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Oct
2018

Causation and epidemiologic evidence: insights from “toxic cases” in the US and in Italy

Stefano Zirulia

Proving causation between exposure to toxic substances and long latency disease is often a challenging task. This is clearly showed by the U.S. toxic tort litigation, as well as by the Italian experience of criminal investigation and trials for occupational and pollution-related diseases. After a summary of the main hurdles surrounding the proof of causation in “toxic cases”, this post addresses the question of whether the most readily available type of scientific evidence – i.e. epidemiologic studies – could be used in a different, more effective way than has been done so far

1. Introduction. It is well known that, since the 1970s, the U.S. has faced a wave of *toxic tort litigation*, i.e. civil lawsuits for diseases and deaths caused by exposure to toxic substances on the workplace, in the environment or when using consumer products. As a result, a significant amount of case-law and of legal doctrine on *mass exposure cases* have developed in the States; even the general public has some familiarity with such cases thanks to famous books and movies based on true stories (e.g. *A Civil Action* and *Erin Brockovich*).

It is probably less known – at least among non-Italian scholars – that over the last 30 years Italy has experienced a similar wave of *criminal* investigations and trials. Employers in dangerous workplaces, as well as managers of polluting industries, have been charged for offences such as negligent homicide, bodily injury and, more recently, endangerment crimes due to the adverse effects of their activities on human health.

Although developed in different branches of the legal order, U.S. toxic tort cases and Italian toxic criminal cases (hereinafter “toxic cases”) must surmount the same hurdles when it comes to assessing someone’s responsibility for the consequences of long-term exposure to toxic substances: providing evidence of *causation* and negligence. This post deals with the former issue (causation), while another will be dedicated to the latter. After a summary of the main difficulties in providing proof of causation (see below §§ 2, 3), I address the question of whether the most readily available type of evidence – i.e. *epidemiologic studies* – could be used in a different, more effective way than has been done so far (§§ 4-7).

2. The hurdles of causation in “toxic cases”. Anyone who is familiar with “toxic cases” (torts or criminal cases) knows that “causation” is the most difficult element of responsibility to prove and consequently becomes the main battleground in any dispute[1]. The plaintiff of a toxic tort, or the prosecutor in a criminal case, must demonstrate that the but-for cause of the victim’s disease was exposure to a certain toxic substance. Even when conclusive scientific evidence from toxicological or epidemiologic studies indicate that the substance is *capable* of causing that category of disease (the general causation issue), it is often extremely difficult, if not impossible, to conclude that the substance is the but-for cause of that particular victim’s disease (the specific causation issue). This situation, often defined by toxic tort scholars as the “indeterminate plaintiff” issue[2], arises due to a number of factors. One must consider, above all, the long latency period between exposure and

diagnosis: unlike cases where the damage is instantaneous or nearly instantaneous (e.g. voluntary assaults), in toxic cases the cause of the disease must be sought over a time span of many years. This is a complex task due to the *multifactorial nature* of many diseases and the possible occurrence of *multiple exposures*.

Lung cancer is a well-known example of a multifactorial disease: although it is well established that exposure to asbestos can cause the disease, it is definitely not the only possible cause. Even when some of the risk factors can be ruled out (e.g. the affected person was not a tobacco smoker), others will probably still stand (e.g. air pollution), thus making it impossible for the judge to decide whether the exposure to asbestos was one of the but-for causes of that specific lung cancer. The argument that lung cancer risk is greater among those who have been exposed to both asbestos and other risk factors cannot be decisive either, as it would require particularistic evidence of the role of asbestos in *that particular victim's case*; unfortunately, current scientific knowledge does not allow us to gather such evidence. There are numerous other similar cases of exposure to toxic substances in which the allegedly related disease is multifactorial: benzene and leukaemia, vinyl chloride and liver disease; dioxin and non-Hodgkin's lymphoma, etc.

The multiple exposures issue, which is relevant to both multifactorial and unifactorial diseases, arises whenever the victim was repeatedly exposed to the same risk factor during the latency period. The infamous U.S. case of the anti-miscarriage drug DES (Diethylstilbestrol)[3] is one example: many daughters of women who took DES during pregnancy developed a particular and recognizable kind of vaginal cancer (soon labelled a DES-signature disease). Because many different companies produced this drug, it was almost impossible to trace each particular cancer back to a particular manufacturer. Likewise, when workers who have been exposed to asbestos under different employers develop mesothelioma (an asbestos-signature disease), it may be impossible to trace it back to a specific employer[4]. Once again, the argument that mesothelioma risk is greater among those who have been exposed longer is not decisive: yet unavailable particularistic evidence of this role would be required to determine whether the exposure that occurred under a particular employer was a contributing factor to the development of the disease (e.g. by shortening the latency period).

3. The troublesome issue of the "attributable number" of diseases found by an epidemiologic study. Epidemiologic studies are often the main source of evidence for general causation in toxic cases. As mentioned above, they can reliably demonstrate whether a certain substance is toxic or innocuous to human beings. For instance, in observational cohort studies scientists verify whether individuals exposed to a certain substance (X) develop a certain disease (D) at a higher rate than those who are not exposed; if so, and if the excess rate of diseases in the observed population cannot be explained by causes other than X, then X can be considered a risk factor for D[5]. This is how, for example, scientists Richard Doll and Austin Bradford Hill discovered that tobacco smoking causes lung cancer: they observed that smokers developed lung cancer in a far higher percentage than non-smokers, and ruled out other possible causes. Similarly, Selikoff's epidemiologic studies of industrial workers demonstrated that asbestos can cause malignant mesothelioma, a deadly cancer affecting the lining of the lungs.

In some toxic cases, epidemiologic studies are carried out *among those who allege to be the victims of a certain exposure*. This was the case of people exposed to asbestos from the Eternit company: epidemiologic studies on workers and residents in the areas surrounding the four Italian facilities (at Casale Monferrato, Cavagnolo, Rubiera and Napoli-Bagnoli), found that these groups developed typical asbestos-related illnesses (asbestosis, lung cancer and mesothelioma) at a much higher rate than the rest of the Italian population. More recently, epidemiologic studies carried out on residents nearby the Ilva steel factory in Taranto (southern Italy) and those near the Tirreno Power coal plant in Vado Ligure (northern Italy) have identified alarming health issues (see § 5 below for more details on these Italian cases).

In such scenarios – i.e. when available epidemiologic evidence highlights an increased incidence of diseases or deaths among those who allege to be the victims – the lack of evidence of specific causation can lead to unfair judicial decisions. If, for example, a reliable study highlights that *a)* in a 5 year-period, among the 100 workers of an asbestos company, there have been 40 deaths from lung cancer instead of the 10 expected cases (the background lung-cancer risk), and *b)* the only possible explanation for this excess mortality is exposure to asbestos, because no other particular hazardous conditions occur (e.g. the percentage of smokers among workers is average, air pollution is not worse than in the rest of the country, etc.), then *it is virtually certain that there are thirty deaths in excess which would not have occurred in the absence of the exposure to asbestos***[6]**. In epidemiology, this measure is called "attributable number", which is defined as «*the excess caseload of a specific outcome attributable to an exposure over a defined time period*»[7].

Whenever evidence of an attributable number is available, the court (either civil or criminal) can come to the conclusion that *the exposure has caused a certain number of victims* (in our example, 30 individuals). However, in the absence of particularistic evidence, the same court cannot pinpoint *who*, among the affected persons (in our example, 40 individuals), fell ill due to the exposure and is part of the excess quota (30 individuals) and *who* would have fallen ill even without the exposure as part of the background risk quota (10 individuals)[8].

If we assume that specific causation is an essential element of liability, then the attributable number alone can never be sufficient evidence of causation in a toxic case. Consequently and unjustly, *even when the court is certain that the exposure has caused a certain number of victims*, if the only available evidence is epidemiologic, *nobody will be held accountable*. In order to avoid such an undesirable outcome, some courts – in both the U.S. (see § 4 below) and Italy (see § 5 below) – have tried to approach the attributable number evidence from a different angle.

4. The solution envisaged by judge Weinstein in the Agent Orange case: the attributable number as "aggregate loss" caused by the defendant. It was 1984 when judge Weinstein of the District Court for the Eastern District of New York signed his "fairness opinion" on the Agent Orange case[9]. The act approved the settlement between plaintiffs – Vietnam veterans and their families – and defendants – manufactures of a herbicide containing dioxin, Agent Orange, sold to the U.S. Government and used to defoliate the forests in which Vietcong were hiding – in one of the most famous class actions in the history of toxic torts. Plaintiffs claimed that the exposure to Agent Orange had caused, a few years after the end of the conflict, diseases such as cancers and leukaemia, as well as miscarriages and birth defects. Because the background risk for these was significant in the general population, the "indeterminate plaintiff" situation arose.

As mentioned above, the case ended with a settlement; however, in the fairness opinion that approved it, judge Weinstein explained how the case would have been tried in the absence of an agreement between the parties. His argument, simple and yet brilliant, started as follows: «*Since the problem results from a plaintiff-by-plaintiff method of adjudication, one solution is to try all plaintiffs' claims together in a class action thereby arriving at a single, class-wide determination of the total harm to the community of plaintiffs*»**[10]**. Taking inspiration from a ground-breaking article by David Rosenberg published the same year[11], Weinstein imagined that the phase dedicated to assessing the defendant's liability could be separated from the subsequent phase dedicated to quantifying each plaintiff's redress: the former phase could well be based on epidemiological evidence alone, because its purpose would be «*to hold a defendant liable for no more than the aggregate loss fairly attributable to its tortious conduct*»[12]; the latter phase would have consisted of some sort of mechanism for the proportional distribution of the compensation.

For example, Weinstein hypothesised a scenario where an epidemiological study among the people exposed to the defendant's toxic agent had found 1,100 cases of cancer instead of the 1,000 expected cases. In this instance the defendant could be held liable for injury to a total of 100 people, i.e. the excess rate of cancers found by the epidemiologic investigation. Since the identity of the 100 individuals injured could not be known, Weinstein devised the following mechanism for the distribution of the redress: one had to quantify the value of a standard injury (say 1 million dollars), multiply this value by the total number of injuries in excess (100 in this case) and then divide the total amount (100 million dollars) by the number of exposed individuals who developed cancer (1.100, in this case): «*while any plaintiff might feel that his or her recovery denigrated the degree of harm* – concluded Weinstein – *the alternative of receiving nothing is far worse […]. Moreover, the deterrent effect of this result on producers would be significant*»[13].

Weinstein's idea had no significant effect on subsequent case-law. This was probably due to its inability to satisfy one of the essential requirements of the tort system: to take into account the specificity of each single case in order to quantify appropriate compensation. For the same reason, a few years later the U.S. Supreme Court expressed an unfavourable opinion on the use of class actions in the field of toxic torts, pointing out the lack of the "predominance" requirement[14] whenever the individual questions (such as time and extent of the exposure, type of injury, the existence of intervening causes) exceed the common questions among the class members[15].

5. Similar approaches recently adopted by Italian prosecutors: the excess rate of disease as an "epidemic phenomenon" or "sanitary disaster". In terms of evaluating the available epidemiologic evidence, prosecutors in the three above-mentioned Italian cases (Eternit, Ilva and Tirreno Power) adopted an approach very similar to that of Weinstein. In all three cases epidemiologists reported hundreds of diseases in excess, and consequent premature mortality among those who had been exposed to the risk factor[16]: in the case of Eternit, asbestosis, lung cancers and mesotheliomas occurred due to exposure, whereas at Ilva and Tirreno Power, respiratory and cardiovascular diseases, as well as cancers, developed after exposure to toxic emissions from the plants.

Instead of charging the companies' managers with negligent homicide and injury – as had been the case in all previous Italian toxic cases – prosecutors chose to charge them with offences against public safety, in particular those provided by articles 434 and 449 of the Italian penal code. Article 434 is at the end of a list of offences against public safety – causing fires, railway disasters, landslides etc. – and punishes the voluntary causation of "any other disaster"; article 449 extends liability to the *negligent* causation of a disaster. Italian jurisprudence agrees that the broad category of "any other disaster" also includes environmental damage due to the progressive accumulation of pollutants, provided that the related danger to public health is demonstrated (see, e.g. Court of Cassation, judgment no. 40330 of 2006).

In the Eternit case, Turin's Court of Appeals (judgment no. 5621 of 2013) went one step further, arguing that "environmental disaster" also encompassed the excess rate of diseases and deaths highlighted by the epidemiologic studies conducted on workers and residents near the facilities. In other words, the Court indicated that epidemiologic evidence can be used to prove the existence of a sort of «*epidemic phenomenon*» attributable to exposure to the risk factor. A similar approach was adopted by the judge for the preliminary investigation in the Tirreno Power case. When explaining the reasons for seizing the coal plant (Decree issued on March 11, 2014), the judge argued that article 434 comprises any sort of «*sanitary disaster*», here consisting in the excess rate of diseases and premature deaths recorded in the area.

However, this position was ultimately rejected by the Court of Cassation (judgment no. 7941 of 2014, which concluded the Eternit trial), according to which article 434 "environmental disaster" is just an endangerment offence that does not include the resulting harm to human beings. Determining the scope of the disaster was particularly relevant in the Eternit case because the offence provided by article 434 is limited to a maximum of 15 years after the event: according to the Court of Appeals, since the excess rate of diseases and premature deaths was an ongoing phenomenon at the time of the indictment, the statute of limitations defence could not be invoked; in contrast, the Court of Cassation ruled that because the Eternit company had committed the offence only up until 1986 (when it went bankrupt), it could no longer be prosecuted.

It is likely that the Court of Cassation ruling in the Eternit case will only in part affect the outcomes of the Ilva and Tirreno Power trials, both ongoing as I write. On the one hand, these two cases refer to very recent events, so that there should be no issue of time limitations. On the other hand, the "environmental disaster" offence under articles 434 and 449 can no longer be considered suitable to sanction the offence in terms of excess disease and mortality rates, but only as an endangerment of the exposed population as a whole.

6. *Why* should criminal law systems deal with the "attributable number"? Expressions such as "aggregate attributable loss" (Agent Orange), "epidemic phenomenon" (Eternit), "sanitary disaster" (Tirreno Power) share the same objective: they try to describe the specificity of the attributable number, i.e. a collective damage which can be seen only through the lens of epidemiologic investigations, from a legal standpoint.

It follows that the cases described have rightly highlighted one of the basic assumptions of epidemiologic science, i.e. that causal links undetected through a case-by-case approach may be found when considering the exposed population as a whole.

As seen above, the attributable number alone has never been the basis for a final judicial declaration of responsibility, neither civil nor criminal. The reason for this, however, is not that epidemiologic evidence as such has been considered insufficiently reliable[17], but rather that legal systems seem to be unable to assign responsibility when the *victims are not identifiable**[18]***. Nevertheless, as demonstrated so far, the specificity of the attributable number is precisely this: *providing sufficient evidence that a certain number of harmful events would not have occurred but for the exposure, even if it is not possible to name the victims*.

Focusing our attention on the European scenario, there are at least two reasons why criminal lawyers should consider the attributable number .

The first reason is grounded in the Environmental Crime Directive (2008/99/EC). According to article 3 (a), (b), (d) and (e) of this directive, Member States shall criminalize a series of unlawful polluting conducts, committed with at least serious negligence, when – *inter alia* – these conducts *cause or are likely to cause death or serious injury to any person.* Nothing in the wording of this provision suggests that the obligation to criminalize is limited to cases where the victims are identified. Moreover, given that article 5 of the same directive provides that penalties shall be "proportioned" to the wrong committed, it follows that Member States should ensure that the actual causation of bodily harm or death is sanctioned by means of more severe penalties than those foreseen for endangerment offences.

The second reason is grounded in the right to life jurisprudence under the European Convention on Human Rights. The Court's case-law on article 2 imposes positive obligations on the State to protect the health of workers and people living near hazardous industrial activities (see Grand Chamber, Judgment 30.9.2004, application no. 48939/99, *Öneryildiz v. Turkey*, § 89; with regard to a case of exposure to asbestos, see Judgment 24.7.2014, application no. 60908/11 and others, *Brincat and others v. Malta*, § 101). Moreover, when someone dies as a consequence of those activities, State parties are called on to carry out official investigations and bring criminal charges against State officials who, although fully aware of the danger, failed to take measures that would have averted it (*Öneryildiz v. Turkey*, § 93; *Brincat v. Malta*, § 121). Now imagine that an official investigation of this kind is dropped because no evidence of specific causation is available, even if a reliable epidemiologic study shows that a certain number of deaths (equal to the attributable number) are linked to a given industrial exposure that could have been averted if the authorities had acted diligently[19]. Would the ECHR consider that the State had fulfilled its procedural obligations? I would say it had not, for there is no reason to make State obligations under article 2 dependent on the condition that victims are *named*, provided that they can be *otherwise quantified*. Nor is there an issue with regard to the competence of the Court *ratione personae*: under article 34 of the Convention, the application can be filed not only by individuals, but also by groups of individuals or associations representing the interests of the exposed people.

7. *How* criminal law systems should deal with the "attributable number" measure?

Whenever the evidence of the attributable number is available, merely charging someone (e.g. the manufacturer of the dangerous product) with an endangerment offence, would mean leaving that person unpunished for the resulting harm of his/her conduct, contrary to the above-mentioned obligations of incrimination from the ECD and the ECHR. Instead, it seems that two other options are available.

The first one does not require any legal reform. As I argued in a recently published monography[20], if one accepts that the attributable number expresses the number of diseases or early deaths which would not have occurred but for the exposure, then the most straightforward solution is to apply the common offences of *negligent bodily injury* and *negligent homicide*, respectively. After all, why should a conduct consisting of causing a certain number of unidentified victims be treated differently than a conduct consisting of causing the same number of identified ones? Compliance with the "beyond any reasonable doubt" rule, even in the absence of specific causation, would be assured by testing the reliability of the epidemiologic study which provides the "attributable number" measure. To that end, the fact finder could use the ordinary criteria through which scientific evidence is admitted into the courtroom and then evaluated. Italian criminal courts, for instance, has recently adopted a series of tests which are clearly inspired by the well-known U.S. Supreme Court's *Daubert* ruling (beginning from the Court of Cassation judgment n. 43786 of 2010, also known as *Cozzini* case).

The second option, on the contrary, does require the input of national legislators. If we are not ready to accept that common offences against the person does not necessarily require the identification of the victim, then in order to comply with the aforementioned obligations of criminalization, the solution is the introduction of an offence specifically designed to sanction the aggregate or collective harm caused to a certain number of non-identifiable victims. For instance, in 2015 Italy has introduced a new offence of "environmental disaster" which is described as causing an offence to public safety where a high number of people have been endangered or harmed (art. 452 *quarter*, lett. c of the penal code). This provision does not apply to the aforementioned pending cases (Ilva and Tirreno Power), for the relevant conducts have been committed before 2015. However, it represents the first attempt to introduce a sort of collective damage offence and its future applications will deserve close attention.

8. Conclusions.

In "toxic cases" it is difficult to put forward evidence of causation which is only based on the epidemiologic measure of an "attributable number" of diseases or premature deaths. Although this number indicates the number of victims that (when the study is reliable) are beyond any reasonable doubt attributable to a certain risk factor, it does not provide sufficient evidence of specific causation because it does not reveal *who* the victims are. As a consequence, there may be situations where the defendant cannot be held accountable, even though it is an incontrovertible fact that he/she caused a certain number of diseases or deaths.

This post has highlighted some of the strategies adopted in attempting to overcome this obstacle, from that suggested in the U.S. Agent Orange case to the ones proposed by Italian prosecutors in the Eternit, Ilva and Tirreno Power criminal cases. Leaving aside the strengths and weaknesses of the mentioned cases, and considering the provisions of the Environmental Crime Directive and ECHR case law on the right to life, it would seem that the issue of criminal liability for "collective damage", as demonstrated by conclusive epidemiologic evidence, can no longer be ignored by criminal courts and scholars.

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[1] Stella (2005); Eggen (2015), 309.

[2] Eggen (2015), 424.

[3] Russel (1991).

[4] Gargani (2011), 401.

[5] For more details on the methodology of cohort studies, see Green, Freedman, Gordis (2011), 556.

[6] Rosenberg (1984), 883; Green, Freedman, Gordis (2011), 598.

[7] Porta (2014), 14.

[8] Green, Freedman, Gordis (2011), 608.

[9] *In re "Agent Orange" Products Liability Litigation*, U.S. Dist. Court E.D.N.Y., 1984.

[10] *In re "Agent Orange"*, at **296.

[11] Rosenberg (1984).

[12] *In re "Agent Orange"*, at **300.

[13] *In re "Agent Orange"*, at **297.

[14] Predominance is among the conditions provided by Rule 23(b)(3) of the U.S. Federal Rules of Civil Procedure for the certification of the "damage class action".

[15] See U.S. Supreme Court, *Amchem Products, Inc., v. Windsor*, 521 U.S. 591, 1997. The case involved a complex asbestos class settlement. More details in Eggen (2015), 450.

[16] Zirulia (2018).

[17] On the contrary, at least in the U.S., Courts have received epidemiologic studies just as well as or better than toxicological studies for the simple reason that they are the only ones conducted directly on human beings rather than animals or isolated cells. See Green, Freedman, Gordis (2011), 571 n. 2, 563, 567.

[18] Masera (2014), 364; Zirulia (2018), 284.

[19] It the case *Smaltini v. Italy* (Decision 24.3.2015, application no. 43961/09), the application was declared inadmissible because the evidence of *general causation* was lacking: the Court stressed that the available epidemiologic studies did not show a causal association between leukaemia and exposure to the Ilva steel plant emissions (§§ 57-58).

[20] Zirulia (2018). The thesis that epidemiologic studies provides sufficient evidence of causation in homicide and personal injury has been previously argued in Masera (2007), although through a partially different reasoning leading to partially different conclusions. See Zirulia (2018), 284.