. g. GORDIS, *supra* note 146; J. Olsen et al., *Global response to non-communicable diseases—the role of epidemiologists*, 41 *INTERNATIONAL JOURNAL OF EPIDEMIOLOGY* 1219–1220 (2012); Adam DM Briggs et al., *Choosing an epidemiological model structure for the economic evaluation of non-communicable disease public health interventions*, 14 *POPULATION HEALTH METRICS* 1–12 (2016).

As of now, science has not fully discovered the biological cellular or subcellular mechanism that explains how exposure to several substances gradually causes non-communicable diseases in individuals.<sup>153</sup> In other words, in medicine (as in law), uncertain causation exists due to the limitations of current scientific knowledge within a specific context of time and space. This hinders the precise description and comprehension of the actual biological events leading to individual harm.<sup>154</sup>

Some sciences seek to unravel all unknown chains of causal events.<sup>155</sup> Others focus on a broader approach, recognizing the existence of multi-factored causes for some events, while seeking to establish causation even in the face of some level of uncertainty.<sup>156</sup> Epidemiology is a prime example of the latter.<sup>157</sup> To determine causation, epidemiology uses an approach that differentiates causation from explanation.<sup>158</sup> In some stances, it is methodologically possible to establish a cause-and-consequence relationship without fully understanding all the biological steps that lead from exposure to a disease. The scientific method points to a cause and an effect, even if the complete explanation remains a “black box.”<sup>159</sup> Therefore, unlike law, the assessment does not focus on sufficiency and necessity,<sup>160</sup> but on a given exposure and disease that are tested and surpass several thresholds of science-based evaluations that eliminate confounding factors and conclude a causal relationship.

Just like law, epidemiology starts with a concept of factual causation, expressed as a hypothesis to be tested. Being a science that focuses on patterns, it evaluates general causation and, with its own methodology, transforms factual causation into scientific causation—or, in other words, into a scientific fact.<sup>161</sup> Hence, epidemiology provides a broad analysis of the capability of an agent (in this case, a substance) to produce disease and of the extent to which a given risk factor is responsible for harm on a population level.<sup>162</sup> It does not aim to establish a direct and infallible cause-and-effect link between environmental agents and diseases,<sup>163</sup> nor does it focus on individualized causation that is relevant only to a specific case. Even so, the epidemiological pathway for discovering causation does not represent a choice for a less strict methodology—quite the contrary. As mentioned above, the legal standard, at least in biological causation

- 153 Dwight C Harvey, *Epidemiologic proof of probability: implementing the proportional recovery approach in toxic exposure torts*, 89 DICKINSON LAW REVIEW 233-, 234 (1984). (“There is often no precise knowledge about how a particular toxin causes injury; no known biological mechanism exists by which to trace the toxin inevitably to the injury. In such cases, the only evidence of causation may be the statistical association between exposure to the toxin and an increased incidence of injury in the total population so exposed.”)
- 154 DAVID G. KLEINBAUM, LAWRENCE L. KUPPER & HAL MORGENSTERN, EPIDEMIOLOGIC RESEARCH: PRINCIPLES AND QUANTITATIVE METHODS 27 (1982). (“[W]e need not regard the occurrence of disease as a random process; we employ probabilistic considerations to express our ignorance of that causal process and how to observe it”)
- 155 See generally Susser and Susser, *supra* note 145. Using epidemiology as example, the authors explain the differences between the universalism and ecologism approaches of the physical and biological sciences. (“It follows that universalism is not universally applicable to the scientific endeavor. Thus, when we enter the physical, biological, and social realms of the human world, we need a parallel set of ideas interwoven with the search for generality. In epidemiology, the poor fit of universalism with human reality is better replaced by a contrasting construct of ecologism. Ecological constructs try to deal with the true complexity of the biological world. Such constructs must in varying degree be localized; they must be bounded if they are to encompass all of the biological world’s less-than-universal levels and their particular interactions.”)
- 156 Parascandola and Weed, *supra* note 94 at 911. (“Unfortunately, philosophical thinking about causation has been largely driven by the physical sciences, focusing on simple chains of events rather than the complex multi-level relations that make up biology.”)
- 157 *Id.* at 906.
- 158 Karhausen, *supra* note 96 at 63. (“The epidemiologic literature sometimes obliterates a distinction between causation and explanation: causes contribute to the existence of their effects whereas explanation, i.e. pathogenesis or mechanism, refers to how a given causal relation operates and requires necessary causes”)
- 159 *Id.* at 63. (“A black box is explained solely in terms of its inputs and outputs; the internal mechanism that converts input into output is veiled. In line with David Hume, it is not necessary to know the internal workings of a black box to ascertain the causal relation which binds the input to the output. We know why the apple fell on Newton’s nose, even though the phenomenon of gravitation is not yet fully understood. In other words, we may have evidence of causation in the absence of explanation. Causes and effects are temporal end points of changes; even though explanation consists in filling the gap between them and in spelling out the intervening steps, it is not essential for resolving causal issues. Actually, most analytic studies are concerned with causal relations, not with explanatory theories. The evidence of a cause-effect relationship between smoking and lung cancer has been unequivocal for several decades, even though the why and how of this relationship remained incomplete until recently.”)
- 160 See generally Honoré, *supra* note 95; Rothman and Greenland, *supra* note 97 at 145. (“A given disease can be caused by more than one causal mechanism, and every causal mechanism involves the joint action of a multitude of component causes. (...) The importance of multicausality is that most identified causes are neither necessary nor sufficient to produce disease.”)
- 161 Zohar Livnat, *The Concept of Scientific Fact: Perelman and Beyond*, 23 ARGUMENTATION 375-386 (2009). (“An interesting perspective that can contribute enormously to the understanding of the nature of “facts” in scientific discourse is provided by Latour and Woolgar (1979) in their book “Laboratory Life,” which discusses the social process of creating a scientific fact. Their ideas are based on a close observation of the work of scientists in an endocrinological laboratory, using a methodology adapted from anthropological research. Their description presents the scientific fact [...] as the product of communication, interaction, and negotiations, and most especially, as the final result of a disciplinary consensus”)
- 162 See Epidemiology is a science of high importance, 9 NATURE COMMUNICATIONS (2018), <https://www.nature.com/articles/s41467-018-04243-3> (last visited Oct 10, 2023).
- 163 De Vreese, *supra* note 54 at 348. (“Epidemiologists study general overall causal patterns of disease causation recurring in the population. These causal patterns are not necessarily exceptionless.”)

chains, is currently assessed by means of an unprincipled<sup>164</sup> and qualitative<sup>165</sup> standard of proof based on beliefs.<sup>166</sup> In epidemiology, beliefs exist as related to “how,” not “if,” exposure caused a given disease. Between “belief systems,” epidemiology is the one with more solid scientific grounds.<sup>167</sup>

The applicability of this field of science focuses on producing knowledge (mainly methods)<sup>168</sup> based on collective data (general causation) for situations where precise causation cannot be determined by medicine or any other science. It uses two concepts that are relevant for the purposes of this paper: relative risk and attributable fraction (sometimes referred to as attributable risk). Relative risk is a statistical measure that evaluates the likelihood that some disease occurs in an exposed and unexposed population during a defined space and time.<sup>169</sup> The relative risk does not produce a value capable of supporting a conclusion about causation on its own. However, it can provide data about how an exposure can represent a statistical difference compared to the not exposed part of the population. It is a first step. Attributable fraction is the proportion of a disease burden within a population that is “attributable” to a given exposure.<sup>170</sup> Some authors sustain that this expression is misleading, arguing that a better one would be “excess fraction,” meaning that if a solid inference is present (based on reliable data and research), it is possible to infer that the excess cases are a consequence of the exposure.<sup>171</sup> If relative risk promotes the separation of and differentiates populations exposed and not exposed to a risk factor, the attributable fraction serves to quantify such differences in a populational stance.

Using its research methods, epidemiology uses a process of calculations to test hypotheses regarding risk factors and diseases. Once relative risk and attributable fraction encounter a solid association between them, another methodological process comes into play to determine if there is a cause-and-consequence relationship. A few methods exist to reach this conclusion, but one of the most known and accepted is the “Bradford Hill criteria,” developed in 1965.<sup>172</sup> Interestingly, Bradford Hill, in the article that introduced such proposal, explained this methodology using as an example a case that has clear legal implications and touches upon the core of the present work: the relationship between product consumption and a non-communicable disease, smoking and lung cancer. His proposal states a series of considerations that should be contemplated and evaluated to qualify an association and, depending on the results, conclude that causation is the more likely scenario. The aspects to be considered are the strength of the association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experimentation, and analogy.<sup>173</sup> Despite these aspects being constantly referred to as a criterion, Bradford Hill did not appear to structure them in a closed and step-by-step way.<sup>174</sup> Of the nine elements, the only indispensable one is temporality, in the logical sense that the exposure must precede the disease.

With all its methodology, epidemiology provides a cause-and-consequence relationship that translates into a quantitative populational measure of causation. For instance, a study examining the association between active and passive smoking and lung cancer risk due to smoking in Norwegian women established that

164 Abel, *supra* note 78 at 801.

165 Lasagna and Shulman, *supra* note 107 at 112.

166 Wright, *supra* note 108.

167 MENDELSON AND FRECKELTON, *supra* note 66 at 52. (“The medical approach, especially in this era of Evidence Based Medicine (EBM), is to review the available evidence, graded according to its scientific level, and then to apply this to the case at hand. The legal approach is quite different: “In contrast, a court may approach the issue from the standpoint of the presumptive inference which a sequence of events inspires in the mind of any common sense person.” Although there is no absolute certainty about the validity of either approach, the scientific approach often requires more “hard” evidence than the legal utility of “presumptive inference”, and is less subjective.”)

168 Mawson, *supra* note 141 at 2. Quoting A. Morabia, stating that (“epidemiology is a scientific discipline that has progressively emerged as a set of research methods, which have contributed to elucidating important questions related to human health. For about 150 years, epidemiologists have developed and refined the methods of outbreak investigations, the design of cohort and case-control studies, the concepts of confounding and interaction, the categorizations of types of bias, and the process of causal inference. In this view, the history of epidemiology is characterized . . . by historical continuity and accumulation of methodological skills . . . Epidemiologists have emphasized different aspects of the methodology according to the exposures and diseases that were investigated”)

169 See e. g. Chittaranjan Andrade, *Understanding Relative Risk, Odds Ratio, and Related Terms: As Simple as It Can Get: (Clinical and Practical Psychopharmacology)*, 76 THE JOURNAL OF CLINICAL PSYCHIATRY e857-e861 (2015).

170 See e. g. Alex Broadbent, *Epidemiological Evidence in Proof of Specific Causation*, 17 LEGAL THEORY 237-278, 240-241 (2011).

171 See e. g. Sander Greenland & James M. Robins, *Conceptual problems in the definition and interpretation of attributable fractions*, 128 AMERICAN JOURNAL OF EPIDEMIOLOGY 1185-1197, 1186 (1988). (“[T]he attributable fraction measures only the fraction of all cases that are excess cases, and this can be much smaller than the fraction of cases that are etiologically attributable to exposure”)

172 Austin Bradford Hill, *The environment and disease: association or causation?*, 108 JOURNAL OF THE ROYAL SOCIETY OF MEDICINE 32-37 (1965).

173 *Id.* at 32-36 All of those are fully explained in the 1965 article; See also; MENDELSON AND FRECKELTON, *supra* note 66.

174 Hill, *supra* note 172 at 36. (“What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question - is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?”).

the population attributable fraction was 85.3%.<sup>175</sup> Similar studies reached causation conclusions between alcohol consumption and liver diseases.<sup>176</sup> Other studies have taken a broader approach and measured the effects of certain types of products, non-communicable diseases, and premature deaths. An example is a study conducted in Brazil that identified the consumption of ultra-processed foods as responsible for approximately 57,000 premature deaths, the equivalent of 10.5% of all premature deaths in adults aged 30–69 years in that country.<sup>177</sup>

At least in the first two examples,<sup>178</sup> it is clear that epidemiology already provides its own path to causation, focusing on general causation and providing a quantitative measure of a reliable populational attributable fraction that peers can methodologically evaluate. Such methods to discover and prove causation are the foundation of medical research,<sup>179</sup> having enabled us to navigate a pandemic<sup>180</sup> and constantly guide public health policies.<sup>181</sup> Unlike law and its “belief system,”<sup>182</sup> epidemiology has long been developing specific concepts and methodologies to address the issues of multi-factored causation and non-communicable diseases.<sup>183</sup>

The hypothesis presented here is that if we are already using such concepts and methodologies to save and steer lives, maybe it is time to also use them to promote financial compensation, deterrence, and address liability derived from product consumption and non-communicable diseases. To do so, instead of trying to adjust epidemiology to the causation path of law, perhaps the answer is to do the opposite, making legal systems more willing to understand and use epidemiology.

### 3. CAUSATION IN NON-COMMUNICABLE DISEASES - SCIENTIFIC CAUSATION IN POPULATIONS

As explained, science is already an indispensable component of law, determining factual causation<sup>184</sup> usually through an observation that has been confirmed reiterated times.<sup>185</sup> It can do more: scientific knowledge, in some aspects related to tort law, is not being used to its full potential. It is the role of law to shape causation<sup>186</sup> to its stated objectives, accommodating several rights and balancing both liberties

175 Merethe S. Hansen et al., *The fraction of lung cancer attributable to smoking in the Norwegian Women and Cancer (NOWAC) Study*, 124 BRITISH JOURNAL OF CANCER 658–662, 658 (2021). (“RESULTS: During the more than 2.3 million person-years of observation, we ascertained 1507 lung cancer cases. Compared with never smokers, current (HR 13.88, 95% CI 10.18–18.91) smokers had significantly increased risk of lung cancer. Female never smokers exposed to passive smoking had a 1.3-fold (HR 1.34, 95% CI 0.89–2.01) non-significantly increased risk of lung cancer, compared with never smokers. The PAF [Population Attributable Fraction] of lung cancer was 85.3% (95% CI 80.0–89.2). CONCLUSION: More than 8 in 10 lung cancer cases could have been avoided in Norway, if the women did not smoke.”)

176 See e. g. Xuanxuan Niu et al., *Global prevalence, incidence, and outcomes of alcohol related liver diseases: a systematic review and meta-analysis*, 23 BMC PUBLIC HEALTH (2023), <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-15749-x> (last visited Dec 2, 2023).

177 Eduardo A.F. Nilson et al., *Premature Deaths Attributable to the Consumption of Ultraprocessed Foods in Brazil*, 64 AMERICAN JOURNAL OF PREVENTIVE MEDICINE 129–136, 129 (2023). (“Results: The contribution of ultraprocessed foods to the total energy intake of the diet across sex and age stratum of Brazilian adults ranged from 13% to 21% of the total energy intake. A total of 541,160 adults aged 30–69 years died in 2019. The consumption of ultraprocessed foods was responsible for approximately 57,000 premature deaths (95% uncertainty interval=33,493, 82,570) or 10.5% of all premature deaths in adults aged 30–69 years. Reducing the contribution of ultraprocessed foods to the total energy intake by 10%–50% could potentially prevent 5,900 deaths (95% uncertainty interval=2,910, 10,613) to 29,300 deaths (95% uncertainty interval=16,514, 44,226), respectively. Conclusions: The consumption of ultraprocessed foods represents a significant cause of premature death in Brazil. Reducing ultraprocessed food intake would promote substantial health gains for the population and should be a food policy priority to reduce premature mortality.”)

178 Since the third example apparently would have to be refined to present a more precise result related to specific products and illnesses.

179 See generally MENDELSON AND FRECKELTON, *supra* note 66.

180 Hussin A. Rothan & Siddappa N. Byrareddy, *The epidemiology and pathogenesis of coronavirus disease (COVID-19) outbreak*, 109 JOURNAL OF AUTOIMMUNITY 102433 (2020).

181 Iris R. Shannon, *Epidemiology and the Public Policy Process*, in EPIDEMIOLOGY AND THE DELIVERY OF HEALTH CARE SERVICES: METHODS AND APPLICATIONS 187–203 (Denise M. Oleske ed., 1995); Sheldon Krinsky, *The Weight of Scientific Evidence in Policy and Law*, 95 AMERICAN JOURNAL OF PUBLIC HEALTH S129–S136 (2005).

182 Wright, *supra* note 108.

183 Mark Parascandola, *The epidemiologic transition and changing concepts of causation and causal inference*, 64 REVUE D'HISTOIRE DES SCIENCES 243, 261 (2011). (“During the postwar years, epidemiologists began to articulate a probabilistic, multifactorial model of causation distinct from the specific, necessary cause model of the germ theory. This change occurred in response to new disease challenges posed by environmental exposures associated with chronic diseases, particularly cancer. This new model of disease causation also prompted novel approaches to causal inference and the evaluation of epidemiologic evidence.”)

184 Moore, *supra* note 62.

185 NATIONAL ACADEMY OF SCIENCES, *supra* note 63.

186 Byrne, *supra* note 71; Stapleton, *supra* note 58.

and deterrence.<sup>187</sup> However, though tort law is also built upon the fundamental principle of noninjury,<sup>188</sup> our legal systems seem to lack application in the context of the main health damages of our time, originating in the industry epidemics. In other words, despite the massive burden of non-communicable diseases in our societies, we are choosing not to hold industries accountable by having the law approach this issue from the limited perspective of individual causation.

Scientific knowledge enters judicial discussions, and our legal systems use part of such knowledge to establish facts but then disregard the following conclusions about causation. This happens because, so far, we have been trying to mold scientific knowledge to individual causation and legal standards of proof. Scientific knowledge is not built in this direction, and our choice has been to insist on impossible results from science, even if this choice relies on unprincipled standards of proof, based on a sense of belief, and prevents us from accomplishing the goals of tort law altogether. Instead, this paper proposes that we start shaping our legal systems to our scientific achievements.<sup>189</sup>

The current understanding of legal causation uses general causation as a step for an almost mandatory assessment of individual causation.<sup>190</sup> This is not to say that there is no debate about the topic among scholars<sup>191</sup> or even discussions related to the significance of a causal chain,<sup>192</sup> but to recognize that most liability cases originated in product consumption require proof that a specific product is the cause of specific damage to a specific consumer,<sup>193</sup> surpassing a standard of proof of “more likely than not.”<sup>194</sup> Moreover, it requires proof of a sufficient and necessary cause<sup>195</sup> that explains all the steps that logically link a product to a disease. The issue is that uncertainty is a trademark of our current damages,<sup>196</sup> a trait that law, possibly due to historical reasons, still has difficulties embracing.<sup>197</sup> Even with profound differences regarding plaintiffs, defendants, and damages,<sup>198</sup> our legal systems still appear to search for a physical, infallible proof of causation<sup>199</sup> that describes all the steps that invariably link an act or product to an individual.<sup>200</sup>

Epidemiology offers an alternative approach with a methodology that is well suited to evaluate exposures and diseases, establishing causation and measuring it in a populational stance, by using methods specifically designed for non-communicable diseases.<sup>201</sup> It reflects the advances in methodological sophistication of the past four decades, harmonizing seamlessly with a gradual, implicit transformation of our understanding of

187 Owen, *supra* note 77.

188 Goldberg, *supra* note 24 at 85; John CP Goldberg, *Ten Half-Truths About Tort Law*, 42 VAL. UL REV. 1221, 1225 (2007). (“Tort law, in turn, is the collection of rules and principles that determines what duties of non-injury (and assistance) are owed by whom to whom, what counts as an actionable breach of such duties, and what sort of recourse, on what terms, is in principle available to victims of such wrongs.”)

189 Or even use them according to our current limitations regarding scientific knowledge.

190 Bernstein E., *supra* note 92 at 51.

191 Gifford, *supra* note 87 at 877.

192 HART AND HONORÉ, *supra* note 74 at 72. (“It is easy here to be misled by the natural metaphor of a causal ‘chain’, which may lead us to think that the causal process consists of a series of single events each of which is dependent upon (would not have occurred without) its predecessor in the ‘chain’ and so is dependent upon the initiating action or event. In truth in any causal process we have at each phase not single events but complex sets of conditions, and among these conditions are some which are not only subsequent to, but independent of the initiating action or event”)

193 Bernstein E., *supra* note 92 at 51.

194 In other words, evaluating the “preponderance of the evidence”. See Guerra, Luppi, and Parisi, *supra* note 103 at 2.

195 As pointed, the concept of a sufficient and necessary cause has several sub-theories and distinct approaches. However, they tend to focus on a full discovery of at least a great part of the causation process, something that biological causation chains do not commonly provide. See e. g. Wright, *supra* note 59; Wright, *supra* note 67; David A Fischer, *Insufficient causes*, 94 KY. LJ 277 (2005); Honoré, *supra* note 95.

196 Namely non-communicable diseases. See e. g. Naghavi et al., *supra* note 5.

197 See J. S. Vernick, *Role of Litigation in Preventing Product-related Injuries*, 25 EPIDEMIOLOGIC REVIEWS 90-98, 93 (2003). (“For most of the history of tort litigation, little or no evidence based on epidemiologic information was presented or needed to be presented. In many cases, that type of scientific evidence was unnecessary because eyewitness accounts of an incident could easily establish the causal link between a breach of duty and the consequent damages.”)

198 See generally NAGAREDA, *supra* note 37.

199 Brennan, *supra* note 70 at 532. (“Causation issues represent a major impediment to the successful resolution of claims based on injuries from hazardous substances. Tort law nurtures a set of causal concepts that emphasize the individual and the elaboration of a causal chain from injured to injurer. The evidence linking hazardous substances to injuries, however, is largely probabilistic; forcing such evidence into a causal chain model generates great confusion.”)

200 Donald G. Gifford, *The Death of Causation: Mass Products Torts’ Incomplete Incorporation of Social Welfare Principles*, 41 WAKE FOREST LAW REVIEW 943-1002, 946 (2006). (“[M]ost victims of latent diseases resulting from fungible products fail to recover because of the traditional tort law requirement that a particular victim must prove that a specific injurer caused her harm. [...] In the case of latent diseases that occur years or even decades after the exposure to the product, it is usually impossible for the victim to identify the manufacturer whose products caused her harm. The court may find that the defendant acted tortiously when producing fungible products and that the victim suffers from a harm caused by some manufacturer’s product. Still, unless the victim can link the two by showing individual causation, traditional tort law offers no recourse.”)

201 Parascandola, *supra* note 183 at 261.



causation.<sup>202</sup> Moreover, it is not a novel solution, but something that such science has been dedicating itself for decades, primarily to deal with the multicausality of non-communicable diseases<sup>203</sup> and it does not focus on necessary and sufficient causes but on concepts with more practical value<sup>204</sup> that acknowledge that, in biological chains of events, causes are multiple and overlap.

In short, epidemiology is available as a science and as a methodology and should be used towards achieving the goals of tort law. However, in order for this to be feasible, it is necessary to accept two premises: embracing a “black box” solution<sup>205</sup> and understanding that our current damages are no longer only individual.

If our primary goal is noninjury, and the tools for achieving said goal are compensation and deterrence, causation must rely on a methodologically sound process to enable them. Regarding the first premise, as previously stated, causation and explanation are not synonyms. In this sense, it is not mandatory to fully understand all the steps that lead from exposure to damage if we are able to conclude that exposure caused damage. So far, the same law that prescribes the need for causation appears to be more preoccupied with explanations,<sup>206</sup> not recognizing that several other sciences have moved from this concept to reach the conclusion of a causal relationship.<sup>207</sup> In several corners of science, a physical, fully explained, and invariable causal chain is no longer sought, and this is not a problem but rather an accepted evolution of scientific concepts and methods. Hence, if science offers a path to causation, it can and should be used not only as a source of scientific facts but also as scientific methodology, even if such methodology does not rely on a complete, step-by-step explanation of the causal chain.

We live in a world of uncertainty, and this fact is the subject of a long debate in tort law.<sup>208</sup> In the realm of uncertainty, epidemiology appears to be a few steps ahead, and its scientific methods could be better applied in tort cases. They are far better than a sense of belief and answer to a predefined methodology that can be contested with other reasoning. Scientific knowledge is pragmatic and only valid until refuted.<sup>209</sup> Hence, perhaps due to its development in a later stage of history,<sup>210</sup> its scientific approach to causation,<sup>211</sup> and the main goal that focuses on a collective view, epidemiology seems better equipped to evaluate cause-and-consequence relationships regarding non-communicable diseases, even inside tort cases and in the realm of legal causation.

Regarding the second premise, our current damages are no longer only individual,<sup>212</sup> and individual damages still appear to be at the center of legal causation.<sup>213</sup> Modern risks<sup>214</sup> and modern damages<sup>215</sup> can affect the whole environment and collective goods, such as public health, where damages can be understood as

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202 Karhausen, *supra* note 96 at 66. (“Causes are multiple and chancy: a prior event causes a subsequent event if the probability distribution of the subsequent event changes conditionally on the probability of the prior event. In applied sciences, medicine and epidemiology, causes reveal what one would have to do to bring about specific kinds of outcomes; they are intrinsically connected with goals and effective strategies; they are changes (facts, events or deeds) which have a potential harmful or successful use; they are contrastive since they make a difference between circumstances in which they are present, and those in which they are absent. Any definition of causation will inevitably collapse into the use made of epidemiologic methods. The progressive methodological sophistication of the last forty years is in perfect alignment with a gradual implicit overhaul of our concept of causation.”)

203 De Vreese, *supra* note 54 at 346.

204 Parascandola and Weed, *supra* note 94 at 910. (“In contrast, the primary aim of science is, as commonly stated, to explain the world; such investigations may or may not lead to effective public health strategies. Thus, some have recommended that epidemiologists abandon the traditional scientific concept of causes as necessary and sufficient conditions in favor of a broader concept with more practical value.”)

205 Karhausen, *supra* note 96 at 63.

206 Brennan, *supra* note 70 at 471. (“The evolution of the philosophy of science has produced a different understanding of the relationship of uncertainty to investigation than existed a century ago. More important, the causal concepts that derived from Newtonian physics are quite similar to those that inform the law, although they are no longer essential to science”)

207 Karhausen, *supra* note 96 at 63.

208 UNCERTAIN CAUSATION IN TORT LAW, *supra* note 39; PORAT AND STEIN, *supra* note 39; Eberhard Feess, Gerd Muehlheusser & Ansgar Wohlschlegel, *Environmental liability under uncertain causation*, 28 EUROPEAN JOURNAL OF LAW AND ECONOMICS 133-148 (2009); LARA KHOURY, UNCERTAIN CAUSATION IN MEDICAL LIABILITY (2006).

209 Chris Miller, *Causation in personal injury: legal or epidemiological common sense?*, 26 LEGAL STUDIES 544-569, 547 (2006). (Science, however complex it might appear, is a similarly pragmatic activity - a theory is only as good as the rigor of the last (unsuccessful) attempt to refute it. And no branch of science is more deliberately pragmatic than that concerned with the cause and distribution of disease, viz epidemiology.)

210 De Vreese, *supra* note 54 at 346.

211 *Id.* at 346.; Mawson, *supra* note 141 at 2.

212 World Economic Forum, *supra* note 33.

213 Steel and Ibbetson, *supra* note 39 at 467.

214 See generally ULRICH BECK, RISK SOCIETY: TOWARDS A NEW MODERNITY (1992).

215 Noncommunicable Diseases—PAHO/WHO | Pan American Health Organization, *supra* note 4.

damages to the whole of society.<sup>216</sup> Therefore, even recognizing that tort law should serve as a mechanism for providing compensation and justice to individuals who suffer harm due to the actions of others, when it comes to addressing diffuse populational damages resulting from widespread product consumption, the concept of individual causation used by our legal systems appears to fall short.<sup>217</sup> Here lies the most significant step that law must take to make epidemiology a feasible tool for addressing the “causation paradox.” Epidemiology as a methodology for the establishment of causation seems to depend on a new understanding of collective rights and their enforceability,<sup>218</sup> which requires tort law, to some extent, to let go of its usual individualistic approach in the common law system.<sup>219</sup>

Epidemiology has been, for decades, focusing on collective information and collective solutions,<sup>220</sup> and the strength of its results starts with the perception that collective information is more than a mere aggregate of individual information; it can also present data that is relevant purely from a collective standpoint, while still offering a methodology to reach a causation assessment.<sup>221</sup> Law should embrace this<sup>222</sup> in substantial and procedural<sup>223</sup> forms, not only recognizing the existence of causation that is relevant only to collective rights,<sup>224</sup> detached from the idea of a mere sum of individual rights, but also providing procedural tools for enforcing these purely collective rights.<sup>225</sup> This recognition is deemed necessary for the legal use of epidemiology and other statistical methods in relation to causation,<sup>226</sup> as well as for an alternative solution to the individual standard of proof of “more likely than not.” With a collective and epidemiological approach, it is possible to conclude “how likely” it is that a given exposure contributed to an outcome, providing a quantitative measure of the damage.<sup>227</sup> Therefore, if rights and interests can be vindicated in a collective manner<sup>228</sup> because damages themselves can also be collective, the road to legal causation can break from its usual path that starts with general causation, passes through individual causation, and ends in a standard of proof.

- 216 Elizabeth W. Leonard, *Tort Litigation for the Public's Health*, in RECONSIDERING LAW AND POLICY DEBATES: A PUBLIC HEALTH PERSPECTIVE, 190 (John G. Culhane ed., 2011). (“By contrast to torts, in which the disputes are between one individual versus another, in public health, often the conflict is one individual versus society.”)
- 217 Bernhard A. Koch, *Multiple Tortfeasors in Mass Tort Cases*, in MASS TORTS IN EUROPE: CASES AND REFLECTIONS 173–196, 173 (W. H. van Boom & Gerhard Wagner eds., 2014) (“This dilemma is already troublesome in a simple one-on-one setting, but gets more problematic the more individuals are involved on either side of the harmful event. The sheer magnitude of the overall losses, specifically in a mass torts scenario, sometimes seems to completely blur or even conceal the traditional mechanisms of tort law”); PARMET, *supra* note 28 at 228. (“[T]he individual causation requirement, referred to sometimes as the specific causation requirement, makes it difficult for plaintiffs to prevail when the determinants of disease are remote and discernable only at a population level. And, for that very reason, the individual causation requirement undermines tort law’s ability to deter many preventable sources of disease and injury.”)
- 218 New in terms of a generally accepted concept, since this understanding is already present in some parts of the world. See Gidi, *supra* note 32; J.A. Jolowicz, *Protection of Diffuse, Fragmented and Collective Interests in Civil Litigation: English Law*, 42 THE CAMBRIDGE LAW JOURNAL 222–256 (1983); Enrique González Mac Dowell, *Juridical Action for the Protection of Collective Rights and its Legal Impact: A Case Study*, 30 THE JOURNAL OF LAW, MEDICINE & ETHICS, SUPPL. SYMPOSIUM: HEALTH, LAW, AND HUMAN RIGHTS: EXPLORING THE... 644–654 (2002).
- 219 Andrea Giussani, *Proof of causation in group litigation*, in UNCERTAIN CAUSATION IN TORT LAW, 240 (M. Martin-Casals & Diego M. Papayannis eds., 2015). (“[E]ither group actions are the means to dispose of aggregate individual rights, or, by contrast, the action is a means to properly vindicate collective rights. This difference results largely from cultural practices: common law systems are much less inclined to waive individualism; in civil law systems the availability of group litigation device often automatically implies construction of a collective right.”)
- 220 Parascandola, *supra* note 183 at 261.
- 221 PARMET, *supra* note 28 at 231. (“In the mid-twentieth century, epidemiology appeared to offer a solution to the problem of proving individualized causation. In cases in which the causal relationship between an agent manufactured or released by the defendant and the plaintiff’s injury was neither readily apparent nor intuitively obvious, epidemiological evidence could be used to demonstrate an association between the agent and the type of injury the plaintiff experienced. Moreover, by using the Bradford Hill criteria, which include the strength and consistency of a statistical association, its specificity, its temporal sequence, and its biological plausibility, epidemiologists could go further and make an inference as to whether an association between a particular agent, such as tobacco smoke, and an illness within a population, such as lung cancer, was causal.”)
- 222 As a few legal systems, with different solutions and objectives, have already done. See Manuel A. Gomez, *Will the Birds Stay South? The Rise of Class Actions and Other Forms of Group Litigation Across Latin America*, 43 INTER-AMERICAN LAW REVIEW 481–521 (2012); Deborah R. Hensler, *The Globalization of Class Actions: An Overview*, 622 THE ANNALS OF THE AMERICAN ACADEMY OF POLITICAL AND SOCIAL SCIENCE 7–29 (2009).
- 223 PARMET, *supra* note 28 at 229. (“A population approach to tort law would also take a liberal attitude toward using class actions and case consolidations to help make complex tort actions economically feasible for plaintiffs to bring, and to overcome some of the difficulties of establishing specific causation. [...] If that population constituted the plaintiff class, then theoretically the problems of determining individualized causation could dissolve as the court focused only on whether the defendant’s actions harmed the plaintiff class.”)
- 224 Giussani, *supra* note 219 at 241. ([A] “fact can be relevant as purely a collective fact”.)
- 225 *Id.* at 241. (“The importance of this difference [between individual and collective rights] regarding the proof of causation lies in the factual issues respectively involved. A collective right is naturally vindicated by a collective remedy: hence, relevant facts have a collective dimension as well. Aggregation of individual claims, by contrast, generally implies relevance of individual facts.”)
- 226 *Id.* at 243. (“The use of statistics to prove causation in court largely reflects the difference [...] between collective and individual facts.”)
- 227 *Id.* at 245–246. (“The main example is when there is a significant epidemiological evidence, supported by a reasonable theory, showing that less than 50% of the occurrences of a disease among the group affected by the defendant’s conduct are not causal and hence, from the legal standpoint, are specifically caused by that conduct: in an individual suit, the plaintiff would just lose, but if all the victims’ claims are conveyed in a single lawsuit and adjudicated wholesale, award of damages corresponding to the percentage of occurrences whose specific causation is proven this way would be possible with respect to the entire group.”)
- 228 Jolowicz, *supra* note 218.

Specifically, this paper proposes using scientific facts and the already scientifically proven general causation that originates from exposure to some products, not as a way to extract individual causation<sup>229</sup> but rather to use general causation itself as a way to apply tort law, focusing on populations as the subject of damages and bearers of enforceable rights. This is what we call scientific causation. This idea does not preclude the possibility of individual damages resulting from the consumption of products linked to non-communicable diseases, but recognizes that the path to causation, from general to individual causation, has been a challenge preventing the application of tort law,<sup>230</sup> since even the unequivocal proof of general causation usually has not been enough to demonstrate individual causation upon the required threshold.<sup>231</sup> Therefore, one alternative seems to be the side-by-side pursuit of a collective solution<sup>232</sup> focusing on the current achievements of epidemiology<sup>233</sup> as a mechanism to relieve the burden of plaintiffs to prove specific and individual causation<sup>234</sup> since our current legal causation theories are not accomplishing compensation, deterrence, and noninjury and based on the premise that our current damages are so diffuse in our populations<sup>235</sup> that they could be evaluated upon measures of general causation.

As mentioned, causation theories must be effective,<sup>236</sup> and if a scientific methodology can contribute to the fulfillment of the goals of tort law, populations are entitled to seek enforcement.<sup>237</sup> Hence, the goals of tort law in our current times also depend on adopting new techniques that better understand uncertainty and bypass the issues of biological causation.<sup>238</sup> The use of epidemiology, general causation, and a population approach to damage, here referred to as scientific causation, appears to be a methodology that effectively promotes the use of tort law as designed,<sup>239</sup> prevents the “causation paradox” from serving as a shield from liability,<sup>240</sup> and improves the health and safety of populations with equity.<sup>241</sup> It is also more closely aligned with the principles of public health that are not usually compatible with tort law.<sup>242</sup>

After all, in several cases of product consumption and non-communicable diseases, there is reliable data about general causation, and it can be transformed into an excess fraction on a population basis, providing a quantitative measure of causation. What is needed is for law to take a step in the direction of existing

- 229 Recognizing the several authors have made some interesting points, in favor or not of such possibility. See Cass R. Sustein & William Meadow, *Causation in Tort: General Populations vs. Individual Cases*, 179 UNIVERSITY OF CHICAGO LAW SCHOOL (2007), [http://chicagounbound.uchicago.edu/public\\_law\\_and\\_legal\\_theory/52/](http://chicagounbound.uchicago.edu/public_law_and_legal_theory/52/); Gifford, *supra* note 87; Cranor, *supra* note 65.
- 230 PARMET, *supra* note 28 at 228. (“For multiple reasons, there can be no quick and easy (never mind definitive) way to jump from population-based studies to individual causation. As a result, the individual causation requirement, referred to sometimes as the specific causation requirement, makes it difficult for plaintiffs to prevail when the determinants of disease are remote and discernable only at a population level. And, for that very reason, the individual causation requirement undermines tort law’s ability to deter many preventable sources of disease and injury.”)
- 231 Sustein and Meadow, *supra* note 229 at 9. (“To establish causation in tort cases, plaintiffs must show that it is more probable than not that the behavior in question caused their injury. A significant absolute risk reduction across a large population does not necessarily establish causation in a tort case.”)
- 232 Side-by-side in terms of a solution that, by no means, implies that individual damage should not be addressed at the same time.
- 233 PARMET, *supra* note 28 at 229. (“[A]lthough epidemiological evidence cannot establish individualized causation, it is well suited to determine the risk a particular agent or product presents to an exposed population.”)
- 234 *Id.* at 238. (“[T]hrough valuing epidemiology, it would respect it as a scientific method designed to increase understanding of the determinants of death and disease, not as a minefield for the unwary plaintiff. And most important, it would liberalize and relax the requirement that plaintiffs prove specific causation.”)
- 235 Rosenberg, *supra* note 106 at 853. (“With increasing frequency, we are witnessing ‘the phenomenon of numerous persons suffering the same or similar injuries as a result of a single pattern of misconduct on the part of a defendant.’”)
- 236 De Vreese, *supra* note 54 at 347.
- 237 Orellana, *supra* note 42; United Nations, *supra* note 42; Organization of American States., *supra* note 42; Organization of the American States, *supra* note 42; Cormier, Tunney, and Mallet, *supra* note 43.
- 238 Brennan, *supra* note 70 at 471. (“Only a thorough understanding of the specifics of scientific uncertainty and causation can lead to the best formula for compensation and deterrence of hazardous-substance injury.”)
- 239 PARMET, *supra* note 28 at 227. (“[F]rom any instrumentalist perspective (including population-based), law’s focus should be less on individual cases than on social consequences. Hence, if a defendant engages in an activity that is known to increase the risk of harm to one or more populations, it is inappropriate to permit that defendant to ignore the external costs of the activity and escape liability simply because no individual plaintiff can establish that the defendant caused his or her own injury.”)
- 240 *Id.* at 235. (“[A] population approach to tort law would not permit defendants to wholly escape liability simply because each plaintiff would have trouble showing that the defendant’s action caused his or her injury.”)
- 241 Vernick, *supra* note 23; PARMET, *supra* note 28 at 197–198. (“Tort judgments, accordingly, operate as incentives for safer conduct in society, thereby protecting the public’s health. [...] Tort damages also punish wrongdoers and sanction socially unacceptable behavior. [...] Torts damages, accordingly, operate simultaneously on both sides of the dispute, compensating victims while also deterring and punishing wrongdoers. A judgment awarding damages does more than merely compensate injured victims or shift the loss from the injured to the injurer. Tort judgments enhance public safety by discouraging members of society from acting in ways that cause harm to others and punishing actors who acted unreasonably with respect to the safety of others.”)
- 242 Leonard, *supra* note 216 at 195. (“[The] public health law’s objective of promoting and protecting health, safety, and welfare of populations seems hard to square with a tort liability system that tolerates some level of accidental harm without liability.”)

science, and to choose an approach to causation that is conducive to the realization of the principle of noninjury through adequate compensation and deterrence. Epidemiology has already filled a causation gap in medicine.<sup>243</sup> It must now do the same in tort law, and scientific causation is a possible way forward.

## CONCLUSION

The main health harms of our time, non-communicable diseases, are a consequence of profit-driven decisions made mainly by transnational corporations, making tort law a relevant and necessary mechanism to address this issue. However, these same harms are multi-factored and pose a challenge to our current legal standards of causation.

Scientific knowledge is used to determine factual causation. However, our understanding of legal causation prevents science from making a bigger dent in tort law, particularly when dealing with biological causation and multi-factored diseases. Legal causation has so far focused on individuals, and scientific knowledge is not designed to produce proof of an individualized chain of events that sufficiently and necessarily produces a given outcome. As a result, legal systems have limited the use of scientific methods and instead used an unprincipled standard of proof based on the sense of belief of a judge or jury.

Thus, while there is consensus on the existence of damages, their complexity has shielded industries from liability, mainly because legal practitioners have chosen and continue to choose a narrow path to legal causation rooted in individual causation, which scientific knowledge is not designed and does not intend to provide.<sup>244</sup> So far, this choice has favored the least scientific path to causation in terms of methodology,<sup>245</sup> and this is partly why we lack a precise application of tort law in the case of product consumption and non-communicable diseases.<sup>246</sup>

Besides factual causation, scientific knowledge also researches causation from several points of view, with distinct methodologies and goals. Epidemiology has developed, for decades now, methodologies tailored to multi-factored diseases, something that law has yet to accomplish.<sup>247</sup> By focusing on general causation and the analysis of populations, epidemiology uses statistical methods to uncover relative risk and attributable fractions of exposure and its consequences, providing causation assessments and a measure of association. This is a science-based approach to causation and one that can bypass the current issues of individual causation that are preventing the application of the tort law principle of noninjury, providing compensation and deterrence for the undisputable existing damages.

This paper proposes that in the case of product consumption and non-communicable diseases, which originate complex damages, the road to legal causation should go beyond the current path of general causation, individual causation, and the standard of proof of “more likely than not.” Instead, law should also use the collective approach of epidemiology and its method of general causation, attributable fraction, and measure of association. This methodology can provide a quantitative populational measure of causation, something that is already used to save and steer lives. It is about time that such knowledge is also applied to tort law.

To do so, law must stop searching for explanations and truly seek causation chains, even if doing so requires engaging with a different discipline. A reliable scientific proof of exposure and disease is a causation assessment, and one that must be made available and applied to tort law provided that it helps meet tort

243 De Vreese, *supra* note 54 at 348. (“Studying disease causation in large groups makes us nevertheless able to answer the question of what causes diseases without knowing much about the precise biological and chemical mechanisms involved.”)

244 PARMET, *supra* note 28 at 237. (“[F]rom a population-based perspective, contemporary tort doctrine is sorely wanting. It is riddled with an individualism that makes it difficult for the field to recognize, never mind to promote, population health. Moreover, with its emphasis on individual plaintiffs, individual causation, and individual responsibility, tort law may even corrode a population-based perspective.”)

245 MENDELSON AND FRECKELTON, *supra* note 66 at 52. (“Developments in medicine are made by experiment and observation; in law they are made by the decisions of legislatures and judges. A medical fact is one which can be empirically supported or clinically determined; a legal fact is one which is more probable than other countervailing facts.”)


246 Brennan, *supra* note 70 at 476. (“Tort litigation, largely because of the courts’ difficulties with scientific evidence, produces inconsistent resolutions of claims deriving from the same hazardous substances.”)

247 As explained by, for example, treating physical and biological chains of events in the same way.

law's goals and has scientific grounds,<sup>248</sup> even if it fails to fully comprehend all the steps between exposure and disease.

In addition to substantial changes, procedural changes are also necessary, broadening the playing field for tort claims from collectivities.<sup>249</sup> Collective rights are not merely the sum of individual rights, just as epidemiology is not the sum of individual data.<sup>250</sup> Granted, a collective approach will not solve all problems in the arena of non-communicable diseases. Individual damages continue to exist and must also be addressed. However, a collective approach in tort law is long overdue to fulfill public health goals.<sup>251</sup> There is consensus that a growing burden of non-communicable diseases has been a trend in the past decades, and it appears that it will continue to harm populations. A collective approach to tort law may be a way to tackle the consequences of our "industrial epidemics."<sup>252</sup>

It cannot be said that epidemiology will consistently deliver sound and indisputable evidence about causation in every single situation.<sup>253</sup> As stated, scientific knowledge is pragmatic, valid if methodologically sound and only until refuted. Depending on the product or the disease in question, we might have insufficient data to reach solid conclusions at this point.<sup>254</sup> Nevertheless, when such data exists, science has to be fully used in tort law, even if this implies that law itself will have to take some steps in the direction of the causation methods of other disciplines.

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- 248 Brennan, *supra* note 70 at 478. ("The courts' difficulty with handling evidence linking a hazardous substance to a disease is largely the result of the courts' inability to understand scientific notions of causation. The assumptions that courts make about causation very much resemble those that provide the foundation for Newtonian physics. Over the past century, science has come to rely on new assumptions about cause and effect. These new assumptions have not been integrated into legal reasoning. As a result, lawyers and judges are often confused when they address scientific causation issues.")
- 249 Goldberg, *supra* note 188 at 1243. ("[B]ecause tort duties are relational duties of non-injury, their breach characteristically gives rise not to an enforcement action by government, but a private right of action, exercisable by the victim or her representative. Because tort duties are duties of non-injuriousness, persons who have not suffered the right sort of adverse effect because of a breach have no grounds to sue for the breach.")
- 250 Giussani, *supra* note 219 at 241.
- 251 PARMET, *supra* note 28 at 236. ("The discussion thus far has argued that neither tort theory nor doctrine adopts a population perspective that places a high value on the prevention of disease and injuries. To the contrary, both tort theory and doctrine [...] reveal a stark individualism that discounts the full social costs of preventable harms and places a high hurdle on those who seek to hold defendants liable for actions or inactions that threaten population health. Ironically, these hurdles are the highest in mass and toxic tort cases in which large numbers of people are harmed by the defendant's actions. Not surprisingly, it is in these cases that the population approach would bring the greatest reform, abandoning unrealistically strict requirements for epidemiological evidence and specific causation.")
- 252 *Id.* at 229. ("Courts adopting population-based legal analysis would likely reverse this trend and be far more willing to apply a market share or similar approach that holds defendants at least proportionally liable for the disease or injuries their actions create in a population, even if a particular plaintiff cannot establish that it was more likely than not that the injury or disease would not have occurred but for the defendant's actions. In other words, causation requirements should be reformed to deter the injuries caused to populations.")
- 253 *Id.* at 228. ("[E]ven if epidemiological studies demonstrating such relationships exist, and they frequently do not, they are not well designed to establish the type of individual causation traditionally demanded by tort law.")
- 254 Rothman and Greenland, *supra* note 97 at 147. ("If the causal mechanism is stated specifically enough, epidemiologic observations under some circumstances might provide crucial tests of competing non-null causal hypotheses. On the other hand, many epidemiologic studies are not designed to test a causal hypothesis.")