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*“Tort Liability for Standards Development in  
the United States and European Union”*

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FACULTY OF LAW

# Tort Liability for Standards Development in the United States and European Union

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## 1. Introduction

Standardization is typically cast in technocratic language. Beneath the technical veneer, however, there is politics.<sup>1</sup> While the development of standards brings about opportunities for innovation and market access for some firms, for others it entails significant switching costs. Product specifications may need to be changed, production processes and methods may require amendment or the manufacture of certain products might need to be abandoned completely. With so much at stake, there are strong incentives to influence standards development.

Political contestation around standardization may lead standards development organizations (SDOs) to adopt suboptimal standards: they may fail to take into account state-of-the-art research, underestimate certain risks, or worse, favor certain industry interests over safety concerns of potential end-users. Incomplete, inaccurate or plainly “bad” standards can cause harm to firms implementing them in business operations, as well as to consumers using products designed in compliance with them. Inevitably, then, the question of tort liability for standards development arises.

This chapter addresses three interrelated questions concerning tort liability for private standards development. First, what theories of tort law govern civil liability for such an activity? Second, what factors and circumstances do courts consider significant when assessing liability for harm caused by inadequate standards? Third and finally, what is the exposure of SDOs to liability given the answers to the first two questions? In answering these questions, this chapter builds on case law and academic literature from the United States (US) and European Union (EU). Case law in these multi-layered jurisdictions is most developed, best documented and electronically searchable and accessible. Data was retrieved by systematic searches using case law databases and secondary sources, such as academic literature, government reports, and industry policy briefs.

This chapter will first draw attention to a number of general aspects of private standards development that scholars of regulation and governance have considered important attributes of standardization and that may impact on the liability of SDOs.<sup>2</sup> This discussion serves to further embed the research questions in the literature on standardization and civil liability, thus providing more focus to the research questions. In discussing these general aspects, *product* standards will be the point of reference. These standards set out technical specifications for the design, production and performance characteristics of manufactured goods. They may prescribe physical attributes for products (including dimensions, size and composition), require certain methods of production, construction and assembly, or concern requirements of what a product must be able to do.<sup>3</sup>

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<sup>1</sup> Bütthe and Mattli 2011, p. 12.

<sup>2</sup> The tort liability of individual participants involved in standards development, as discussed in *e.g. Bay Summit Community Ass'n* (1996), is beyond the scope of this contribution. The focus is on the liability of the SDO as the actor that promulgated the allegedly inadequate private standards.

<sup>3</sup> Brunsson and Jacobsson 2001, 4-5; Schepel 2005, 3-4; Scott 2010, 107 and 109; Bütthe and Mattli 2011, 5.

Examples of such performance characteristics concern interoperability with other products, resistance to temperature exposure, the level of user safety, testing methods, and quality assurance. Along the category of product standards, standards for services and system management have come to play an important role in our contemporary 'world of standards'.<sup>4</sup> So far, however, very little case law has developed with respect to these complementary types of standards. Most of the civil litigation against SDOs to date concerns product standards. The maturity of this body of case law allows for a rich and coherent analysis and therefore this chapter is concerned primarily with product standards.

## ***2. General Aspects of Tort Liability for Standards Development***

Standards development is celebrated for providing a wide range of important benefits to individuals, firms, and society at large. Sometimes, however, it may harm the interests of individuals and firms. Firms that suffer economic loss either because standards limit competition, restrict market access or violate pre-existing intellectual property (IP) rights, will principally have to look to antitrust, trade or IP law for protection.<sup>5</sup> Tort law may instead provide a remedy to firms who suffer economic loss because they relied on incomplete, outdated or otherwise inadequate standards in their business operations, or to those who suffer physical harm (i.e. personal injury or property damage) because they used a product that was manufactured in conformity with such bad standards.

As a general rule in the US and EU, tort law exposes an SDO to civil liability when it fails to exercise reasonable care in its activities and that failure causes direct or foreseeable physical harm to another. Standards development does not ordinarily cause direct or foreseeable harm to others, however. Harm occurs primarily after inadequate standards are relied upon in the business operations of the addressees of these standards, typically manufacturers or sellers, who design or construct, install and maintain products in accordance with the standards. If standards turn out to be inadequate, these actors, by complying with the standards, place on the market a defective product. Accordingly, they may be held primarily responsible under the strict liability rules of products liability law.<sup>6</sup>

However, there are valid reasons to bring a civil liability claim against the SDO as a tortfeasor secondary to manufacturers or sellers. These may include the moral consideration that the SDO's standards are the origin of the harm given that manufacturers or sellers routinely implement these standards in their business operations. More practical considerations to target the SDO involved include the insolvency of the manufacturer, the ability of the manufacturer to escape liability

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<sup>4</sup> Brunsson and Jacobsson 2001. See for a recent perspective on the rise of system management standards Galland 2017 (discussing how the global certification industry is further pushing the adoption of these standards by SDOs and governments).

<sup>5</sup> These actions are discussed extensively elsewhere in this volume and in Volume I.

<sup>6</sup> Whether such strict liability exists depends amongst others on the type of defect and the type of harm suffered.

under the so-called ‘regulatory compliance defense’,<sup>7</sup> or the potentially ‘deeper pocket’ of the SDO (e.g. because of its comprehensive insurance coverage). If a liability claim is to prevail, however, the plaintiff must show that the conduct of the defendant SDO created a risk of direct or foreseeable harm. Thus, a key question for the inquiry in the chapter is: What factors do courts consider relevant in constructing foreseeability of harm and a sufficiently close relationship between the SDO’s activities and the plaintiff’s harm? Such factors are likely to be addressed in relation to the existence of a duty of care in negligence and the breach of that duty (or any other equivalent concepts of national tort law). They may also be found in considerations around causation, however, by asking: Did the inadequate standards proximately cause the harm suffered by the plaintiff, without any significant interference by the standards’ addressee? Viewed in this way, a plaintiff may establish liability by following the chain of causation all the way up to the negligent adoption of the inadequate standards.

This discussion on the relationship between standards development and the plaintiff’s harm draws attention to the degree to which the contested standards are binding upon manufacturers. Within that context, a distinction is typically made between ‘technical regulations’ and ‘voluntary standards’. The first category, following the parlance of international economic law, involve standards that are adopted by public, state actors and that are mandated by law.<sup>8</sup> This chapter is only concerned with voluntary standards, which are standards developed by private, non-state actors. They are non-mandatory in that actors can choose to abide by them. This voluntariness can be compromised in various ways, of course.<sup>9</sup> Private standards can be *de facto* mandatory if they constitute a condition for market access or the ability to effectively compete on it. Moreover, SDO internal regulations (e.g. bylaws, company statutes and rules of association) may impose compliance with private standards on membership and may employ mechanisms of certification and accreditation to enforce that obligation.<sup>10</sup> In addition, supply chain partners may require compliance with standards via commercial contracts or procurement policies.<sup>11</sup> In the public law domain, legislative measures, public authorities and courts may encourage or demand compliance with such standards once they have been adopted by a particular SDO, thus mandating them *de facto* or *de jure*.<sup>12</sup> Clearly, such public intervention blurs

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<sup>7</sup> Manufacturers and sellers in the US and EU may be able to escape liability under this defense if compliance with the inadequate standards was mandated by public statute. See on this defense and its relation to private standards Schepel 2005, 361-374.

<sup>8</sup> WTO Agreement on Technical Barriers to Trade (TBT) Annex 1: Terms and their Definitions for the Purpose of this Agreement, Articles 1 and 2. See also Article 1(f) Directive 2015/1535/EU of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services [2015] OJ L241/1. This definition does not exclude the possibility that private actors (including SDOs) participate in the development of a technical regulation. As noted, however, the liability of individual participants in standards development is beyond the scope of this contribution (see at footnote 2).

<sup>9</sup> See in detail Cafaggi 2012, 22.

<sup>10</sup> *E.g.* the American National Standards Institute (ANSI) requires its members to comply with its ANSI Essential Requirements (2018) as a condition to have their standards accredited as American National Standards.

<sup>11</sup> Verbruggen 2017a, 312 (with further references).

<sup>12</sup> The inclusion and reliance on private and technical standardization in statute is increasingly popular among state actors. See for a US perspective Mendelson 2014.

the lines between public mandatory 'technical regulations' and private, voluntary standards. This chapter takes the resulting hybridity into account by asking: To what extent does (the degree of) public recognition of privately developed standards affect the liability risk of SDOs? What difference exists, if any, if compared to liability for developing purely private standards?

A related issue concerns the legal form and institutional embedding of SDOs. Most SDOs are private, not-for-profit bodies. They may be organized as individual companies, but more frequently they are collective, membership-based organizations for business, civil society or combinations of these.<sup>13</sup> Sometimes, however, SDOs are established by public statute or have acquired a public law status because of a delegation of public law powers to them.<sup>14</sup> Alternatively, SDOs may be recognized to have a 'public law function' through the exercise of its regulatory activities.<sup>15</sup> Acting as bodies governed by public law the question arises whether the rules of state liability apply to SDOs setting voluntary product standards and whether they can avail themselves of state immunity doctrines to escape liability. Heidt (2010, 1280-1284) has argued that, because of the governmental nature of SDO decision-making, courts should shield SDOs from overly burdensome liability by recognizing a qualified privilege. Such a privilege would protect SDOs from civil liability where their decisions are taken in good faith, but would simultaneously guard against abusive standards development should they act in bad faith.<sup>16</sup>

Heidt's suggestion should be read against the background of the inherently political nature of standards development. Setting standards implies the making of policy-bound trade-offs between the conflicting interests of the owners, users and potential beneficiaries of the standards. Concerns of health and safety need to be balanced against concerns of cost, inconvenience and consumer choice.<sup>17</sup> How is this balancing reflected in cases concerning liability for standards development? Do courts show (high) levels of deference when evaluating these policy choices, as they typically do in judicial review procedures concerning public policy and decision-making? More generally, to what extent is the way in which contentious standards were designed or governed part of the liability assessment?

What is more, SDOs fulfill an important societal function when they promulgate standards that intend to enhance the collective welfare in assistance or in the absence of government. Imposing liability on SDOs, it is argued, challenges this laudable function and may inhibit the deliberation of possible standards.<sup>18</sup> It has therefore been suggested that courts, in making the threshold determination whether a private association should be exposed to civil liability for standards

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<sup>13</sup> Abbott and Snidal (2009) have shown that transnational standard setting increasingly involves business and civil society actors, thus moving from a state-driven toward a multi-actor approach. See for an overview of the international "ecosystem" in ICT-standardization Vol. I, Chapter 2 (Biddle).

<sup>14</sup> See for an overview of technical standardization bodies in Europe Schepel and Falke 2000, 62-68.

<sup>15</sup> This is the case for the national SDO for technical standardization in France called AFNOR. See in detail at footnote 107 below.

<sup>16</sup> Heidt 2010, 1280-1284.

<sup>17</sup> *Id.*, 1227-1232.

<sup>18</sup> *Id.*, 1278.

development or other activities, must weigh conflicting considerations of policy and justice, including ‘any existing social interest in permitting the type of conduct of which the plaintiff complains, the burden which would be imposed on [private associations] by judicial intervention in similar cases in the future, the burden on courts were they to take cognizance of such disputes, and the extent to which such intervention might interfere with other socially recognized values promoted by such associations.’<sup>19</sup>

Finally, SDOs may not only be engaged in the setting of standards. At times they also pursue certification and/or accreditation activities. In the case of product standards, both activities in essence involve the assessment of a firm’s compliance with a normative document, i.e. the product standard. If the assessment is positive the firm is typically awarded some form of endorsement, such as an approval, enlisting, certificate or accreditation of the product or of the firm itself.<sup>20</sup> These endorsements do not reveal the specific details of performance, yet offer an aggregate, discrete judgment on compliance.<sup>21</sup> The attestations therefore generally signal packaged information on compliance to specific audiences (either businesses, consumers or governments), which may come to rely on it in making decisions. Certification and accreditation activities clearly go beyond standards development *per se*. The question arises of whether these activities make SDOs more or less vulnerable to liability claims. A discussion of the liability of ‘pure’ certification and accreditation activities, i.e. without any standards being developed by the certifier or accreditor, is beyond the scope of this chapter.

### ***3. Perspectives from the US***

Individuals and firms in the US have sought compensation for harm from SDOs based on several theories of tort law. Actions other than those alleging negligence have been unsuccessful for the most part.<sup>22</sup> Three actions grounded in negligence will be discussed here: negligence; an action based on the so-called ‘voluntary undertaking’ rule; and an action for negligent misrepresentation. In each of these actions considerations around the existence of a duty of care owed by the defendant SDO to the plaintiff are central to the success (or defeat) of the claim.

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<sup>19</sup> Editorial Note Harvard Law Review 1963, 990. .

<sup>20</sup> For a more detailed discussion of certification, see Chapters x and x in this volume.

<sup>21</sup> Bartley 2011, 443.

<sup>22</sup> An exception is the case of *Hall and Chance* (1972). In this case, which developed out of a series of separate incidents across the US in which infants were injured by exploding blasting caps, a US District Court in New York held that the industry trade association, which administered a safety program covering the use of warning labels for explosives, and the entire national blasting cap industry could be held jointly liable under a strict theory of ‘enterprise liability’. *Hall and Chance* has not been followed by other courts: the theory of ‘enterprise liability’ has been abandoned in products liability law and SDOs have not been considered subject to strict products liability law as they do not normally engage in selling, distributing or offering products in the stream of commerce. See Rockwell 1992, at §3, §4a and 4b (with further references).



### A. *Negligence Actions in General*

The elements of a negligence action in American common law are a duty owed by the defendant to the plaintiff, breach of that duty by the defendant, and damages proximately caused by that breach. In a negligence action a duty may be defined as an obligation, recognized and enforceable by law, to conform to a certain standard of behavior to another.<sup>23</sup> American common law normally imposes a duty on an actor when he directly or foreseeably creates a risk of physical harm for another, that is, personal injury and property damage.<sup>24</sup> When a duty is owed, the standard of care to be applied by the court is usually that of reasonable care under the circumstances. In general terms, then, SDOs are subject to civil liability in an action of negligence for any failure to exercise reasonable care in their activities when such failure causes direct or foreseeable physical harm to another.

The element of duty is a threshold issue. If an SDO cannot be found to owe a duty to use reasonable care, it is not answerable under common law for any of the harm sustained by the plaintiff. The claim will thus be denied. Whether an SDO owes a duty to the plaintiff, and what standard of care is required from it, are questions of law. These questions are determined by the judge, not the jury.<sup>25</sup> An SDO may as a preliminary matter petition the judge, via a motion to dismiss or, after discovery, in a motion for summary judgment, to hold that it owes no duty to the plaintiff. If either motion is granted, the action is rejected before questions on breach or proximate cause as addressed by a jury in trial. If, however, a motion is denied and the judge considers that a duty is owed, liability does not automatically follow: also the other elements of a negligence action have to be established. The judge thus only exposes the SDO to potential civil liability for harm. There is a good chance that a final decision on liability may not follow in the end, as a duty decision can lead the defendant to settle the case before trial.

### B. *A Duty of Care in Negligence for SDOs?*

To assess whether an SDO owes a duty of reasonable care in negligence courts frequently balance competing considerations of policy and justice that determine the fairness of exposing it to civil liability for harm allegedly caused by its standards development. These considerations include the foreseeability of harm to the plaintiff as a result of the defendant's conduct, the closeness of the connection between the defendant's conduct and the plaintiff's harm, the moral blame attached to the defendant's conduct, the potential impact of imposing liability on preventing such harm in the future, the burden of liability on the defendant and the community, the availability and cost of insurance to cover the risk of liability involved, and the potential volume of litigation that liability would

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<sup>23</sup> Cf. Keeton et al. 1984, § 53, at 356.

<sup>24</sup> Dobbs, Hayden, and Bublick 2016, § 10.1, at 204 (with further references to case law and literature). See also Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 7 (2010).

<sup>25</sup> The jury determines questions on fact, unless no reasonable person can differ as to the correct answer. These questions concern, most prominently, whether the duty is breached and whether that breach proximately caused the harm. American common law thus typically assigns to the jury the determination of the other constitutive elements of a negligence claim. See also Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 7, cmt. i (2010).

generate and its impact on the court system.<sup>26</sup> The weight of these factors may either be in favor or against imposing a duty.

The majority of the cases involving the liability of SDOs for standards development have been rejected through motions to dismiss or motions for summary judgment. Key in such ‘no-duty decisions’ are considerations of policy and justice, together with due regard to the relationship between the plaintiff and defendant SDO. In *Beasock v. Dioguardi Enterprises Inc.*, for example, the Supreme Court of Monroe County, New York allowed the motion for summary judgment of the Tire and Rim Association (TRA) in a wrongful death action. An employee of one of TRA’s members, a tire manufacturer, was fatally injured while inflating a truck tire that was mistakenly mounted on a bigger size rim. The plaintiff, the wife of the deceased employee, claimed that TRA was liable in negligence because it set dimensional standards which permitted mismatch injuries to occur. Leaving aside the factual question of whether TRA’s standards were indeed inadequate, the Supreme Court considered that liability of associations such as TRA, which do not directly cause injury to others by the promulgation of their standards, is dependent on their authority to control compliance with their standards amongst the membership. As the court held in this case, even though TRA standards had become industry standards, they were voluntary in nature and the defendant lacked the control over any culpable and fatal mismatch in the production process since it ‘neither mandates nor monitors the use of its standards by any manufacturer’.<sup>27</sup>

This ‘control thesis’ has emerged as a centerpiece in the judicial reasoning around the existence of an SDO’s duty of care in negligence actions. Unless the SDO is in a position of authority to direct or control the implementation of the standards by the addressees, the harm of the plaintiff was not reasonably foreseeable for the defendant SDO and there is no sufficiently close relationship between the latter’s conduct and the plaintiff’s harm. In those situations, no duty of care is ordinarily owed in negligence to third parties suffering physical harm allegedly caused by inadequate standards.<sup>28</sup> Several courts have relied upon the thesis to give no-duty decisions in actions alleging negligent standards development.<sup>29</sup>

However, in one specific line of cases courts have used the control thesis as a principal argument to impose a duty of care on an SDO. These cases all concerned

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<sup>26</sup> Dobbs, Hayden, and Bublick 2016, § 10.3, 208-209.

<sup>27</sup> *Beasock* (1985), 979.

<sup>28</sup> Cf. Keeton et al. 1984, § 56, at 385 (‘[i]n the absence of the [relationship of control], there is generally no duty to protect others against harm from third persons.’) This discussion relates to the distinction between misfeasance and nonfeasance, on which see Section B.3 below.

<sup>29</sup> See *Bailey v. Hines* (1999) (a non-profit trade association that developed standards for the design and construction of wood trusses used for roof framing systems owed no duty to severely injured construction workers who relied on the its standards to install such systems since the association exercised no control over the manufacturer of the product, intended the standards as a guide, and could not require the manufacturer to follow its installation instructions; *Howard v. Poseidon Pools* (1986) (non-profit swimming pool trade association owed no duty to a swimmer who sustained diving injury for it had no authority to control the manufacturer of the pool); and *Commerce and Industry Ins. Co. v. Grinnell Corp* (1999) (non-profit trade association setting fire safety standards owed no duty to owners of property that was damaged in a warehouse fire because it had no control over which of its minimum standards were incorporated into mandatory municipal building codes or over any construction that purported to conform to its standards).

patients who contracted HIV/AIDS after receiving a blood transfusion with HIV contaminated blood. The defendant in these actions of personal injury or wrongful death was the American Association of Blood Banks (AABB), a private, not-for-profit trade association setting national standards for blood banking and blood transfusion services. It was alleged that AABB had failed to timely implement changes in its standards to ensure that its member blood banks employed surrogate testing or alternative practices that could prevent the collection and distribution of contaminated blood at the time it became clear that HIV could spread by transfusion.

The first in this line of cases, *Snyder v. AABB*, the New Jersey Supreme Court carefully assessed the role the SDO played in the blood-banking industry. The Supreme Court held that by the time the plaintiff received the contaminated transfusion AABB 'exerted considerable influence over the practices and procedures over its member banks' and '[i]n many respects, the AABB wrote the rules and set the standards for voluntary blood banks'.<sup>30</sup> Such dominance was fostered by AABB's annual inspection and accreditation of its members to assure compliance with its standards, its presentation as an industry leader in setting policy and standards of practice,<sup>31</sup> as well as the strong deference of federal and local governments to AABB standards and inspection results.<sup>32</sup> In holding that AABB owed a duty of care to recipients of blood transfusions the Supreme Court further gave weight to the fact that its standards were not only adopted for the benefit of the industry, but also for patients, who had to rely on those standards for the safety of donor blood.<sup>33</sup> The court also considered the risk of contracting HIV/AIDS through transfusions of contaminated blood both foreseeable and severe given the available government reports and scientific publications.<sup>34</sup> Considerations of policy and justice as raised by AABB could not trump the existence of a duty of care.<sup>35</sup> Accordingly, the Supreme Court held, the trial jury could have found that AABB had been negligent in not recommending in its standards surrogate testing and that this negligence was a substantial factor in causing the plaintiff to contract HIV/AIDS. AABB was held liable to pay damages in excess of USD 400.000.

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<sup>30</sup> *Snyder v. AABB* (1996).

<sup>31</sup> *Id.*, 1048 ('Society has not thrust on the AABB its responsibility for the safety of blood and blood products. The AABB has sought and cultivated that responsibility. For years, it has dominated the establishment of standards for the blood-banking industry. (...) By words and conduct, the AABB invited blood banks, hospitals, and patients to rely on the AABB's recommended procedures.')

<sup>32</sup> *Id.*, 1040 ('Both the state and federal government, as well as the blood-banking industry, generally accept AABB standards as authoritative. Consequently, blood banks throughout the nation rely on those standards.') and at 1043 ('Thus, if a blood bank failed the annual AABB inspection on the taking of medical histories, that bank could lose its [state] license to operate in New Jersey. In sum, (...) the AABB was not a mere advisory body. It exercised control of its member banks (...)').

<sup>33</sup> *Id.*, 1048 ('Blood banks, hospitals, and patients rely on the AABB for the safety of the nation's blood supply. A patient contemplating surgery cannot assure the safety of blood drawn from others. Of necessity, patients rely on others, including the AABB, for that assurance.')

<sup>34</sup> *Id.*, 1048-1049.

<sup>35</sup> *Id.*, 1049-1050.

*Snyder* was followed by courts in Louisiana, New York and Virginia.<sup>36</sup> It was rejected, however, by the California Court of Appeals in *N.N.V. v. AABB*.<sup>37</sup> In this case, which involved a minor who contracted AIDS after receiving a contaminated donor blood during surgery, the Court ruled that liability should not be imposed on AABB as a matter of public policy and fairness. In reaching that conclusion it, by and large, rejected all factors that were considered relevant in *Snyder* to establish a duty of care, and in particular AABB's dominance in the sector and patients' reliance on AABB standards for their safety. In *Snyder*, AABB had advanced the argument that it should not be found liable 'for taking the "wrong side" of a debate involving medical uncertainties and public policy.'<sup>38</sup> The California Court of Appeals agreed and placed strong emphasis on the lack of medical or scientific consensus regarding the effectiveness of available methods and practices to reduce the risk of HIV/AIDS contamination via blood transfusion. Such absence made it not reasonable foreseeable that the promotion of new testing methods in its standards would have reduced the risk of AIDS contraction for the plaintiff. This state of evolving knowledge also led the court to hold that imposing liability on the SDO would not further the goal of preventing future harm under the circumstances.<sup>39</sup>

Moreover, the court considered in its no-duty decision, AABB had to balance the legitimate concern of the safety of blood supply against the equally legitimate concern of the availability of blood to needing patients and the costs of rejecting unaffected blood through new testing methods. As the implications for availability and costs of blood supply were unknown, AABB's conduct 'warrants no moral blame'.<sup>40</sup> The court also expressed the fear that AABB would be exposed to an extensive burden of litigation if a duty of care were to be imposed. Opening the floodgates would also have a chilling effect on the SDO and would be detrimental for the community in that the SDO would be held back to further pursue its standard setting activities, which support otherwise laudable public policy goals

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<sup>36</sup> *Weigand v. University Hospital of New York* (1997) 399 (AABB's motion to dismiss is denied); *Douglass v. Alton Ochsner Medical Foundation* (1997) (overturning a summary judgment in favor of AABB); and *Jappell v. AABB* (2001) 481 (AABB's motion to dismiss is denied).

<sup>37</sup> *N.N.V.* (1999), 1388-1392.

<sup>38</sup> *Snyder* (1996), 1049.

<sup>39</sup> *N.N.V.* (1999), 1383.

<sup>40</sup> *Id.*, 1382-1383. The *Snyder* court had dismissed this argument by holding that such concerns should not have diverted AABB from 'its paramount responsibility to protect the safety of the blood supply'. *Snyder* (1996), 1050.

such as health and safety.<sup>41</sup> Finally, the costs of taking out insurance against such liability could also be high.<sup>42</sup>

The previous analysis suggests that courts, in determining the threshold issue of duty in a negligence action, consider primarily the foreseeability of harm as a result of the SDO's conduct and the closeness of the connection between its standard-setting activities and the plaintiff's harm. The ability to control or direct compliance with its standards by the standards' addressees (e.g. by mandating compliance on SDO members or administering a certification and accreditation scheme for the purposes of monitoring compliance) will normally show such foreseeability and/or close connection. Alternatively, the fact that the standards enjoy government endorsement in (agency) regulations or guidelines and that the SDO represents itself to the public as an industry leader for the development of standards may serve to demonstrate the two factors.<sup>43</sup> Other considerations of policy and justice may nonetheless weigh against imposing on an SDO a duty to exercise reasonable care in the promulgation of its standards under the circumstances. Courts have, in similar wording as the California Court of Appeals in *N.N.V.*, drawn attention to the societal importance of promulgating standards and argued that this function should not be hindered by exposing SDOs to liability in order to support their no-duty decisions.<sup>44</sup>

### C. *The Voluntary Undertaking Rule*

An alternative way to impose a duty on SDOs and subject them to potential tort liability is by applying the rules concerning the American common law doctrine on affirmative duties. American common law, like English law, makes a distinction

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<sup>41</sup> *N.N.V.* (1999), 1384 ('If liability were imposed here, then the AABB and other similar medical associations could be faced with a significant burden of litigation that might be impossible to avoid') and at 1386-1387 ('[W]e believe imposition of liability here would have adverse consequences to the public by chilling scientific and medical debate on important issues (...) Additionally, we note imposition of liability could hinder reconsideration of established standards.'). See in the same vein Feldmeier 1999, 795 (arguing that the result of cases like *Snyder* could be 'an unwarranted expansion of liability that could have the detrimental effect of discouraging trade association standards setting') and Heidt 2010, 1254-1255 (noting that cases like *Snyder* 'herald an area of increased liability' and raise 'the specter of unlimited liability once a duty was imposed'). *Contra*, *Weigand v. University Hospital of New York* (1997), in which the Supreme Court of New York County held that 'the parties who would be covered by a duty on the part of the industry trade association were specifically foreseeable, i.e., the recipients of blood collected and screened according to the trade association standards by member blood banks complying with those standards. Imposition on the trade association of a duty of care to those blood recipients would not expose the trade association to liability to the public at large and its liability would be within manageable limits.' (at 400).

<sup>42</sup> *N.N.V.* (1999), 1388.

<sup>43</sup> See *Snyder* (1996) (citations at footnotes 30 and 31 above) and *Prudential Property and Cas. Ins. Co. v. American Plywood Ass'n* (1994), 3 (trade association developing standards for plywood roofing construction and nailing patterns owes a duty to exercise due care in promulgating its standards vis-à-vis homeowners who incurred extensive property damage as a result of a hurricane because these standards enjoyed wide public law recognition and the association had made representations to the public as the world leading expert body in the field).

<sup>44</sup> See e.g. *Meyers v. Donnatacci* (1987), 404 (non-profit swimming pool trade association owed no duty to a swimmer who sustained diving injury for it had no authority to control the manufacturers of the pool and imposing such a duty would undermine the many laudable purposes that organizations such as these serve in society) and *Bailey* (1999), 183 (citing *Meyers* favorably in holding that a non-profit trade association setting standards for the design and construction of wood trusses used for roof framing systems owed no duty to severely injured construction workers). See also *Commerce and Industry Ins. Co.* (1999) (as discussed in section B.4 below).

between misfeasance and nonfeasance for the purposes of establishing whether the defendant owes a duty of care to the plaintiff. Whereas misfeasance – understood as active conduct working positive harm to others – generally creates a duty of care in relation to physical harm, nonfeasance – held to be passive inaction to protect from harm – does not.<sup>45</sup> Thus, if the defendant does not directly create the risk of harm for others, the failure to prevent or minimize that risk does not normally expose him to liability. Nonfeasance is not a tort, unless there is a duty to act imposed on the defendant in specific circumstances.<sup>46</sup> Put differently, affirmative duties (i.e. duties to protect others from pre-existing risk of harm) only exist in special circumstances. Courts have been able to shield SDOs from liability by reference to the distinction between malfeasance and nonfeasance. By strategically characterizing the plaintiff's allegations regarding the SDO's conduct as nonfeasance (or omission), some courts have argued that no duty of care was owed in negligence in the absence of any special circumstances.<sup>47</sup>

However, one of the special circumstances that has enabled courts to impose an affirmative duty on an SDO is when it voluntarily undertakes to perform an activity that is aimed at reducing the risk of harm for another caused by some other source. American common law then allows the imposition of a duty of care on the SDO vis-à-vis the other or even to third parties. One articulation of this so-called 'voluntary undertaking' rule is found in Section 43 of the Restatement (Third) of Torts:

An actor who undertakes to render services to another and who knows or should know that the services will reduce the risk of physical harm to which a third person is exposed has a duty of reasonable care to the third person in conducting the undertaking if:

- (a) the failure to exercise reasonable care increases the risk of harm beyond that which existed without the undertaking,
- (b) the actor has undertaken to perform a duty owed by the other to the third person, or
- (c) the person to whom the services are rendered, the third party, or another relies on the actor's exercising reasonable care in the undertaking.<sup>48</sup>

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<sup>45</sup> Keeton et al. 1984, §56, at 373.

<sup>46</sup> See in general Dobbs, Hayden, and Bublick 2016, §25.1, at 615 and Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 37 (2010).

<sup>47</sup> See e.g. *Meyers* (1987), 401 (New Jersey Superior Court interpreting the claim against the SDO as allegations concerning the failure to take action to prevent harm resulting from shallow water diving while being aware of the correlation between the two, and not that the standards the SDO undertook to set were inaccurate, false or improper). See also *People v. Arcadia Machine & Tool, Inc.* (2003), 21 (granting a motion for summary judgment by trade associations in the gun industry after holding that the claim is premised on nonfeasance and that the plaintiffs failed to present authority that these associations owed a duty to develop standards for gun safety design).

<sup>48</sup> Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 43 (2010). The rule can be traced back to *Glanzer v. Shepard* (1922) in which Justice Cardozo held: 'One who assumes to act, even gratuitously, may thereby become subject to the duty of acting carefully, if he acts at all' (at 276). The rule has therefore also been known as the 'Good Samaritan' rule.

This guideline was previously laid down in similar wording in Section 324A Restatement (Second) of Torts, which ‘has been widely recognized by the court’.<sup>49</sup>

Plaintiffs have relied upon the voluntary undertaking rule to establish civil liability for standards development, frequently in parallel to actions in negligence.<sup>50</sup> The service that is rendered concerns the development of product standards (including warnings) aimed to prevent or minimize risk of physical harm caused by dangerous products. The situation described under (a) suggests that an SDO has a duty of reasonable care in standards development when that activity leads to ‘some physical change to the environment or some other material alteration’ that increases the risk of physical harm.<sup>51</sup> In the absence of evidence to the contrary, courts have considered the risk to exist independently of any standards development. In *Rountree v Ching Feng Blinds Industry Co. Ltd.*, for example, the US District Court of Alaska held that the risk of physical harm of strangulation posed by cords of window coverings does not vary as a function of the allegedly wrongful safety standards the Window Covering Manufacturers Association had developed to reduce the risk of injury to infants.<sup>52</sup> The SDO’s failure to decrease that risk was not considered sufficient. This meant that even if the plaintiffs in this case, the parents of a deceased girl who got strangled in the inner cord of a window blind, would prove the inadequacy of the standards, a duty of care could not be imposed on the SDO following the rule under (a).<sup>53</sup>

Applied to the context of product standardization, the situation set out under (c) of Section 43 of the Restatement subjects an SDO to a duty of care when the plaintiff shows that the manufacturer of the product that caused the physical harm (‘the other’) relied on negligently developed standards in the production or sale of that product, or, alternatively, that plaintiffs themselves (‘the third person’) placed such reliance on the standards when buying or using that product. Plaintiffs relying on this rule have seen their claims frequently defeated because of their inability to show that they (or the manufacturer of the dangerous product) actually relied on the negligently developed standards.<sup>54</sup> In *Sizemore v. Georgia-Pacific Corp.*, for example, the plaintiffs sought damages for personal injuries resulting from a fire that occurred in their home. They alleged that the Hardwood Plywood & Veneer Association (HPVA), a non-profit trade association for plywood manufacturers, had been conducive in promoting and adopting wrongful fire safety standards, with which the plywood paneling installed in their home

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<sup>49</sup> Dobbs, Hayden, and Bublick 2016, §25.7, at 628 (with references to case law). See also the Reporters’ Note with Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 43, cmt. c (2010).

<sup>50</sup> In *N.N.V.* (1999) the plaintiff relied on Section 324A Restatement (Second) of Tort in its appeal against AABB’s summary judgment, which had been granted in first instance in relation to a negligence action.

<sup>51</sup> *Patentas v. United States* (1982), 717 (referring to Section 324A Restatement (Second) of Torts, cmt. c, Illustration 1).

<sup>52</sup> *Rountree* (2008), 808.

<sup>53</sup> *Id.*, 808 (‘A standard or warning that explicitly accounted for the danger posed by the inner cord may have decreased the risk of injury to plaintiffs [but] it does not show that an inadequate standard *increased* the risk of harm to the third-party consumer’ (emphasis as in original)).

<sup>54</sup> Negligent misrepresentation actions have for the very same reason been denied. However, where SDOs engage in certification or accreditation plaintiffs are more successful in showing reliance, namely on the certificate, accreditation or any other label or seal attesting compliance with the product standards. See at section B.4 below.

complied. It was clear from the file, however, that they had only learned about HPVA and the standards after the fire.<sup>55</sup>

Most of the substantive discussion on the question of whether an SDO owes a duty to exercise reasonable care in standards development concerns the situation under (b). Such a duty exists, the Restatement proposes, if the SDO has undertaken to perform a duty one of its business members (i.e. a manufacturer or seller) owed to the plaintiff. In the case of developing product standards, the SDO must thus have assumed the duty manufacturers or sellers have to individuals or firms to produce or sell safe products. In determining whether that duty was indeed assumed, courts have frequently relied on the 'control thesis' discussed above and have made the determination of the duty element dependent on the SDO's ability to control compliance with its standards by its membership, or in the industry more broadly.<sup>56</sup> Again, the lack of such authority or control, for example due to the voluntary, non-binding legal status of the standards involved or the absence of any instruments to inspect and sanction non-compliance, is then frequently considered sufficient for a no duty decision.<sup>57</sup>

In *King v. National Spa and Pool Institute, Inc.*, however, the lack of control did not withhold the Alabama Supreme Court from imposing on the NSPI, a non-profit trade association which promulgated standards for the size, shape and dimensions of residential swimming pools, a duty to exercise due care under the voluntary undertaking rule as laid out in Section 324A of the Restatement (Second) of Torts. In this case, the plaintiff's husband broke his neck after diving into his pool from the jump board. Some months later he died of pneumonia secondary to his injury. In previous claims involving diving injuries, courts in New Jersey and New York had forthrightly refused to accept that NSPI owed a duty to pool users based on the theory that it had no control over pool manufacturers or sellers.<sup>58</sup> The Alabama Supreme Court held differently. Reading the case as premised on malfeasance rather than nonfeasance, it considered that NSPI 'had no

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<sup>55</sup> *Sizemore v. Georgia-Pacific Corp.* (1996), 8 ('plaintiffs did not rely upon any publication or other activity on the part of HPVA, nor were they even aware that HPVA existed prior to suffering their injuries.'). See also *e.g. Friedman v. F.E. Myers Co.* (1989), ('there is no evidence that plaintiffs relied on [the SDO's] performance (...) Plaintiffs state that they had not read any allegedly false or misleading information or publication concerning PCBs in well pumps prior to the date of the incident') at 383 (applying Section 323 Restatement (Second) of Torts).

<sup>56</sup> *Cf. Commerce and Industry Ins. Co.* (1999), 4 ('Under the Restatement analysis advanced by plaintiffs, most courts have focused on the amount, if any, of control a trade association wields over the behavior of its members concerning, for example, the proper implementation of its standards.')

<sup>57</sup> See *e.g. Bailey* (1999), 185 (a non-profit trade association developing standards for the design and construction of wood trusses used for roof framing systems owed no duty to severely injured construction workers since its 'instructions were advisory' and it 'could not force the carpenters to abide by its admittedly general instructions'. See also *Commerce and Industry Ins. Co.* (1999), 4 (non-profit trade association setting fire safety standards owed no duty to owners of property that was damaged in a warehouse fire because it has no control over compliance with its standards as it 'does not list, inspect, certify or approve any products or materials for compliance with its standards. It merely sets forth safety standards to be used as minimum guidelines that third parties may or may not choose to adopt, modify or reject.').

<sup>58</sup> See *Meyers* (1987), 406 ('NSPI had no authority to mandate compliance nor did it attempt to force its members to comply. It acted merely as a secretariat for its members; a forum where those who chose to make suggestions could do so. There were no penalties for failing to respond to the survey') and *Howard* (1986), 55 ('NSPI did not have the duty or the authority to control the manufacturers who did produce the product here in question, viz., the swimming pool') (discussing the existence of a duty of care in an action sounding in negligence).



statutorily or judicially imposed duty to formulate standards', but nonetheless did so voluntarily.<sup>59</sup> It furthermore held that the SDO developed its standards for swimming pools having in mind 'the needs of the consumer' and had declared that safety was 'one of the basic considerations upon which these design and construction standards are founded'.<sup>60</sup> Under those circumstances the Supreme Court held that harm for consumers was foreseeable for NSPI if due care was not exercised in promulgating its standards.<sup>61</sup>

The approach in *King* was confirmed by the Washington Court of Appeals in *Meneely*, in which NSPI was held liable for rendering a young swimmer quadriplegic who dove from a jump board into a pool, while it knew that the combination of the specific pool and board at hand posed a risk for certain divers and failed to amend its safety standards accordingly.<sup>62</sup> While NSPI may not have had any formal control over compliance with its standards by the industry, NSPI members followed its standards out of economic imperative.<sup>63</sup> The damages award against NSPI of \$6.6 million, along with settlements in other cases, sent the SDO into insolvency.<sup>64</sup>

Emerging from bankruptcy in 2004, NSPI was again faced with a personal injury action of an injured swimmer. In assessing the action, the courts in first instance and on appeal reaffirmed the control thesis, and held that NSPI owed no duty of care to the plaintiff. The US District Court in Georgia found at first instance that the 'standards are voluntary, consensus standards' and that the association 'has no power to enforce compliance with those standards' and 'had no control over [the contractor's] installation of the [plaintiff's family] pool or over whether [the contractor] complied with the NSPI Standard when installing the pool'.<sup>65</sup> The Eleventh Circuit Court confirmed these findings on appeal and added that NSPI did not owe a duty to warn consumers about the danger of swimming pools and diving boards covered by its standards following Section 324A of the Restatement (Second) of Torts: it did not increase the risk of diving injuries for swimmers, sufficient proof of actual reliance on NSPI standards was missing, and NSPI did not undertake to perform a duty owed by pool manufacturers to swimmers.<sup>66</sup>

Applying the voluntary undertaking rule to impose a duty of care on an SDO finds it limit in the scope of the undertaking: What was it that the SDO voluntarily

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<sup>59</sup> *King* (1990), 614.

<sup>60</sup> *Id.*, 615-616.

<sup>61</sup> *Id.*, 616. See also *Rountree* (2008) in which the US District Court of Alaska considered (at 809) 'It is of no consequence that [the SDO] did not have control over the blinds because [it] had control over the content of the warning. The warning itself provides a critical nexus between [the SDO], the manufacturer and the consumer.' Instead, the court focused its duty analysis on a number of public policy factors, including foreseeability (at 810).

<sup>62</sup> *Meneely v. S.R. Smith, Inc.* (2000) (applying the Washington voluntary rescue doctrine, which is broadly similar to the rules proposed in the Restatement).

<sup>63</sup> *Id.*, 57.

<sup>64</sup> See in detail Heidt 2010, 1231, at footnote 15.

<sup>65</sup> *Lockman v. S.R. Smith, LLC* (N.D.Ga. 2010), 7.

<sup>66</sup> *Lockman v. S.R. Smith, LLC* (11th Cir. 2010), 474.

undertake to do?<sup>67</sup> Courts have given particular importance to the addressees of the standards and the purpose for which the standards are developed, using both factors to argue either in favor or against the imposition of a duty.<sup>68</sup> Thus, in no-duty decisions courts have pointed to a limited undertaking by noting that the SDO develop standards for the purposes of sharing knowledge amongst peers in the industry, that it sought to address its membership exclusively, and that its standards were minimum standards only.<sup>69</sup> In duty decisions, by contrast, courts have stressed the public interests involved in having adequate standards for third parties, namely for the health and safety of ultimate consumers of the products for which standards are set.<sup>70</sup>

A second important limit in applying the voluntary undertaking rule is found in the courts' sense of policy and justice. Even if a duty can be imposed on SDO's following the voluntary undertaking rule, considerations of policy and justice may still trump the existence of a duty of care.<sup>71</sup> Thus, again, considerations regarding the foreseeability of harm, the closeness of connection between the defendant's conduct and the plaintiff's harm, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the burden on the defendant and the consequences to the community if a duty is imposed, and the availability and cost of insurance to cover the risk involved.<sup>72</sup>

#### D. *Negligent misrepresentation*

Finally, plaintiffs who allegedly suffered harm caused by the standard-setting activities of SDOs have on several occasions brought a negligent misrepresentation action to recover their harms. Such action may enable plaintiffs who reasonably relied upon false information supplied to them by the defendant to obtain from it compensation for the physical or economic harm caused by that reliance. For those seeking to establish liability for physical harm the existence of the SDO's duty of care is usually supported by the rules of a general action in negligence.<sup>73</sup> The success of the claim, if recognized under state law,<sup>74</sup> then turns

<sup>67</sup> See *e.g.* *Bailey* (1999), 184 ('Under the voluntary undertaking theory of liability, the duty of care to be imposed on a defendant is limited to the extent of the undertaking.') and *Rountree* (2008), 809 ('The court agrees that "the scope of one's duty is limited by the scope of [their] undertaking."')

<sup>68</sup> See in general Dobbs, Hayden, and Bublick 2016, §25.6, at 627.

<sup>69</sup> See *e.g.* *Meyers* (1987), 406 ('Although NSPI rendered services to its member by providing a forum, NSPI did not assume the duty to warn consumers of the danger of shallow water diving which it recognized as necessary for the protection of a third party.')

<sup>70</sup> See *King* (1990), 615-616 (citations at footnote 59 above) and *Rountree* (2008), 810 ('[T]he objective of the ANSI standard sponsored by WCMA was "to reduce the possibility of injury, including strangulation, to young children from "the bead chain, cord, or any type of flexible loop device used to operate the product." This factor favors imposition of a duty.')

<sup>71</sup> Dobbs, Hayden, and Bublick 2016, §25.7, at 630 and Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 43, cmt. b (2010).

<sup>72</sup> See *e.g.* *Rountree* (2008), 810-811 (considering that these policy considerations do not weigh against the imposition of a duty on an association of manufacturers of window covering which undertook to develop an ANSI national safety standard intended to address the strangulation hazard of window blinds).

<sup>73</sup> Dobbs, Hayden, and Bublick 2016, § 43.3 (suggesting that actions to recover personal injury, property damage or emotional harm based on risks created by misrepresentation are best recognized as negligence actions).

<sup>74</sup> Not all states recognize an action of negligent misrepresentation resulting in physical harm. Compare *e.g.* *Flynn v. Am. Home Prods. Corp.* (2001), 351 (explaining that Minnesota only recognizes negligent misrepresentation actions for pecuniary loss and not for risk of physical harm) with *Randi W. v. Muroc Joint*

on the questions whether the standards at issue were developed without exercising reasonable care and thus constituted false information, whether that information was actually and reasonably relied upon, and whether that reliance caused the physical harm.

For those claiming pure economic loss, a duty of care not to be negligent in supplying information will not normally exist for an SDO, unless it has undertaken to perform such a duty for the plaintiff, or there is a special relationship (e.g. a fiduciary or confidential relationship) between the parties that led the plaintiff to expect that reasonable care would be exercised for its interests.<sup>75</sup> Following the proposal of the Restatement, liability for stand-alone economic harm is limited to those for whose benefit and guidance the misinformation was supplied or to those the SDO knew the recipient intends to supply it.<sup>76</sup> Once these elements are satisfied the questions regarding the inadequacy of the standards, actual and reasonable reliance, and causation must also be affirmatively answered if the claim is to prevail.

Courts hearing actions of negligent misrepresentation against SDOs have dismissed these actions primarily because of the plaintiffs' failure to establish that the SDO owed a duty to them, and that there was actual reliance on the standards. A case in point is *Commerce and Industry Ins. Co. v. Grinnell Corp*, which involved a fire that consumed an entire warehouse in New Orleans. The insurance company of a firm that had stored (and lost) its merchandise in the fire sought recovery of over \$27 million it had paid to its insured. It thus brought a subrogation action against the National Fire Protection Association (NFPA), a not-for-profit, voluntary membership organization which developed and published model consensus codes and standards concerning fire safety. These standards are applied throughout the US and frequently incorporated in federal and state safety regulations.

In this case, the plaintiff alleged that the NFPA fire safety standards led the warehouse sprinklers system to be ineffective as they failed to provide accurate information on the distance between that system and a potential fuel source for a fire. Interpreting this allegation as a negligent misrepresentation claim, the US District Court in Louisiana considered that in the absence of a contract or fiduciary relationship, NFPA could only owe a duty to the plaintiff when the misinformation is directly communicated to the plaintiffs' insured, the insured was part of the limited group of persons for whose benefit and guidance the misinformation was supplied, and the insured actually relied on that information. However, there was no evidence that the plaintiff had any direct or indirect contact with NFPA, or that it even knew about the NFPA standards.<sup>77</sup> Actual reliance upon those standards in

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*Unified Sch. Dist.* (1997), 593 (holding that California recognizes the action based on the conditions set out in Restatement (Second) of Torts (1965) § 311).

<sup>75</sup> Dobbs, Hayden, and Bublick 2016, § 43.5.

<sup>76</sup> Restatement (Third) of Torts: Liability for Economic Harm (2012) § 5, which sets rules that are 'largely identical' (Reporter's note) to Restatement (Second) of Torts (1979) § 552. Many courts have followed the Restatement analysis. See for an extensive list *Kohola Agriculture v. Deloitte & Touche* (1997), 159.

<sup>77</sup> *Commerce and Industry Ins. Co.* (1999), 3.

any business transaction the plaintiff undertook was therefore impossible.<sup>78</sup> The court further reasoned that policy considerations weigh against imposing a duty of care on NFPA vis-à-vis third parties which occupied a building that was built by others in compliance with its standards. More specifically, it held that:

“Promoting public safety by developing safety standards is an important, imperfect, and evolving process. The imposition of liability on a nonprofit, standards developer who exercises no control over the voluntary implementation of its standards under circumstances like those presented here could expose the association to overwhelming tort liability to parties with whom its relationship is nonexistent and could hinder the advancement of public safety.”<sup>79</sup>

Where SDOs engage in certification and accreditation activities, however, they are at greater risk of incurring liability in a negligent misrepresentation action. A case in point is *Hempstead v. General Fire Extinguisher Corp.*, which involved a fire extinguisher that exploded when put to use by an employee. An injured co-worker brought a claim in negligence and misrepresentation against the manufacturer and Underwriters’ Laboratories (UL). The latter had tested, for a fee and upon the manufacturer’s request, the type of fire extinguisher concerned. Using for that purpose its own standards for construction and performance, UL found the design of the extinguishers compliant and had publicly communicated this approval in its professional publications. UL also allowed the manufacturer to affix to the fire extinguishers a label declaring that it was UL tested and inspected.<sup>80</sup>

UL had thus approved the defective design of the products based on its own standards. Saying otherwise would be ‘straining at words’, the US District Court in Delaware held.<sup>81</sup> This meant that UL’s standards failed to ensure the safe use of the products, whereas UL ‘knew or should have known of construction and materials which would be required if the hazards involved in the use of the extinguishers were to be avoided.’<sup>82</sup> UL certification was ‘unquestionably’ of aid to the manufacturer in selling the products and reliance on the certification was further bolstered by the statutory backing it had received in the local Fire Prevention Code.<sup>83</sup> Liability for negligent misrepresentation could thus follow.<sup>84</sup>

In *Hempstead* the court second-guessed the product standards UL had adopted. In other cases involving the liability of SDOs engaged in certification, courts have

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<sup>78</sup> See also *Howard* (1986), 52-53 (negligent misrepresentation action against NSPI is denied because the plaintiff had neither alleged reliance on NSPI’s activities when he dove in an above-ground pool, nor had he demonstrated that he belonged to the group of beneficiaries NSPI could reasonably have intended to rely on the information supplied, which presumably were only the manufacturers of pools).

<sup>79</sup> *Commerce and Industry Ins. Co.* (1999), 3.

<sup>80</sup> *Hempstead* (1967), 116-117.

<sup>81</sup> *Id.*, 117.

<sup>82</sup> *Id.*, 117.

<sup>83</sup> *Id.*, 117 (‘The Fire Prevention Code authorized the Fire Prevention Supervisor to rely upon the services of any recognized testing authority, including Underwriters, to determine the suitability of a particular type of fire extinguisher, and a listing by any such authority permitted the Fire Prevention Supervisor to find such extinguisher suitable for installation.’)

<sup>84</sup> *Id.*, 118. The success of the negligent misrepresentation action is not determined by the court in its summary judgement. Rather, it holds that UL would be liable on the basis of the voluntary undertaking rule.

been more reluctant to review the substance of standards. Instead, their concerns have been with the accuracy of the certification process and the attestations of compliance that have been awarded.<sup>85</sup> In these cases, the rationale for holding SDOs liable under the theory of negligent misrepresentation is no different from the rationale underpinning liability of certification bodies and other sorts of endorsers under such theory.<sup>86</sup> That rationale is perhaps best expressed in *Hanberry v. Hearst Corp.*, a California case establishing the liability of a certifier that had awarded the 'Good Housekeeping Seal' to ladies' shoes that were extremely slippery when worn on certain floor coverings, and had so caused severe personal injury:

'Since the very purpose of respondent's seal and certification is to induce consumers to purchase products so endorsed, it is foreseeable certain consumers will do so, relying upon respondent's representations concerning them, in some instances, even more than upon statements made by the retailer, manufacturer or distributor. Having voluntarily involved itself into the marketing process, having in effect loaned its reputation to promote and induce the sale of a given product, the question arises whether respondent can escape liability for injury which results when the product is defective and not as represented by its endorsement.'<sup>87</sup>

Thus, actions sounding in negligent misrepresentation have been largely defeated because of plaintiffs' inability to show actual and detrimental reliance on the standards involved.<sup>88</sup> This failure, as noted, has also led to the failure of actions based on the voluntary undertaking rule.<sup>89</sup> However, if SDOs combine standard setting with certification activities, such as in *Hempstead*, the chances of such actions prevailing increase. After all, these activities provide public, expert-based representations on key characteristics of the certified product or producer itself that carry currency in commerce and serve to encourage individuals and firms to rely on its representations to buy or use the product.

#### ***4. Perspectives from the EU***

It is striking to observe just how little case law has developed in the EU compared to the US on liability for the development of product standards. As Spindler notes, 'it is surprising that there is almost no case to be found [in the EU] that holds standardising organisations liable for standards which have been exceeded by

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<sup>85</sup> See e.g. *Benco Plastics, Inc. v. Westinghouse Elec Corp.* (1974), 786; *Groppel Co., Inc. v. United State Gypsum Co.* (1981), 66 and; *Rottinghaus v. Howell* (1983) 907.

<sup>86</sup> See in general Rockwell 1992 and Belson 2017, 112-118 (each with further references to case law). See on accreditation bodies Schuck 1994, 188-191.

<sup>87</sup> *Hanberry v. Hearst Corp.* (1969), 684. See also *United States Lighting Serv, Inc. v. Llerad Corp.* (1992), finding that UL is required to act with ordinary care in the conduct of its certification process given the reliance placed in its mark by consumers and suggesting that it may incur liability for economic loss under the theory of negligent misrepresentation.

<sup>88</sup> See for a similar observation in relation to liability of accreditation bodies Schuck 1994, 188-191.

<sup>89</sup> See at footnotes 53-54 above.

new knowledge'.<sup>90</sup> Judicial control over private standards development in the EU has for the most part taken place in the context of EU internal market law (i.e. competition and free movement law),<sup>91</sup> and judicial review at both the European<sup>92</sup> and Member State level.<sup>93</sup> In addition, there is hardly any theorization in European legal scholarship about the civil liability of SDOs, how such liability relates to the liability of, for example, public regulators, individual professionals or collective associations engaged in standardization or certification, and what policy considerations should support or limit the imposition of liability on these actors.<sup>94</sup> This stance may be explained by the lack of case law on this issue, but also in part by the fact that tort law is principally regulated at the level of the EU Member States, where concepts and theories of liability vary notoriously along long-lasting national traditions of common and civil law, or mixes in between. In other words, no general EU framework exists that covers the liability of SDOs.

Nevertheless, there are recent developments in the case law of the Court of Justice of the EU that should be taken into consideration. To put these developments into perspective, this section will first briefly set out the legal framework that applies to EU standardization called the 'New Approach'. It will then discuss the liability of SDOs for activities pursued within that framework. Finally, we will look beyond the scope of the New Approach and consider liability for the development of market-based product standards.<sup>95</sup>

#### A. *The New Approach*

Voluntary product standards in the EU are developed within the framework of the 'New Approach'. This legislative program was developed in the 1980s to improve the free movement of goods within the internal market.<sup>96</sup> Within the program, the legislative institutions of the EU adopt secondary legislation that set out the 'essential requirements' with which products have to comply to be lawfully traded

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<sup>90</sup> Spindler 1998, 331.

<sup>91</sup> See Mataija 2016, 233-244.

<sup>92</sup> In the recent case of *James Elliott Construction Ltd. v. Irish Asphalt Ltd.* (C-613/14, ECLI:EU:C:2016:821) the Court of Justice of the EU held itself competent to review European harmonized standards developed within the legislative framework of the New Approach (see section C.1 below). This expansion of the Court's jurisdiction to the domain of technical standardization has triggered a lively debate on the desirability of judicial control over standards development in Europe. See for more detailed analysis of the case its likely consequences see Lundqvist (Chapter x in this volume); Volpato 2017.

<sup>93</sup> Schepel and Falke 2000, 131-134.

<sup>94</sup> Notable exceptions are Spindler 1998; Schepel 2005, 384-387; Cafaggi 2006, 58-73.

<sup>95</sup> Beyond the scope of inquiry is therefore the liability for certification activities under the New Approach. The breast implants scandal that unfolded around the French manufacturer of silicone breast implants Poly Implant Prothèse SA (PIP) has triggered various claims from victims against the certification body that inspected and approved PIP's manufacturing processes within the New Approach framework, yet failed to discover the illegal use of substandard silicone gel to manufacture the implants. In 2017, the Court of Justice of the EU held in the case of *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH* (C-219/15, ECLI:EU:C:2017:128) that certification bodies conducting conformity assessments under the New Approach owe a general duty of care to end users of certified products 'to act with all due diligence' when performing such assessments (para 46). This implies that they have to be alert on non-compliance and must take appropriate action once they receive evidence that indicates that products may no longer be compliant. However, EU law does not offer a basis to hold liable these actors for breach of this duty and their liability must be established under the tort law regimes of the Member States. See in detail Verbruggen and Van Leeuwen 2018.

<sup>96</sup> See in general Schepel 2005, 227-246; Hodges 2005, 53-73.

in the EU. The precise technical specifications are then laid down in a European harmonized standard that is developed by European standardization organizations – CEN, CENELEC or ETSI.<sup>97</sup> After the European Commission has published a reference to this voluntary standard in the Official Journal of the EU, a presumption arises that products that comply with the standard also comply with the essential requirements of the relevant EU legislation. As such, establishing compliance with a European harmonized standard has become the principal way for manufacturers to show that their products comply with the law. Although it is possible for manufacturers to demonstrate legal compliance through other means, in practice most manufacturers opt to show compliance with the European standard.<sup>98</sup>

Regulation 1025/2012/EU, which since 2012 constitutes the legal framework underlying the New Approach, recognizes CEN, CENELEC and ETSI as the European standardization organizations.<sup>99</sup> These SDOs are no institution or agency of the European Union, however. CEN and CENELEC are private not-for-profit associations (*association internationale sans but lucratif*) under Belgian law.<sup>100</sup> ETSI is also a private non-profit association, but is incorporated in France.<sup>101</sup> This means that the liability of the three European standardization organizations is governed by Belgian and French tort law, and not by EU law.<sup>102</sup> The liability of national SDOs that are members of CEN, CENELEC and ETSI is equally governed by national tort law. These national SDOs participate in the creation of European harmonized standards and implement them at the national level, that is, they translate the standards and make them available, usually upon payment of a fee. The national SDOs are free to engage in the development of standards outside the scope of New Approach. The development of such market-based standards in areas like cyber security, environmental sustainability and worker safety now constitutes an important business activity for many. In that domain they compete against trade associations, NGOs and other standards developers at both national and international levels.

### B. *Liability Under the New Approach*

Only very few national courts in the EU have been concerned with claims involving the liability of SDOs, both within and beyond the New Approach. Strict liability for personal injury and property damage caused by defective products is not the proper basis for bringing such claims. In the EU, this domain of tort law is

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<sup>97</sup> CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization) and ETSI (European Telecommunications Standards Institute) develop standards for different sectors.

<sup>98</sup> Schepel 2013, 528.

<sup>99</sup> Article 2(8) read in conjunction with Annex I of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation [2012] OJ L 316/12.

<sup>100</sup> CEN (2015) and CENELEC (2015). CEN and CENELEC have as their membership national standardization bodies of the EU Member States and a number of additional European countries.

<sup>101</sup> ETSI (2017). ETSI has over 800 members including standardization bodies, government representatives, trade associations and individual businesses.

<sup>102</sup> More specifically, Article 340 of the Treaty on the Functioning of the EU (TFEU) governs the tort liability of institutions or agencies of the EU. It reads: 'In the case of non-contractual liability, the Union shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties.'

exclusively regulated by the Product Liability Directive, unless pre-existing special liability regimes apply.<sup>103</sup> The Directive, as implemented by the EU Member States, imposes such liability on business actors that fall within the scope of the 'producer' concept as set out in Article 3 of the Directive. While this concept 'embraces a wide range of actors', it does not extend to those that are not involved in the manufacturing, sale or distribution of products.<sup>104</sup> Accordingly, SDOs fall outside the scope of the Directive.<sup>105</sup> Similar to the US, liability claims against these private actors in Europe must be brought under theories of negligence to prevail.

A comprehensive comparative study commissioned by the European Commission and the European Free Trade Association called 'Legal Aspects of Standardisation' concluded as regards the potential of tort law to hold liable SDOs for negligent standard setting 'even though the theoretical possibility is open in all jurisdictions under discussion here, France and Italy seem to be the only Member States where it has actually happened'.<sup>106</sup> The Italian case involved the alleged violation of intellectual property rights for the use of geographical denominations by the national standards body as it developed a new standard to compete with an existing one. The outcome of the case was unknown at the time of this writing.<sup>107</sup>

In France, the liability of the national SDO for technical standards called *Association Française de Normalisation* (AFNOR), is a matter for the administrative courts since AFNOR is considered to fulfil a public law function (*mission de service public*) when developing technical standards in fields covered by New Approach legislation.<sup>108</sup> The comparative study reports just one tort law claim brought against AFNOR. In the case, AFNOR had licensed a manufacturer of a certain type of concrete pavement to use its conformity mark 'NF'. After a very severe winter, however, these pavements had cracked. The manufacturer was held liable by the municipalities where the defective pavements had been placed and by the contractors that placed them there. The manufacturer enjoined AFNOR in the proceedings and sued for damages for developing 'inadequate' standards. The *Tribunal Administrative de Paris* denied the claim. First, it upheld AFNOR's exclusion clause included in the license contract for use of its NF mark, implying that it could not be held liability for all defects in products that were awarded that mark. Second, it considered AFNOR not to be at fault given that its standards cannot be held to cover all characteristics of a product. Moreover, once AFNOR became aware of the problems concerned, it amended the relevant standard.<sup>109</sup>

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<sup>103</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29), Directive as last amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4 Jun. 1999, p 20), Article 13.

<sup>104</sup> Weatherill 2013, 175.

<sup>105</sup> Some commentators have presented arguments to suggest that standards could be seen as a 'product' within the scope of the Product Liability Directive. By extension, SDOs could then be considered 'producer'. So far, none of these arguments have been considered by the Court of Justice of the EU in the interpretation of the Product Liability Directive. See for a discussion: Stuurman and Wijnands 2000, 617-618.

<sup>106</sup> Schepel and Falke 2000, 238.

<sup>107</sup> See Menchetti 2000, 540.

<sup>108</sup> Conseil d'État, No. 73230 (1992). See also Décret No. 2009-697 of 16 June 2009 relatif à la normalisation.

<sup>109</sup> *Société Les Grands Travaux de l'État c/ Pottier et Oth* (1993). See in detail (Champigneulle-Mihailov 2000), 318-319.



If the national SDO is awarded a specific legal status or special powers by national statute or decree, its liability for standardization and certification activities is typically governed by rules on state liability in so far as it acts within the scope of that status or powers. While immunity from liability is rarely accepted in Europe, policy considerations may put more stringent demands on the conditions of duty and breach (or any equivalent under national tort law) when SDOs make use of their public law status or powers.<sup>110</sup> These considerations may thus further limit the risk of liability these SDOs face.<sup>111</sup>

The apparent insignificance of the theme of SDO liability in the case law of national courts in the EU hides the fact that, in practice, SDOs are concerned about the risk of incurring liability for their standard-setting activities. The cited study on 'Legal Aspects of Standardisation' reports that several SDOs operating under the New Approach have taken out liability insurance.<sup>112</sup> Others try to exonerate themselves in general terms of sale or service.<sup>113</sup> The Dutch NEN (*Nederlands Normalisatie Instituut*), takes a rather defensive approach and includes in its general conditions of sale sweeping indemnity clauses that require its contracting parties, for which NEN undertakes to perform services such as standards development or certification, to indemnify it for any civil liability vis-à-vis third parties caused by the performance of the contract, including violations of intellectual property rights, privacy laws or any other laws and regulations that are in force (Articles 5.3 and 12.6). NEN further limits its contractual liability by limiting the extent of damages to its insurance coverage (Article 12.2), excluding liability for indirect damages (Articles 12.3 – 12.4) and damages related to any printing errors in the materials provided by the contracting party (Article 12.5), and by setting the limitation period to three months after the damage manifested (Article 12.7).<sup>114</sup> The NEN internal regulations also include a general clause exonerating NEN from liability for direct or indirect damages against members caused by or in relation to its norms (Article 10.2.2).<sup>115</sup>

The British Standards Institute (BSI) seemingly admitted that it owes a duty of care to anyone relying on its standards in the first version of its 'Standard for Standards' publication.<sup>116</sup> In the version currently in force, this magnanimous assumption of a duty can no longer be found.<sup>117</sup> The study on 'Legal Aspects of Standardisation' also reported the German *Deutsches Institut für Normung* (DIN) to admit to a duty of care (*Garantenstellung*) to users of its standards in its ground

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<sup>110</sup> Van Dam 2013, 532.

<sup>111</sup> Schepel and Falke 2000, 239.

<sup>112</sup> *Id.*, 238.

<sup>113</sup> See for ANFOR's terms and condition of sale ANFOR (2018), Article 9.

<sup>114</sup> NEN (2016).

<sup>115</sup> NEN (2005). The validity of these limitation and exclusion clauses may be questioned. In business-to-business relationships they may be allowed only where the extent to which the liability is limited is not disproportionate to the loss incurred. In business-to-consumer dealings, however, they are likely to be challengeable under EU consumer law, in particular Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts *OJ L 95/29*. See for a discussion of this EU Directive, its implementation in commercial and consumer law in England and Wales, and the extensive case law developed on it by the Court of Justice of the EU: Lawson 2017.

<sup>116</sup> BS 0: 1997 A Standard for Standards, Part 2 – Recommendations for committee procedures, Section 6.9.1.5.

<sup>117</sup> BSI 2017.

rules for standardization that were previously in force.<sup>118</sup> Still, the reporters of the study considered, the risk of the British and German SDOs incurring liability is relatively low since they have put in place several procedural safeguards that would mitigate against a breach of the duty.<sup>119</sup> Such safeguards include ensuring participation of interested stakeholders and knowledgeable experts in standards development, having available to these actors all relevant technical and scientific information, and ensuring that standards are developed for the common good and not for individual commercial benefit.<sup>120</sup> The AFNOR case discussed above demonstrates that it is also helpful in this respect to have in place a review procedure once shortcomings have become clear.

### C. *Liability Beyond the New Approach*

In the absence of a common legal framework on tort liability and the limited discussion in European legal scholarship about liability for standards development, the landscape regarding such liability can be said to be even sketchier beyond and within the New Approach framework. The reach of EU law is generally limited here and divergent national regimes of liability hold sway. While tort claims against SDOs have reached the supreme courts of (some) Member States, these claims first and foremost disputed the certification activities the SDOs were engaged in, rather than standards development.<sup>121</sup> Liability for standards development is extremely rare and plaintiffs may not be able to meet the elements that national tort laws require for their actions to prevail.

In English law, for example, considerations around the existence of a duty of care will defeat most claims as it does in American common law. The leading case law of the Supreme Court on the tort of negligence and on negligent misstatements suggests that no such duty exists because of a lack of a sufficiently proximate relationship between the plaintiff and defendant SDO, or the absence of the assumption of a responsibility by the SDO on which the plaintiff reasonably relied.<sup>122</sup> Policy factors concerning the public role of SDOs in society as non-profit organizations promoting the collective welfare and the consequences in terms of liability exposure for SDOs and their public role if a duty were imposed would further militate against a duty being recognized.<sup>123</sup>

<sup>118</sup> Schepel and Falke 2000, 240-241.

<sup>119</sup> *Id.*, 241-242.

<sup>120</sup> See e.g. BSI 2017 and DIN 'DIN 820-1. Normungsarbeit – Teil 1: Grundsätze'.

<sup>121</sup> See e.g. for England and Wales *Marc Rich & Co AG and others v. Bishop Rock Marine Co Ltd. and others* (1995) (held: a classification society does not owe a duty of care to cargo owners arising from negligent inspections of a damaged ship); for France Cour de Cassation, No. 06-19.521 (2007) (held: a certifier is not liable for economic losses caused by a defect that arose in a certified television within the period of warranty set by the producer); for Germany Bundesgerichtshof, VII ZR 36/14 (2017) (a certifier is not liable for personal injury caused by defective breast implants if the manufacturer of the implants had used materials not intended to be used for manufacturing such medical devices and had fraudulently concealed that use from the certifier); and for the Netherlands Hoge Raad *Strawberry Mite* (2007) (a certifier is liable for pure economic loss sustained by a strawberry farmer and caused by the violation of its own certification protocol for pest control in horticulture products).

<sup>122</sup> *Hedley Byrne & Co. Ltd. v. Heller & Partners Ltd.* (1964); *Caparo Industries plc v. Dickman* (1990); and most recently *Banca Nazionale del Lavoro SPA v. Playboy Club London Ltd. & others* (2018).

<sup>123</sup> Cf. *Marc Rich* (1995), 12-13 (Per Lord Lloyd of Berwick) and 28 (Per Lord Steyn). *Contra, Perrett v. Collins* (1998) (aircraft inspector owes a duty to aircraft passengers to act with reasonable care so to ensure that they are not injured by reason of a defect in the aircraft's construction that was part of the inspection

In civil law countries, in particular those that may be considered to stand in the Napoleonic tradition (e.g. Belgium, France, Italy, the Netherlands, Spain), the duty element in negligence liability (or any equivalent concept used) does not involve the same kind of considerations as in American or English common law. Nonetheless, considerations around the foreseeability of the type of plaintiff's harm, the closeness of connection between the SDO's conduct and the harm, and the societal function of standard-setting are likely to surface in the determination of breach and legal causation.<sup>124</sup> Accordingly, breach and causation serve as the main control mechanisms to guard against overly burdensome liability for SDO. These elements are, unlike in the US, decided by judges only.

Importantly, however, violations of EU law may serve as a catalyst of liability claims against SDOs based on national tort law. The case of *Fra.bo v. DVGW*, a German case which concerns the civil liability for product standardization and certification activities, may serve to illustrate that role.<sup>125</sup> Fra.bo was an Italian manufacturer of copper fittings used for water and gas piping. These copper fittings, which fell outside the scope of the New Approach legislation regulating the sale of construction materials in the EU, serve to make piping water tight and airtight. To sell these fittings in Germany, Fra.bo applied for certification by a German non-profit association called DVGW (*Deutsche Vereinigung des Gas- und Wasserfaches eV*). DVGW adopts technical standards for the performance of construction materials used in the gas and water sector and certifies products on that basis. Initially DVGW awarded Fra.bo certification of its copper fittings for both the water and gas sector. This award essentially revolved around compliance of the fittings with DVGW's technical standard 'Worksheet W534', which specified the norms that products that come in contact with water have to meet in order to attain certification. Fra.bo applied for DVGW certification since such certification would show conformity with mandatory national product safety law. While in theory other certifications were available, in practice DVGW was the only body Fra.bo could turn to have its fittings certified.

Fra.bo's certification was soon subject to a re-assessment procedure because a competitor had complained to DVGW that it was technically impossible to satisfy the quality standards for water and gas supply by one and the same type of fitting, as Fra.bo did. As a result of that procedure DVGW no longer accepted the positive test results provided by a state-accredited Italian laboratory upon the request of Fra.bo, whereas the same laboratory had also provided the test results that initially led DVGW to grant Fra.bo certification. Furthermore, DVGW amended its technical standard W534 by introducing a test consisting of exposing the copper fitting to a temperature of 110 degrees Celsius in boiling water for 3,000 hours,

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protocol). The latter case suggests that the duty element in personal injuries actions is not insurmountable in actions against inspectors or certifiers. The position of the developer of aircraft safety standards, here the government, was not addressed.

<sup>124</sup> See in general Van Dam 2013, 208-217 (discussing the different policies and control mechanisms used in English, France and Germany law to limit the scope of protection offered by tort law in the context of pure economic loss).

<sup>125</sup> *Fra.bo v. Deutsche Vereinigung des Gas- und Wasserfaches eV* (2012). See for a comprehensive overview of the academic literature on this case: <http://eur-lex.europa.eu/legal-content/EN/NOT/?uri=CELEX:62011CJ0171>.

claiming this was needed to ensure a longer life cycle for certified products. The conditions for certification as included in the contractual arrangement between DVGW and Fra.bo required that if a technical standard was amended, certificate holders must apply for a renewal of their certification. Fra.bo did not make such an application and as a result DVGW withdrew Fra.bo's certification. In response, Fra.bo brought a damages claim against DVGW for breach of contract and EU law. It argued, among other things, that the introduction of the 3,000-hour test was arbitrary and had no other goal than to limit access to the German market. Moreover, there was no reason to deny the Italian test results since these were produced according to the procedures DVGW had itself stipulated.<sup>126</sup> Accordingly, Fra.bo argued, DVGW violated EU rules on competition and free movement of goods in the performance of its obligations under the certification contract.

The district court denied the claim. The court hearing the appeal referred several preliminary questions to the Court of Justice of the EU as it was unsure how to interpret and apply the EU law rules concerned. In delivering its judgment, the European Court of Justice held that the standardization and certification activities of DVGW are covered by the EU rules on free movement of goods, which prohibits the imposition of measures by Member States that limit the import of products from other Member States. Even though DVGW is a private association, the Court applied a functional approach and considered that it restricted the free movement of goods 'in the same manner as do measures imposed by the State'.<sup>127</sup> German product safety law indeed held that DVGW certification signified legal compliance. DVGW was also the only body capable of certifying Fra.bo's copper fittings for the application at issue, whereas the lack of such certification constituted a significant restriction for companies seeking to market their products in Germany.<sup>128</sup> Therefore, the Court concluded, DVGW 'in reality holds the power to regulate the entry into the German market'.<sup>129</sup>

The judgement of the Court of Justice has attracted significant scholarly attention for its importance regarding the internal coherency of EU free movement law,<sup>130</sup> for its implications on the New Approach framework,<sup>131</sup> and for the way in which the Court has strengthened judicial review in the field of technical standardization.<sup>132</sup> Our principal interest in this chapter -- the civil liability of SDOs for standardization and certification activities -- has been of far less concern to scholars.<sup>133</sup> In concrete terms, for DVGW the *Fra.bo* judgment meant that it needed to be able to justify the adoption of the 3,000-hour test and its refusal to recognize testing results from an accredited laboratory in another Member State. In more general terms, it was challenged to provide justifications for the adoption of stricter standards and (de)certification decisions that harm the economic

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<sup>126</sup> Cf. Landgericht Köln (2008), paras 31, 32 and 36.

<sup>127</sup> *Fra.bo* (2012), para 26.

<sup>128</sup> *Id.* paras 27-30.

<sup>129</sup> *Id.* para 31.

<sup>130</sup> See e.g. Van Harten and Nauta 2013; Van Leeuwen 2013; Mataija 2016, 246-250.

<sup>131</sup> See e.g. Chapter x in this volume (Lundqvist); Schepel 2013.

<sup>132</sup> See e.g. Van Gestel and Micklitz 2013.

<sup>133</sup> See in detail Verbruggen 2017b, 72-73.

interest of firms like Fra.bo. If it cannot provide these, liability for damages may arise, either in contract or in tort.

After the Court of Justice of the EU rendered its judgment, the referring court of appeal in Germany held that DVGW was liable vis-à-vis Fra.bo for breach of contract. The national court considered that the DVGW performance standards for product certification in the water sector, including the 3,000-hour test, were contrary to the free movement of goods, as these could restrict the import of goods otherwise lawfully traded in other Member States. DVGW could not make the continuity of Fra.bo certification dependent on the meeting of that test. Accordingly, the revocation of Fra.bo's certification was without any ground and unlawful.<sup>134</sup> Moreover, DVGW was wrong to discard the testing results provided by an accredited laboratory in another Member State since this is contrary to the mutual recognition principle underpinning EU free movement law.<sup>135</sup>

DVGW's breach of the rules on the free movement of goods, the court of appeal further reasoned, could not be justified. The protection of public health, as DVGW claimed, did not serve as an appropriate justification for the adoption of the 3,000-hour test. The SDO failed to provide evidence that the adoption of the new standard was instrumental to such protection, for example by offering a detailed risk analysis of the hazards it claimed to control by introducing the test, that is, bacterial contamination of water or gas explosions caused by failing copper fittings. Apparently, such risks did not play any role when DVGW adopted the new standard. Moreover, the decision to fix the duration of the test at 3,000 hours was unsubstantiated. DVGW did not sufficiently establish that the test is the accepted state-of-the-art, which might as well be shorter (or longer) than 3,000 hours.<sup>136</sup> Accordingly, DVGW unlawfully and negligently withdrew Fra.bo's certification, which likely caused the latter's (pure economic) losses consisting in the loss of profit it could have made the period in which it was cut off from the German market.<sup>137</sup>

The case of *Fra.bo* neatly demonstrates how national private law and EU public law complement each other in the regulation of technical standardization and certification in the EU. As shown, a civil damages claim gave rise to a discussion of whether EU rules applied and were violated. While in this case the rules at stake concerned free movement of goods, in others it may involve rules of competition law or non-discrimination. After the Court of Justice established that EU rules did apply, the national court held that these rules were violated in the performance of contractual obligations, thus giving rise to a remedy in private law. Clearly, in *Fra.bo* it was contract law that provided the plaintiff with a remedy against the SDO, but had a contractual relationship been absent between the two, as is usually the case in standards development, an action in tort could have provided the means for addressing any allegedly wrongful activities. More generally, any breach of EU law that is directly applicable to the activities of an SDO and that is

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<sup>134</sup> Oberlandesgericht Düsseldorf (2013), paras 48-50.

<sup>135</sup> *Id.*, para 54.

<sup>136</sup> *Id.*, para 63-64.

<sup>137</sup> *Id.*, para 73 and 78.

protective of the interests of the actor affected by those activities (i.e. EU free movement law of persons and services, competition law or non-discrimination law), constitutes a ground to bring a claim in tort against the SDO.<sup>138</sup> Tort law constitutes a key branch of the law to privately enforce those EU law rules at the national level and can, as such, be said to contribute in significant ways to the regulation of standards development in the EU.

## 5. Comparative analysis

The previous discussions highlight a number of themes worthy of further comparative analysis. The research questions set out in the introduction, as further developed in Section A, guide the analysis.

### A. *Duty Considerations in Negligence Law*

Liability for standards development in the US and EU is established exclusively on theories based in negligence. Central to all actions sounding in negligence, the voluntary undertaking rule or negligent misrepresentation in the US are considerations around the existence of a duty of care. The duty element proves to be a formidable requirement that the plaintiffs in the majority of these actions fail to meet. Considerations to impose on the defendant SDO a duty to exercise reasonable care in promulgating standards have frequently turned on the question to what extent the SDO exercises control over the standards' addressees to comply with its standards. In these actions, control is then seen a necessary proxy for establishing the foreseeability of harm to the plaintiff as a result of the development of standards and/or the closeness of the connection between that activity and the plaintiff's harm.<sup>139</sup> Such control can follow from any legal arrangement (e.g. contracts, rules of association, bylaws) that enables the SDO to mandate the standards, or the SDO's administration of a certification or accreditation scheme that monitors compliance with its standards amongst addressees. The SDO's lack of such leverage over compliance with its standards usually leads to a no-duty decision.

An obvious criticism against this reasoning is that, in practice, members routinely follow SDO standards in their business operations. Even without formal control, compliance rates are usually high amongst SDO members. A number of courts in the US have therefore rightly looked beyond the control thesis and have sought to establish a duty of care by reference to the degree to which the standards enjoy a high level of market uptake, receive government endorsement, and to public representations made by the SDO as regards its expertise in developing standards in the field.<sup>140</sup> Considerations of whether the standards serve the purpose of

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<sup>138</sup> Verbruggen 2017b, 59-71.

<sup>139</sup> The exponent of this position perhaps is *Meyers* (1987), in which a New Jersey Superior Court granted summary judgment for NSPI because 'the crucial element of foreseeability is lacking' upon the finding that the SDO 'had absolutely no power to force a member to comply with its promulgated standards' (at 403).

<sup>140</sup> See e.g. *Meneely* (2000), 56; *Snyder* (1996), 1040 and 1048; and *Prudential Property and Cas. Ins. Co.* (1994), 3. In *Beasock* (1985), however, the court admitted that the SDO's dimensional standards for tires, rims and wheels had become industry standards, but nonetheless held that no duty was owed to the

protecting third parties against personal injury or property damage have been further added to the mix of relevant circumstances that justify the imposition of a duty.<sup>141</sup> In the EU, the *Fra.bo* case has echoed this functionalism where public law support of the contested standards and the economic significance of complying with those standards were considered as arguments to apply EU law rules on the free movement of goods to a private standardization and certification activities. Accordingly, the defendant SDO was under a legal duty to comply with EU rules of mutual recognition of market regulations and non-discrimination of goods lawfully traded in other Member States.<sup>142</sup>

Other considerations of policy and justice may nonetheless militate against imposing a duty to exercise reasonable care in standards development in negligence. Some US courts have awarded particular weight to the moral blame attached to the defendant's conduct, the potential impact of imposing liability on the policy of preventing plaintiff's harm in the future, and the consequences of exposing SDOs to liability on their important societal function of promulgating standards in a given domain.<sup>143</sup> The absence of any commercial interest of the SDO in developing standards may further be relevant.<sup>144</sup> Such considerations, next to the plaintiff's failure to show actual reliance on the allegedly inadequate standards or that the SDO undertook to perform a duty owed by its members to the plaintiff, have also barred the imposition of a duty of care on SDOs in actions based on negligent misrepresentation and the voluntary undertaking rule.<sup>145</sup> Similar considerations would appear to lead courts in England and Wales to refuse to expose SDOs to civil liability for standards development under the tort of negligence or negligent misstatements.

### B. Factors Bearing on Breach

The use of foreseeability of harm and the moral blame attached to the SDO's conduct as factors to determine the existence of a duty of care in negligence can be criticized for confusing duty with breach.<sup>146</sup> Foreseeability, it is contended, first

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plaintiff (at 979). In *Commerce and Industry Ins. Co.* (1999), the court that the incorporation of the allegedly inadequate NFPA fire safety standard in government construction regulations did not help to impose a duty of care on the NFPA since that incorporation made the relationship between NFPA and the plaintiff's insured too remote to warrant the imposition of a duty. (at 3).

<sup>141</sup> See e.g. *Snyder* (1996), 1048 and 1050; *King* (1990), 616; *Rountree* (2008), 810.

<sup>142</sup> *Fra.bo* (2012), paras 27-30.

<sup>143</sup> See e.g. *Meyers* (1987), 404; *N.N.V.* (1999), 1382-1387.

<sup>144</sup> See e.g. *Meyers* (1987), 403 (holding that the development of design and construction standards for swimming pools 'is not a money-making operation'). See also *Commerce and Industry Ins. Co.* (1999), 4 ('The NFPA is not even a trade association which acts in the economic self-interest of its members. The organization consists of 68,000 individuals and over 80 organizations. It is not a trade group consisting of businesses with homogeneous economic interests.'). In *Snyder*, however, the economic interests involved in the development of standards for the blood banking industry was an important consideration to impose a duty on AABB. See *Snyder* (1996), 1050 ('Although the AABB's mission doubtless has altruistic overtones, the bottom line is that the AABB represents its interests and those of its members. At stake for its members was a substantial financial interest in the regulation of the industry. (...) Blood is big business.'). Similar considerations emerge in relation to civil liability for negligent certification (e.g. *Hempstead* (1967); *Hanberry* (1969); and *Rottinghaus* (1983)).

<sup>145</sup> See e.g. *Commerce and Industry Ins. Co.* (1999), 3.

<sup>146</sup> See e.g. Heidt 2010, 1256-1258 (criticizing the approach in *Snyder*) and *N.N.V.* (1999), 1404 (Amos J., dissenting as regards the majority's no-duty decision and criticizing the decision for confusing duty with breach).

and foremost bears on the issue of breach and determines whether an SDO has acted with reasonable care under the circumstances.<sup>147</sup> Blameworthiness also speaks to the reasonableness of the SDO's activities in the light of the particular circumstances.<sup>148</sup> By confusing the duty with breach, courts invade the province of the jury, prevent a full legal analysis of the dispute, and effectively shield SDOs from being exposed to civil liability. To minimize this strategic behavior of courts the Restatement (Third) of Torts proposes, amongst others, that foreseeability is a factor to be considered only on the breach issue, not duty, and that moral blameworthiness is not a valid consideration of policy.<sup>149</sup>

Once an SDO is considered to owe a duty of care, it is held to exercise reasonable care in the development of its standards. That standard of care implies that it is required to avoid harm that was known to it or reasonably foreseeable. American common law permits the plaintiff to present at trial a wide range of evidence to show that the defendant SDO breached its duty and that the process of standards development administered by it fell short of the level of care it was reasonably required to exercise. Such evidence generally includes internal company rules or rules of association, industry practice, private standards, statutes, government regulation and guidance, and cost-benefit analysis.<sup>150</sup> Accordingly, a violation of the SDO's own guidelines or bylaws for standards development can be considered as evidence showing breach, but also non-compliance with government or industry-endorsed principles on how standard-setting procedures should be organized in terms of due process or good governance may be used to show that the defendant SDO fell short of the level care required.<sup>151</sup>

Courts in the cases reviewed here do not explicitly refer to these principles of due process or good governance in the determination of breach. In fact, there is very little consideration around the question of what factors may establish the reasonableness of the care that the defendant SDO exercised. In *Meneely* and *Snyder* – the only two US cases resulting in a damages award against the SDOs involved – the issue of breach turned on the narrow question of whether the SDOs could have reasonably refused to amend their safety standards while being aware of the risk of physical harm these standards posed to others.<sup>152</sup> More generally, however, these two cases suggest that in establishing breach it is important that the SDO uses the knowledge gained from experience with the implementation of its standards in practice to inform and direct its decision-making around the revision or adoption of new standards.<sup>153</sup>

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<sup>147</sup> See extensively Cardi 2005.

<sup>148</sup> Dobbs, Hayden, and Bublick 2016, §10.4, at 210.

<sup>149</sup> Restatement (Third) of Torts (Liability for Physical and Emotional Harm) § 7, cmt. j (2010). See for a discussion Dobbs, Hayden, and Bublick 2016, at 212-213.

<sup>150</sup> See in general Dobbs, Hayden, and Bublick 2016, §§12.1-12.10, at 263-289.

<sup>151</sup> Particularly important for this purpose appear to be Circular No. A-119 (2016) (promoting the adoption of private standards by US Federal agencies provided they meet attributes of openness, balance of interest, due process, having an appeals procedure, and operate on the basis of consensus (at para 4)) and the ANSI Essential Requirements (2018) (further detailing the elements set out in Circular No. A-119).

<sup>152</sup> *Snyder* (1996), 1038 and *Meneely* (2000), 57.

<sup>153</sup> See also *Commerce and Industry Ins. Co* (1999), 4 (holding that if the NFPA had owed a duty to plaintiffs, it would not have breached the duty because the plaintiffs did not provide evidence that the SDO knew or should have known of the alleged fire safety risk. Instead, NFPA periodically reviews and revises its



Such considerations can also be found in the sparse European case law on the matter. In the *ANFOR* case the French court held that the defendant SDO could not be at fault in developing standards for concrete pavement because of the limited protective scope of the standards and the fact that the SDO swiftly amended these standards once inadequacies surfaced.<sup>154</sup> Likewise, the German court in *Fra.bo* considered the defendant SDO to have breached its duty under EU law since it failed to provide evidence that the adoption of the contentious new standard was necessary and proportionate to the protection of health and safety. Moreover, the SDO had refused to recognize available testing results from a state-accredited laboratory in another Member State.<sup>155</sup> Thus, whenever an SDO does not take into consideration the state-of-the-art when promulgating or revising its standards, or altogether fails to adopt new standards in the face of evidence showing the existence of apparent risks to others, it does not act with ordinary care. SDO compliance with important good governance attributes such as impact evaluation, responsiveness to new insights from practice and technology, and recursive learning may thus be rewarded in the assessment of breach.

Some courts in the US have also shown appreciation of the SDO's efforts to ensure inclusive and transparent rulemaking. In *Meyers*, for example, the court drew attention to the practice of public solicitation of comments and suggestions of non-members on draft standards to ensure a fair representation of interests to argue that the element of foreseeability was lacking.<sup>156</sup> In *N.N.V.*, the plaintiff alleged that AABB's standard setting procedure was biased towards the interests of private organizations concerned with blood products and transfusions and that there was no active participation of those representing other interests in the standards development. The California Court of Appeal discarded the argument by holding that there was no evidence to support the assertions and that the private organizations involved did not represent industry alone. Each had different classes of membership representing a variety of interests and many voices.<sup>157</sup> In *Snyder*, however, the New Jersey Supreme Court sanctioned the absence of inclusive and transparent procedures of the AABB, along with the SDO's commitment to promote the financial interests of the blood banking industry at the expense of patients' health and safety.<sup>158</sup> Clearly, the courts in these cases weigh the facts of the cases in a very different way. However, when read together, the judicial considerations involved do reveal that concerns around fair stakeholder participation and transparency in procedures for standards development, as well as other principles of good governance, can weigh in on the determination of whether the SDO reasonably decided on its standards under the circumstances.<sup>159</sup>

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standards 'to keep current with new fire protection knowledge and technologies' and 'to include fire safety lessons learned from significant fires'.)

<sup>154</sup> See at footnote 108.

<sup>155</sup> See at footnotes 134-135.

<sup>156</sup> *Meyers* (1987), 403.

<sup>157</sup> *N.N.V.* (1999), 1393-1394.

<sup>158</sup> *Snyder* (1996), 1050.

<sup>159</sup> Compare Marasco 2005 (arguing that ANSI-accredited SDOs should not be subject to civil liability when they meet ANSI's requirements for openness, consensus and other due process safeguards).

Importantly, the standard of reasonable care does not require a perfect decision from the defendant SDO, yet only one that is fair and reasonable at the time of consideration. Standards development typically is an 'imperfect and evolving process'.<sup>160</sup> While a delay in setting a particular standard in relation to a known and foreseeable risk may be negligent, SDOs enjoy a certain level of discretion in making choices on what the standard is that it adopts, particularly in times of uncertain knowledge about risks.<sup>161</sup> Given the nature of decision making in standards development, which always involves the balancing of competing interests, courts (and juries in the US) should not lightly second-guess the decisions of the SDO, but assess whether they, at the time they were made, were fair and reasonable to those affected by them.

In the light of the apparent difficulty of conducting such assessment having the bias of hindsight, some commentators have suggested that SDOs should be protected from such inquiries by awarding them a qualified immunity or privilege.<sup>162</sup> Such award would mean that SDOs are liable only if they act in bad faith. With that, it is suggested, the exposure of SDOs to civil liability does not distort the delicate decision-making process around standards development and the many laudable goals that SDOs seek thereby to serve. The counter argument is that granting (any form of) judicial immunity or privilege is to impute 'power without responsibility' on private associations that, in their activities, are first and foremost concerned with the private interests of those they represent.<sup>163</sup> The award would furthermore undermine the regulatory potential for tort law to encourage SDOs to pursue public policy objectives rather than narrow private interests, adopt and review standards based on state-of-the-art scientific evidence, and engage in inclusive and transparent procedures of rulemaking.<sup>164</sup>

## 6. Conclusion: The Risk of Tort Liability for Standards Development

What then is the risk of incurring tort liability for standards development? Based on the review of case law in the US and EU, it must be concluded that this risk is relatively low. In the US, the majority of the actions against SDOs have been dismissed via motions to dismiss or motions for summary judgment with courts holding that the SDO involved did not owe a duty to exercise reasonable care in the promulgation of its standards to the plaintiffs. Accordingly, many SDOs have been shielded from civil liability for harm allegedly caused by their inadequate standards. In so holding, a number of courts have strategically played on the

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<sup>160</sup> *Commerce and Industry Ins. Co* (1999), 3.

<sup>161</sup> *Cf. Jappell* (2001), 481 ('Where delay in setting a particular standard would be negligent, the duty to act without negligence may require Defendant to make difficult choices somewhat earlier than it would prefer.'). See also Amos, J. dissent in *N.N.V.* (1999), holding at 1404 that 'If a duty were imposed on AABB, it would not be breached if there was an ongoing debate and the state of knowledge in a particular area was still evolving'.

<sup>162</sup> Feldmeier 1999, 796-797 and Heidt 2010, 1079-1084. See also the dissent of Garibaldi J. in *Snyder* (at 1056-1057) (arguing that AABB should be granted a qualified immunity based on the quasi-governmental nature of its activities in regulating blood banks).

<sup>163</sup> *Snyder* (1996), 1052-1053.

<sup>164</sup> *Cf. Schepel* 2005, 399-400.

doctrinal complexities in distinguishing between the elements of duty and breach in negligence with the view to exclude a defendant's standard setting activities from a jury inquiry. In those no-duty decisions considerations around the absence of a specific relationship between the standard-setting activities of the SDO and the plaintiff's harm (i.e. the foreseeability of harm and its closeness of connection with the SDO's conduct) and the consequences of exposing the SDO to liability on the important societal function of promulgating standards in a given domain have been particularly instrumental in the reasoning of the courts.

The American cases in which a duty of care was imposed have for the most part turned on the question of whether the SDO was in a position of authority such that its standards were followed by businesses, either out of legal or economic imperative. Accordingly, the necessary relationship between the plaintiff and defendant SDO to sustain a duty could be constructed. All but one of these cases concerned wrongful death actions or actions involving severe personal injury.<sup>165</sup> Liability for negligent standard setting causing pure economic loss has not been accepted in the US.<sup>166</sup>

In the EU, there has been very little civil litigation on the development of product standards, both within and outside the scope of the New Approach. Judicial control over standards development takes place primarily in the context of EU internal market law (competition law and free movement law), and judicial review in administrative law. However, as the case of *Fra.bo* shows, the breach of directly effective EU rules of internal market law may trigger civil litigation on standards development before Member State courts subject to national regimes of tort law. Such litigation may enable the recovery of personal injury and property damage, but also pure economic loss as was the case in *Fra.bo*. Accordingly, EU law may function as a catalyst for damages actions against SDOs in Europe.

The comparative analysis in this chapter has revealed that there are a number of circumstances related to the activities and governance of an SDO that affect its exposure to civil liability for standards development. These include:

- *Legal or de facto control to direct compliance with standards.* If the SDO enjoys a position of authority such that its standards are followed by those using them for business operations, i.e. manufacturers and sellers of products, it is more likely to be subject to civil liability than if it has no such position. Authority or control can exist either *de facto* or *de jure*, and may be evidenced by showing that the standards are followed out of imperative market demands, enjoy a strong degree of government recognition, or are

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<sup>165</sup> The exception is *Prudential Property and Cas. Ins. Co.* (1994) (involving extensive property damage caused by a hurricane).

<sup>166</sup> See for example *Waters v. Autuori* (1996) (professional association for accountants owes no duty in negligence to the plaintiff who lost money on investments in a failed limited partnership the accounts of which had been audited by a member accounting firm based on allegedly inadequate standards developed by the association and *Appalachian Power Co. v. American Institute of Certified Pub. Accountants* (1959) (professional association for accountants is not liable for the pure economic loss third parties could allegedly sustain as a result of the promulgation of accounting standards, which would adversely affect the third parties' ability to obtain credit).

coupled with mandatory periodic certification or accreditation inspections.

- *Intended purposes of developing standards.* If an SDO explicitly and actively commits to protect the interests of non-members or industry-outsiders by developing standards, the failure to do so in an adequate way will more likely lead to civil liability than if the SDO only commits to develop standards to promote the (economic) interests of its industry membership.
- *Representations about expertise in standards development.* Similarly, public statements and promotions by an SDO concerning the importance and currency of its standards in economic, government or community practice makes the SDO more susceptible to tort liability when the standards it promulgates cause harm to others.
- *Commercial benefits.* If the SDO stands to gain commercial benefits from the development of standards or related certification and accreditation inspections, the failure to pursue these activities adequately make it more likely to be subject to civil liability if it carries out these activities without commercial interests.
- *Good governance.* Lastly, the failure of the SDO to observe accepted principles of good governance, such as inclusive and transparent rulemaking and adoption and review of standards based on state-of-the-art scientific evidence, makes it more prone to liability. Compliance with such principles may show that the SDO exercised reasonable care in developing its standards.

These circumstances underline the very basic idea that an SDO should be answerable for harm caused to individuals and firms when it possesses, or holds itself out to possess, the power to affect these parties' interests. With power comes responsibility. As the analysis in this chapter has shown, tort law should be considered a key legal mechanism through which individuals and firms can hold an SDO responsible for the harm they suffered as a result of its negligent activities.

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