

# FETAL INJURY IN CLINICAL TRIALS AND ACCOUNTABILITY TO THE CHILD ONCE BORN

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## ABSTRACT

Sponsors of clinical trials have excluded pregnant women from trial participation mainly because of the fear of legal liability for fetal injury. Yet, to prevent untested treatments exposing fetuses generally to unwarranted risks, it is necessary that pregnant women are included in clinical trials. Despite sponsors' fears there, however, are major stumbling blocks for the child once born claiming compensation under English law. Neither the new EU Regulation 536/2014 on clinical trials nor tort law or statutory regulations have achieved a clear and fair avenue for the compensation of children injured in utero. There are also inadequacies with the voluntary pharmaceutical industry guidelines regarding such compensation. Greater clarity and fairness regarding tort and civil liability might encourage sponsors to conduct more trials in pregnant women and more pregnant women to volunteer taking part in research in the knowledge that their children will be compensated if they sustained injuries in utero.

## KEYWORDS

clinical trial, trial participant, disabled child, fetal injury, negligence and civil liability, no-fault liability, compensation.

## 1. Introduction

Historically, sponsors<sup>1</sup> have largely excluded pregnant women from participating in clinical trials.<sup>2</sup> Paradoxically, exclusion from trial participation was one of the consequences of the thalidomide tragedy in the late 1950s and early 1960s when babies with severely deformed limbs were born to women who had taken the drug during pregnancy.<sup>3</sup> Thalidomide had, however, not been tested in clinical trials in pregnant women.<sup>4</sup> Rather than discouraging the inclusion of pregnant women in clinical trials such an outcome should have been reason for inclusion in clinical research to avoid unnecessary risk from eventuating in future. By enrolling pregnant women in clinical trials many more women and fetuses might in future not be exposed to the unknown harm of treatments which have not been tested.<sup>5</sup>

Although a number of reasons have been advanced to justify the exclusion of pregnant women,<sup>6</sup> it is to a large extent, the fear of legal liability and the legal uncertainty which have contributed to their

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<sup>1</sup> A sponsor is a commercial or non-commercial organisation responsible for initiating, managing and financing or arranging the financing of clinical trials, see Medicines for Human Use (Clinical Trials) Regulations 2004, s.3.

<sup>2</sup> M. Fox, 'Research Bodies: Feminist Perspectives on Clinical Research', in: S. Sheldon and M. Thomson (eds.), *Feminist Perspectives on Health Care Law* (London: Cavendish, 1998) for a feminist perspective on the exclusion of women from clinical trials.

<sup>3</sup> V. Wild, 'How are Pregnant Women Vulnerable Research Participants?' *International Journal of Feminist Approaches to Bioethics* 5(2) (2012) 82-104; J. Le Fanu, *The Rise and Fall of Modern Medicine* (New York: Abacus, 2011) p. 282.

<sup>4</sup> R. Macklin, 'The Art of Medicine: Enrolling Pregnant Women in Biomedical Research', *The Lancet* 375 (2010) 632-633.

<sup>5</sup> D. Giesen, 'Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination', *Medical Law Review* 3(1) (1995) 22-52; M. Fox, *supra* note 2, p. 128.

<sup>6</sup> Their exclusion has, for example, been justified because of the potentially greater complexity of the trial design and the costs of conducting scientifically valid research with women as trial participants. For instance, women's changing hormone levels may alter a drug's efficacy. Thus, more research subjects would be needed in order to determine whether the variation in a drug's effectiveness was caused by the changing hormone

exclusion from clinical trial participation.<sup>7</sup> One of the main reasons for this is that while liability for injury to a female trial participant may be indistinguishable from liability for injury to a male participant, it is the additional concern about possible liability to the fetus injured during the course of a trial which reduces the willingness of sponsors to include pregnant women.<sup>8</sup> Ignoring any moral concerns by sponsors, their fear is largely based on the child once born acquiring the right to sue for fetal injury occasioned in the course of a clinical trial and obtain compensation from them.<sup>9</sup>

This article scrutinises this fear of liability and argues that the statutory regulations and tort law in England currently do not provide a clear avenue for the compensation of the child born disabled in these circumstances. To set the scene I will first describe the clinical trial structure with specific reference to trials in pregnant women. I will then discuss the range of statutes and regulations which are based on international ethical standards<sup>10</sup> and might be called upon to assist the child in her claim. I will show that the Medicines for Human Use (Clinical Trials) Regulations 2004 excludes specific reference to the participation of pregnant women in clinical trials whereas the new EU Regulation 536/2014 on clinical trials on medicinal products for human use<sup>11</sup> amends this omission. However, the latter leaves the question of compensation determined through the national law of each Member State and only requires insurance to be in place for damage suffered by a research *subject* without any reference to liability for fetal injury to the child once born. Next, the situation of the child born disabled with research-related injuries sustained in utero under English tort law and then under the Congenital Disabilities Act 1976 as amended by the Consumer Protection Act 1987 is considered in detail. This leads to a discussion of the drawbacks of the voluntary compensation system and of *ex gratia* payments in this situation. It is concluded that a development of the rules of the law of negligence and civil liability and revisiting the no-fault compensation scheme for injuries in clinical trials suggested by the Pearson Commission in 1976<sup>12</sup> might achieve more adequate provision of compensation of the child disabled due to her mother's participation in a clinical trial during pregnancy.

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levels, see H. Sandomire, 'Women in Clinical Trials: Are Sponsors Liable for Fetal Injury?' *Journal of Law, Medicine and Ethics* 21(3) (1993) 217-230. Requiring larger trials to detect differences based on sex would lead to increased costs and might cause an ethical problem if money would then not be available to fund other research, see C. Grady and C. Denny, 'Research Involving Women', in: E.J. Emanuel and others (eds.), *The Oxford Textbook of Clinical Research Ethics* (Oxford: OUP, 2008) p. 412.

<sup>7</sup> C. Grady and C. Denny, *ibid.*, p. 414.

<sup>8</sup> E. Clayton, 'Liability Exposure when offspring are injured because of their parents' participation in clinical trials' in: A.C. Mastroianni, R. Faden and D. Federman (eds.), *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies, volume 2. Workshop and Commissioned Papers* (Washington D.C.: National Academy Press, 1994).

<sup>9</sup> The exclusion of pregnant women from clinical research is, no doubt, also influenced by the religious and political debate over the moral status of the fetus giving weight to maternal and fetal interests, see C. Grady and C. Denny, *supra* note 6, p. 413.

<sup>10</sup> These international ethical standards have, however, only recently started to include any reference to pregnant women and their fetuses in clinical trials. Neither the World Medical Association Declaration of Helsinki 2013 nor the Oviedo Convention 1997 (the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine Human Rights and Biomedicine) make a specific mention of clinical trials in pregnancy or the protection of pregnant women and their fetuses. Only the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, adopted by the Council of Europe in 2005, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organisations of Medical Sciences (CIOMS 2002) refer to trials in pregnancy restricting such research to research of potential benefit to the pregnant woman or her fetus or to other pregnant women or their fetuses. However, none of the international agreements refer to the compensation of the child for injury sustained in utero in the course of a clinical trial.

<sup>11</sup> REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

<sup>12</sup> The Royal Commission on Civil Liability and Compensation for Personal Injury (Cmnd 7054, 1978)

## 2. Clinical trial structure

Clinical trials in pregnancy come in all shapes and sizes and the trials referred to for the purpose of this article are trials of medication and also of other treatments which concern illnesses and conditions affecting either pregnant women<sup>13</sup> or their fetuses<sup>14</sup> or both<sup>15</sup> but in all cases the pregnant woman is the essential trial participant. Generally the standard clinical trial sequence consists of 4 phases: Phase I trials assess the toxicity of the compound or treatment and are usually conducted in healthy volunteers; phase II trials assess the effectiveness and side effects of the compound or treatment in a small number of people with the condition to be treated; phase III trials monitor a larger group of patients receiving the drug or treatment over a longer period of time; phase IV trials assess how the drug or treatment works in practice and are conducted once the drug has been licensed.<sup>16</sup> Although harm, whether due to negligence or without any apparent fault, can manifest itself in any trial phase it raises particular concern in early phase trials, i.e. phase I and phase II trials, as these tend to have minor or no therapeutic intent for the trial participants.<sup>17</sup> For this reason the article will concentrate on the discussion of pre-natal harm occasioned during early phase trials in pregnancy.

On legal and ethical grounds, phase I and phase II trials in pregnant women will generally only be conducted once clinical trials in non-pregnant trial participants of the drug or treatment being investigated have been completed. The information gained from trials conducted in non-pregnant women or indeed in men will often be inapplicable to pregnant women as a number of physiological changes take place during pregnancy which may change the effect of and adverse reactions to an intervention.<sup>18</sup> Early phase clinical trials in pregnant women will of course also be conducted where the condition investigated is pregnancy-specific.<sup>19</sup> As a pre-condition for a clinical trial involving pregnancy one would want to ensure that the woman is not at risk of losing her pregnancy or there is harm to the child she wants nor that there is harm to herself.

Specifically regarding the prevention of harm to the future child the guidelines of the Royal College of Physicians stipulate that the risk of the clinical trial to the fetus must be minimal.<sup>20</sup> A minimal risk is defined as being of no greater risk to the fetus than routine procedures which are usually performed on pregnant women.<sup>21</sup> The Council of Europe suggests that the research bears minimal risk if it is to be expected that it would result, at the most, in a very slight and temporary negative

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<sup>13</sup> Such as morning sickness, pregnancy-related headache and backache.

<sup>14</sup> Such as fetal heart defects, neural tube defects and fetal growth restriction.

<sup>15</sup> Such as pre-eclampsia, gestational diabetes and sexually transmitted infections.

<sup>16</sup> D. Machin, 'General Issues', in: D. Machin, S. Day and S. Green (eds.), *Textbook of Clinical Trials* (Chichester: Wiley, 2004) 12-13; E. Jackson, *Law and the Regulation of Medicines* (Oxford: OUP, 2012) ch. 2.

<sup>17</sup> As phase I trials assess the safety of a drug or intervention in healthy volunteers and phase 2 trials assess the efficacy of a drug or intervention in a small number of patients it is difficult to maintain that these trials have therapeutic intent and therefore must carry higher risks for the trial participants, see generally E. Jackson, *ibid.*, referring to R. Wachbroit, 'Assessing Phase I Clinical Trials', *Law, Probability and Risk* 9(3-4) (2010) 179-186.

<sup>18</sup> R. Chin and B.Y. Lee, *Principles and Practice of Clinical Trial Medicine* (London: Elsevier, 2008) p.210; H. Sandomire, *supra* note 6.

<sup>19</sup> *Supra* notes 13-15.

<sup>20</sup> Royal College of Physicians (2007) Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants (4th edn) para. 8.39  
<<https://www.rcplondon.ac.uk/sites/default/files/documents/guidelines-practice-ethics-committees-medical-research.pdf>> accessed 10 August 2014.

<sup>21</sup> *ibid.* 5.11 for a general definition of minimal risk in clinical research; R. Chin and B.Y. Lee, *Principles and Practice of Clinical Trial Medicine* (London: Elsevier, 2008) p.210.

impact on the health of the person concerned.<sup>22</sup> Risk and minimal risk in the context of clinical trials have been frequently debated in the literature;<sup>23</sup> nonetheless, it is by no means clear how the minimal fetal risk condition can always be adhered to, particularly in early phase trials, as the outcome of any trial is, by definition, unknown.<sup>24</sup> Fetal risk and injury, even if not actionable prior to the child's birth, can therefore not be completely excluded in an early phase clinical trial in pregnancy.

In addition, to test the safety of a treatment, phase I trials use healthy volunteers or patient volunteers who are not affected by the condition under investigation. Phase I trials therefore tend to be non-therapeutic as by definition these volunteers will generally not receive any therapeutic benefit from the experiment.<sup>25</sup> An exception to starting the trial regime with a phase I trial and enrolling healthy volunteers or patient volunteers without the condition would be where the treatment is, for example, known to be toxic with severe side effects such as treatment with a chemotherapy agent. In such a case a pure phase I trial is not acceptable for ethical reasons<sup>26</sup> as the risk to benefit ratio for volunteers without the condition under investigation would be unacceptable. A large number of clinical research programmes therefore use a hybrid phase I/II trial design instead, investigating both safety and efficacy, and involving patients with the condition from the outset.<sup>27</sup> Thus, although a pregnant woman with a healthy pregnancy may be enrolled in a phase I trial testing the safety of a treatment where it is foreseeable that there are minimal risks and burdens, generally when the risks and burdens are unknown, a hybrid phase I/II trial in pregnant women with the medical condition in question is preferable for ethical reasons.<sup>28</sup>

This will also be the chosen trial programme where the treatment is aimed at the fetus such as for example treatment for fetal growth restriction, fetal heart defects or neural tube defects. For ethical reasons, any fetus-regarding trials are unlikely to be pure phase I trials but hybrid phase I/II trials investigating both safety and efficacy of a treatment in women whose pregnancies are affected by the fetal developmental abnormality under investigation. In any case, clinical trials investigating both safety and efficacy are almost always superior—at least ethically—to phase I trials<sup>29</sup> because phase I trials have a less favourable risk-benefit ratio and never have a therapeutic benefit. In contrast, hybrid phase I/II trials and phase II trials have *the potential* of benefitting the research subjects; they may be borderline therapeutic even though research is clearly not therapy, trial participants are research subjects and not patients and clinical trials may have negative outcomes. The importance of the distinction between phase I, phase I/II and phase II trials needs to be born in mind when considering the voluntary compensation guidelines of pharmaceutical industry sponsors.

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<sup>22</sup> Steering Committee on Bioethics. Draft additional protocol to the Convention on Human Rights and Biomedicine on Biomedical Research (Strasbourg: Council of Europe, 2003).

<sup>23</sup> C. Strong, 'Defining Minimal Risk in Research Involving Pregnant Women and Fetuses', *The Journal of Law, Medicine & Ethics* 39(3) (2011) 529-538; K. Liddell et al, 'Medical Research Involving Incapacitated Adults: Implications of the EU Clinical Trials Directive 2001/20/EC', *Medical Law Review* 14(3) (2006) 367-417; E. Cave, 'Seen But not Heard? Children in Clinical Trials', *Medical Law Review* 18(4) (2010) 1-27; J.V. McHale, 'Guidelines for Medical Research – some Ethical and Legal Problems', *Medical Law Review* 1(2) (1993) 160-185.

<sup>24</sup> E. Jackson, *supra* note 16, p.33.

<sup>25</sup> But note an exception are clinical trials in children, see the Medicines for Human Use (Clinical Trials) Regulations 2004, sch. 1, part 2, para. 10 which demands that trials can only be conducted in children if there is direct benefit to the group of children involved in the trial; see also E. Cave, *supra* note 23.

<sup>26</sup> See Additional Protocol on Human Rights and Biomedicine to the Oviedo Convention, Article 18.

<sup>27</sup> R. Wachbroit, *supra* note 17.

<sup>28</sup> This would be also be the case for more serious conditions where it is likely to treatments to be investigated are likely to have more serious side-effects as e.g., *supra* note 14.

<sup>29</sup> R. Wachbroit, *supra* note 17 arguing that generally clinical trials that investigate both safety and efficacy (hybrid Phase I/II trials) are almost always superior—at least ethically—to phase I trials.

However, first of all, it is necessary to discuss the legal framework in the UK regarding research in pregnancies.

### **3. The Medicines for Human Use (Clinical Trials) Regulations 2004 and the new EU Regulation 536/2014 on Clinical Trials on Medicinal Products for Human Use**

Although regulatory ethical instruments serve as useful indicators of the fundamental ethical and legal principles underlying this area<sup>30</sup> in the UK, the principles regarding clinical trials have been enshrined in domestic law. Clinical trials are defined by the Medicines Act 1968 as an investigation or series of investigations consisting of the administration to patients of one or more potentially beneficial medicinal products<sup>31</sup> for the purpose of ascertaining what effects, beneficial or harmful, this product or these products may have.<sup>32</sup>

The most important regulations in this area currently are the Medicines for Human Use (Clinical Trials) Regulations 2004, henceforth the CTR 2004, which transposed the EU Directive 2001/20/EC into UK law. The Directive was introduced to facilitate the conduct of trials across the EU to ensure patient safety, guarantee the fundamental human rights of trial participants and to encourage scientific and economic development.<sup>33</sup> Accordingly, the CTR 2004 relate to good clinical practice in the conduct of trials of investigational clinical medicines but do not regulate trials of non-drug treatments, such fetal heart surgery or neural tube surgery in the womb. Amongst other things they specify the need for a properly constituted Research Ethics Committee (REC)<sup>34</sup> and a sponsor.<sup>35</sup> The latter must obtain the ethical review and approval for the clinical trial from the REC<sup>36</sup> and clinical authorisation from the licensing authority, the MHRA.<sup>37</sup> The CTR 2004 make no specific reference to women or pregnant women as clinical trial participants. The omission of a special mention of pregnant women as trial participants follows the provisions of the EU Directive. Of course, UK law could have provided for express authorisation of clinical trials in pregnant women, but in view of the strict conditions for the initiation of trials generally this was probably considered unnecessary. Thus, the CTR 2004 provide that before the trial is initiated, foreseeable risks need to have been weighed against the anticipated benefit for the individual trial subject and other present and future patients and that 'a trial should be initiated and continued only if the anticipated benefits justify the risks'.<sup>38</sup>

It goes without saying that even when a clinical trial in pregnant women has received approval by the relevant REC(s) and has been authorised by the MHRA, injuries to the trial participant and her as yet unborn child are possible. Such injuries may occur due to the negligence of the clinical investigator or without any apparent fault. The CTR 2004 include an obligation on the sponsor and/or clinical investigator to have an insurance or indemnity in place to cover their liability in the event of injury, disablement or death of a research participant attributable to participation in

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<sup>30</sup> See *supra* note 10.

<sup>31</sup> But note that on 16 April 2014 the new Regulation No 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use was adopted repealing Directive 2001/20/EC. The new EU Regulation, para. 3, introduces the broader concept of clinical study of which the clinical trial is a category.

<sup>32</sup> Medicines Act 1968 s 31; see the CTR 2004, reg 2.

<sup>33</sup> J.V. McHale, 'Reforming the EU Clinical Trials Directive: Streamlining Process or a Radical "New" Agenda', *European Journal of Health Law* 20(4) (2013) 363-381; K. Liddell, *supra* note 23.

<sup>34</sup> The Trial Regulations 2004, reg 12.

<sup>35</sup> *ibid.*, reg 28.

<sup>36</sup> *ibid.*, reg 12.

<sup>37</sup> *ibid.*, reg 17.

<sup>38</sup> *ibid.*, sch. 1, part 2 para. 2.

research.<sup>39</sup> They do not, however, guarantee compensation to the trial participant should things simply go wrong in a trial. Trial participants have to prove negligence to receive compensation; there is no provision for no-fault compensation for mishaps in clinical trials. Despite the sponsors' concerns of liability for fetal harm<sup>40</sup> the fetus is not a trial participant; it has no legal personality and does not enjoy the legal protection of the child born alive.<sup>41</sup> In any case, the CTR 2004 do not specifically refer to insurance or indemnity to compensate the child for fetal injury.

The CTR 2004 are being replaced by the new EU Regulation 536/2014 on clinical trials on medicinal products for human use, henceforth the EU Regulation 2014, introducing a raft of changes.<sup>42</sup> It entered into force on 16 June 2014 but will not apply before 28 May 2016. This new Regulation was agreed on as it was recognised that the EU Directive 2001/20/EC had contributed to a significant fall in the number of clinical trials conducted in Europe due to overly bureaucratic and complex requirements imposed on organisations conducting research.<sup>43</sup> Unlike the CTR 2004 the EU Regulation 2014 sets conditions for clinical trials in pregnant women in that the trial has to be of direct benefit to the pregnant woman or her fetus while outweighing any risks.<sup>44</sup> Where there is no such benefit a clinical trial can only be conducted in a pregnant woman where a trial of comparable effectiveness cannot be carried out on women who are not pregnant or the trial contributes to the attainment of results capable of benefitting other pregnant women or other women in relation to reproduction or fetuses and the trial poses minimal risk to the pregnant woman concerned or her fetus.<sup>45</sup> Thus, it largely follows the provisions of the Additional Protocol on Human Rights and Biomedicine to the Oviedo Convention,<sup>46</sup> a Protocol which has, however, not been ratified by most EU Member States including the United Kingdom.

As with the CTR 2004 the new EU Regulation 2014 also contains provisions dealing with the protection of research subjects when mishaps occur in a clinical trial. Specifically, it requires that systems for compensation for any damage suffered by a research subject resulting from participation in a clinical trial are in place in the form of insurance, a guarantee, or a similar arrangement.<sup>47</sup> All the same it makes no special case for the compensation of pregnant women or their children born with research-related injuries. In addition, the EU Regulation 2014 leaves the question of compensation for harm suffered by research participants generally determined by the national law of each Member State.<sup>48</sup> Where damage is caused to the research subject during the course of a trial in England and Wales for which the investigator or the sponsor are liable, the conditions for liability will therefore remain governed by English law and compensation will depend on whether the requirements of English statutory or common law are fulfilled. It is therefore necessary to consider the position under the English law of torts with regard to compensation generally, and then to consider the position of the child claiming for prenatal harm due to her mother's participation in a clinical trial specifically.

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<sup>39</sup> CTR 2004, sch. 1, part 2 para. 16; see also M.A.R. Aviles, 'Compensation of Research-Related Injuries in the European Union', *European Journal of Health Law* 21(5) (2014) 473-487.

<sup>40</sup> C. Grady and C. Denny, *supra* note 6.

<sup>41</sup> *Paton v British Pregnancy Advisory Service Trustees* [1979] QB 276; A. Alghrani and M. Brazier, 'What is it? Whose is it? Re-Positioning the Fetus in the Context of Research?' *Cambridge Law Journal* 70(1) (2011) 51-82.

<sup>42</sup> E.g., the EU Regulation 2014 (Article 2.2) streamlines the trial approval process by introducing an EU harmonised application process which is aimed at speeding up the trial approval process, improving administrative efficiency and making the EU commercially viable, see generally J.V. McHale, *supra* note 33.

<sup>43</sup> E. Zanon, 'With EU red tape cut, the shackles are off clinical innovation' (2014) HSJ, available at <http://www.hsj.co.uk/comment/with-eu-red-tape-cut-the-shackles-are-off-clinical-innovation/5075995.article>; J.V. McHale, *supra* note 33.

<sup>44</sup> The EU Regulation 2014, Article 33(a).

<sup>45</sup> *ibid.*, Article 33 (b).

<sup>46</sup> Additional Protocol on Human Rights and Biomedicine, concerning Biomedical Research.

<sup>47</sup> The EU Regulation 2014, chapter XII, Article 76(1).

<sup>48</sup> *ibid.*, paras. 61 and 62.

#### 4. Accountability under English tort law and the Congenital Disabilities Act 1976

The question then is whether any cause of action under the English law of tort is open to the child, once born, for her research-related injury whether or not the clinical trial had been targeted at the pregnant woman for a pregnancy related condition, or whether it had been targeted at the fetus for a condition of the fetus, or at both.

##### 4.1 Accountability under Tort Law

English law does not permit the child to sue her mother for fetal injury sustained<sup>49</sup> and this also applies where the injury was sustained in consequence to the mother's participation in the trial. The question to be answered therefore is whether the child has a claim against the clinical investigator or the sponsor which in turn depends on whether, under English law as it stands, the investigator or sponsor owe a duty of care not only to the mother but also the fetus.

The debate as to whether a duty is owed to the fetus by a third party hinges on the question of the moral and legal status of the fetus,<sup>50</sup> whether the fetus is simply an adjunct of the mother or whether it is a patient in its own right. The *moral* status of the fetus is most often discussed in connection with the abortion debate which is not the issue here.<sup>51</sup> As regards the *legal* status of the fetus, the English common law position is that the fetus is not owed a duty of care as it has no legal standing.<sup>52</sup> As was held in *Paton v British Pregnancy Advisory Service Trustees*: '... in order to have a right the foetus must be born and be a child ... there can be no doubt ... that in England and Wales, the foetus has no right of action, no right at all, until birth'.<sup>53</sup> In English law, the fetus has no independent legal status; rather consent over the pregnancy and the fetus is a matter for the pregnant woman. Therefore nothing can be done to the fetus without the pregnant woman's consent.<sup>54</sup> Thus, the woman's ability to consent on behalf of her pregnant self to treatment or to participating in a trial is unquestioned. She cannot be compelled to undergo treatment,<sup>55</sup> undergo a Caesarean section even if it is, erroneously, considered to be in the 'fetus's best interests',<sup>56</sup> nor can she be made to stop taking drugs,<sup>57</sup> just as she cannot be forced to participate in a clinical trial. However, under English common law, if she does participate in a trial, any duty of care that is owed is owed to her, her pregnant self and not her fetus. Nevertheless, it does not follow that the fetus does not have any legal interests of its own; it has, for example, statutory protection from abortion, except under four specific conditions.<sup>58</sup> A neonate is able to sue for injury resulting from negligent acts or omissions, including embryonic selection, during the course of assisted reproduction<sup>59</sup> but

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<sup>49</sup> Congenital Disabilities (Civil Liabilities) Act 1976, 1(1) but with the exception for maternal liability for negligent driving under s.2.

<sup>50</sup> C. Grady and C. Denny, *supra* note 6.

<sup>51</sup> See e.g., J.K. Mason, *The Troubled Pregnancy* (Cambridge: CUP, 2007) ch. 2; B. Steinbock, *Life Before Birth* (OUP, 2001 Oxford) ch 2.

<sup>52</sup> A. Alghrani and M. Brazier, *supra* note 41 arguing that English case law focuses on the woman's right to bodily integrity versus fetal claims.

<sup>53</sup> [1979] QB 276 at [279] (per Sir George Baker P).

<sup>54</sup> A. Alghrani and M. Brazier, *supra* note 41.

<sup>55</sup> *Re T (Adult: Refusal of Treatment)* [1992] 4 All ER 649.

<sup>56</sup> *St George's Healthcare NHS Trust v S* [1998] 3 All ER 673.

<sup>57</sup> [1988] 2 WLR 1288.

<sup>58</sup> The Abortion Act 1967; see generally J. Fortin, 'Legal Protection of the Unborn Child', *The Modern Law Review* 51(1) (1988) 54-83; J.K. Mason, *supra* note 51.

<sup>59</sup> Congenital Disabilities (Civil Liabilities) Act 1976, s. 1A as amended by the Human Fertilisation and Embryology Act 1990, s. 44.

this is a right accruing to the child under statute and is not an exception to the born alive rule nor does it establish general accountability in tort law to the child prior to conception.<sup>60</sup>

Because of the unsatisfactory situation of the law of tort regarding children born disabled a Law Commission was set up whose terms of reference were to advise the Lord Chancellor what the nature and extent of civil liability for antenatal injury should be.<sup>61</sup> The resulting Act of Parliament<sup>62</sup> enshrines the current law regarding legal liability for injuries sustained in utero.

#### **4.2 Accountability under the Congenital Disabilities (Civil Liabilities) Act 1976<sup>63</sup>**

The Congenital Disabilities Act, henceforth CDA 1976, applies to all births after 1976 only. Births before the Act was passed continue to be governed by the common law.<sup>64</sup> While it does not recognise the fetus's legal existence prior to birth this Act confirms the existence of liability for prenatal injuries. It imposes liability to the child for injuries sustained in utero when the child is born alive suffering from a disability caused by an occurrence affecting either parent in his or her ability to have a healthy child or affecting the mother during pregnancy, or the mother or the child in the course of birth.<sup>65</sup> However, the defendant is only liable to the child if she had been liable in tort to the parent.<sup>66</sup> The liability to the child is derivative and based upon a breach of duty owed by the defendant to the parent. In the case of a clinical trial in pregnancy, liability to the child by the clinical investigator or sponsor would derive from liability to the mother, which if there had been injury to her, would have given rise to an action by her. The CDA thus avoids the illogical situation that a duty of care is owed to a legal non-entity, the fetus.<sup>67</sup> The Act might therefore be viewed as adopting the fiction that the injuries are sustained *after* birth when the child becomes a legal entity when the duty of care crystallises.<sup>68</sup> A different view could be that the harm eventuates after birth when there is a child suffering from the disability so that the possibility of an action is not defeated by the fact that the injury causing the harm was sustained while the child was a fetus in utero. However, this would not be the correct reading of the Act.

Whether the early phase clinical trial in pregnancy is aimed at a condition affecting the pregnant woman, the fetus or both, for liability to the child to exist the occurrence affecting the mother during the pregnancy needs to be shown to have led to the child's disabilities which would otherwise not be present.<sup>69</sup> Such disabilities are to be regarded as resulting from the wrongful act of the tortfeasor to the mother, a departure from the ordinary principles of civil liability. In any trial involving a fetus either with an underlying condition and not developing normally or affected by a condition of the mother, establishing proof of a causative link between an event occurring affecting the woman while carrying the fetus and subsequent disability at birth is likely to be rather difficult.

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<sup>60</sup> cf E. Jackson, *Medical Law: Text, Cases and Materials* (Oxford: OUP, 2013) p. 736 stating that Congenital Disability Act 1976 s 1A comes close to acknowledging a wrongful life action by the neonate, see also JK Mason, *The Troubled Pregnancy* (CUP 2007) 213.

<sup>61</sup> The Law Commission Report on Injuries to Unborn Children, Law Commission Working Paper No. 47, 1973 (Cmnd 5709).

<sup>62</sup> Congenital Disabilities (Civil Liabilities) Act 1976.

<sup>63</sup> *ibid.*, as amended by the Consumer Protection Act 1987.

<sup>64</sup> *ibid.*, s 4 (5).

<sup>65</sup> *ibid.*, s 1 (2).

<sup>66</sup> CDA 1976 s.1 (3) provides: Subject to the following subsections, a person (here referred to as " the defendant ") is answerable to the child if he was liable in tort to the parent or would, if sued in due time, have been so; and it is no answer that there could not have been such liability because the parent suffered no actionable injury, if there was a breach of legal duty which, accompanied by injury, would have given rise to the liability.

<sup>67</sup> J. Fortin, *supra* note 58.

<sup>68</sup> E. Jackson, *supra* note 60, p. 735.

<sup>69</sup> CDA 1976, s. 1(2).



Liability under the Act is further excluded in that the defendant is not answerable to the child if she took reasonable care when treating or advising the parent.<sup>70</sup> In the context of fetus-regarding clinical trials it is important to note that the CDA provides a defence if the mother has contributed to the fetal injuries; her contributory negligence will be taken into account and the child's damages reduced accordingly.<sup>71</sup>

There is a dearth of English case law under the CDA 1976 regarding claims for compensation by the disabled child with injuries sustained in utero in the course of a clinical trial so we are in uncharted territory. Nevertheless, several scenarios regarding potential claims for fetal injury by the child can be envisaged and are discussed in turn applying the legal principles identified above: a) the child is survives less than 48 hours; b) the child is born disabled but survives the first 48 hours; c) the child is born disabled but might not have been born but for her mother's trial participation.<sup>72</sup>

#### 4.1.1 The child survives less than 48 hours.

Clearly in the case of the child being still-born,<sup>73</sup> no cause of action exists under the CDA. As under the common law there is no actionable breach of duty to the pre-natal fetus. Before the fetus is born, it is not a person and after it is still-born, it has no legal rights and therefore cannot sue as it has never lived.<sup>74</sup> However, under the CDA 1976, the condition of being born alive for the purpose of recovering damages is more stringent than under the common law. Although 'born' means born alive with the moment of a child's birth being when she first has a life separate from her mother,<sup>75</sup> liability is only imposed if the child lives for 48 hours after birth.<sup>76</sup> The personal representatives<sup>77</sup> of a child surviving for less than two days therefore have no cause of action under the Act as compensation depends on the dead child having had a right of action and the clinical investigator who has conducted the trial negligently harming the fetus would be absolved from liability as long as the child dies in time. As has been suggested, under the CDA a doctor may even be tempted to let the child die before she has lived 48 hours to avoid liability.<sup>78</sup> In effect, therefore, the CDA withholds legal rights not only from the still-born child but from any neonate for 48 hours, whether or not there might otherwise be a case to answer for her injury in utero.

#### 4.1.2 The child is born disabled but survives the first 48 hours.

If the child survives the first 48 hours for the neonate to have legal rights under the CDA her legal representatives would need to show that her disabilities resulted from an 'occurrence' which affected the mother during her pregnancy, thus causing the child to be born with disabilities she

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<sup>70</sup> *ibid.*, s 1(4)

<sup>71</sup> *ibid.*, s. 1(7); I. Kennedy and R.G. Edwards, 'A critique of the Law Commission Report on Injuries to Unborn children and the Proposed Congenital Disabilities (Civil Liability) Bill', *Journal of Medical Ethics* 1(3) (1975) 116-121.

<sup>72</sup> Scenario d) can be envisaged in the case of a fetus-regarding trial where the trial intervention leads to the survival of a very premature baby where there was no or a very low chance of survival because of the fetus's age of gestation.

<sup>73</sup> The Births and Deaths Registration Act 1953 as amended by the Still-Birth Definition Act 1992, s 41 defines a still-born child as a child born after 24 weeks which did not at any time after being completely expelled from its mother breathe or show any other signs of life.

<sup>74</sup> Fatal Accidents Act 1976 s 1A(4); R. Scott, 'Maternal Duties Towards the Unborn? Soundings from the Law of Tort', *Medical Law Review* 8(1) (2000) 1-68; A. Whitfield, 'Common Law Duties to Unborn Children', *Medical Law Review* 1 (1993) 28-52.

<sup>75</sup> CDA 1976, s 4(2)(a).

<sup>76</sup> *ibid* s 4(4).

<sup>77</sup> See Law Reform (Miscellaneous Provisions) Act 1934 s 1(1) which applies only on the death of any person.

<sup>78</sup> I. Kennedy and R.G. Edwards, *supra* note 71; J. Fortin, *supra* note 58.

would not otherwise have had.<sup>79</sup> They would also have to show that, judged by the standard of the received professional opinion at the time,<sup>80</sup> the clinical investigator has breached his duty of care in that she did not follow the trial procedure or ought to have known that the drug posed more than a minimal risk to the fetus. The latter may be difficult to prove when the trial treatment has been approved by the regulatory authorities and the REC. These problems are compounded in fetus-regarding trials where in addition there remains the difficulty of proving that the child's disablement is a consequence of the breach of duty to the mother.<sup>81</sup> The fetuses of women participating in a fetus-regarding phase I/II trial usually have developmental abnormalities. These abnormalities may be due to genetic, environmental or unknown factors so that it may be difficult to identify the risk added by the research intervention aimed at the fetus.<sup>82</sup> But also in a trial aimed at a condition of the pregnant woman, if the breach of duty cannot be demonstrated, the disabled child may be left without a remedy even if the treatment under investigation is the most likely cause of her disability. And if the child's action succeeds, the measurement of damages will be rather modest where the child only survives for a few weeks. The claim will be for pain and suffering and loss of amenity of the child before death. The award will generally be greater the longer the child survives.<sup>83</sup>

#### 4.1.3 The child is born disabled but might not have been born but for her mother's trial participation – the position under the CDA 1976 compared with the situation under the law of tort.

The situation of a child born disabled who might not have been born but for her mother's trial participation is more likely to arise in a fetus-regarding trial than in others although it is possible to imagine that experimental treatments aimed at a condition of the pregnant woman<sup>84</sup> could also lead to the survival of an otherwise doomed fetus. Unlike the action for wrongful birth by the mother the child's action would be one of wrongful life. The child alleges negligence in that she would not have been born had it not been for the clinical investigator's failure to inform of the risk of serious disability when enrolling her mother in the trial or during the course of the trial,<sup>85</sup> that her mother's trial participation led to her survival with severe disabilities and that her disabilities are such that she would be better off had she not been born. Her claim is not that her disabilities would not have been present but that her fetal developmental abnormality would have ordinarily led to her being miscarried or stillborn. In *McKay v Essex AHA*,<sup>86</sup> the Court of Appeal considered the claim for wrongful life by the child contrary to public policy because, in the words of Stephenson LJ, 'it would mean regarding the life of a handicapped child as not only less valuable than the life of a normal child, but so much less valuable that it was not worth preserving ...'.<sup>87</sup> In this case the child was born disabled as a result of a rubella infection contracted by the mother during her pregnancy but her doctor had not so informed her. Had she been informed about the infection she claimed she would have undergone an abortion. Mary McKay's birth preceded the passing of the CDA and was

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<sup>79</sup> CDA 1976, s 1(2)(b) but note that prior to the Act a child born alive with disabilities caused by the defendant's negligence before the child's birth has an action in negligence against the defendant because the injury is deemed to be sustained at birth as the fetus has no legal personality, see *De Martell v Merton and Sutton Health Authority* [1993] QB 204.

<sup>80</sup> CDA 1976, s 1 (5); I. Kennedy and R.G. Edwards, *supra* note 71.

<sup>81</sup> CDA 1976, s 1(3).

<sup>82</sup> J.C. Fletcher and K.J. Ryan, 'Federal Regulations for Fetal Research: A case for Reform', *Law, Medicine and Healthcare* 15(3) (1987) 126-138.

<sup>83</sup> A. Grubb and others, *Principles of Medical Law* (Oxford: OUP, 2010) 740; M. Jones, *Medical Negligence* (London: Sweet & Maxwell, 2008) p.322 referring to the case of *Kerby v Redbridge HA* (1993) 4 Med LR 178 where the child survived for 3 days and the award was £750.

<sup>84</sup> E.g., experimental treatment of severe pre-eclampsia.

<sup>85</sup> In effect it would be the child's claim that her mother was given insufficient information about the benefits and risks of the trial and the possible trial outcomes.

<sup>86</sup> [1982] QB 1166.

<sup>87</sup> *ibid.*, 1180.

therefore not covered by the Act.<sup>88</sup> Could the child in scenario 3 have a wrongful life action against the clinical investigator and does the CDA exclude wrongful life actions?

According to its wording the CDA only applies to occurrences that affected the mother during pregnancy so that the child is born with disabilities which would not otherwise have been present.<sup>89</sup> In scenario 3 the child's claim is that she was born disabled because of an occurrence during her mother's pregnancy and the damage she claims for are her disabilities *once born*. Thus it seems illogical to argue that she could have an action for wrongful life; under the CDA, without being born, she would have no claim.<sup>90</sup>

If this is so then *McKay* or the legal principles for a wrongful life in tort may well be precedent for my fictitious scenario. Some authors argue that the problem with wrongful life actions is that they concentrate on 'metaphysical meditations on non-existence' rather than on the negligent act or omission which leads to the child's life being adversely affected by her disabilities<sup>91</sup> or on the damage or lack thereof.<sup>92</sup> In scenario 3 the child would claim that there was a negligent act or omission which caused her to be born and if the clinical investigator had fully informed her mother of the risks and benefits of the trial her mother would not have become a trial participant and nature would have taken its course resulting in miscarriage or stillbirth. However, even assuming that she can establish a breach of duty it will be almost impossible to establish that either miscarriage or stillbirth would have followed if it had not been for the trial intervention. Developmentally abnormal fetuses do survive against all odds as they do maternal complications.<sup>93</sup> The issue therefore is not whether the child can show that there was damage since she was born with disabilities nor that that she would not have been less affected by her disabilities if the clinical investigators had done their duty. The issue is that if the clinical investigator had performed her duty she, the child, would not exist at all.<sup>94</sup> The damage would be being alive<sup>95</sup> but the law considers life as beneficial. And their Lordships in *McKay* concluded that non-existence was unsusceptible of measurement.<sup>96</sup> This conclusion can be criticised not only because to decide that existence is always better than non-existence presupposes that non-existence has been compared with disabled existence; it can also be criticised because the courts do award damages for loss of expectation of life.

Although the situation regarding claims for injuries sustained in utero by the child thus seems generally unsatisfactory both under the law of torts and under the CDA some of the problems could be avoided in the context of clinical trials with the acceptance of the concept of no-fault compensation to which I now turn.

## 5. No-fault compensation and ex gratia payments

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<sup>88</sup> J.K. Mason, *supra* note 51, p. 211.

<sup>89</sup> CDA 1976, s 1(2)(b).

<sup>90</sup> *McKay v Essex AHA* [1982] QB 1166, 1186 where Ackner LJ states that subsection (2)(b) assumes that 'but for the occurrence giving rise to the disabled birth the child would have been born normal and healthy – not that it would not have been born at all'; see generally J.K. Mason, *supra* note 51, p 212.

<sup>91</sup> A. Morris and S. Saintier, 'To be or not to be: Is that the question? Wrongful Life and Misconceptions', *Medical Law Review* 11(2) (2003) 167-193; see also J.K. Mason, *supra* note 51, pp. 204-213.

<sup>92</sup> T. Weir, 'Wrongful Life – Nipped in the Bud', *Cambridge Law Journal* 41(2) (1982) CLJ 225-228.

<sup>93</sup> Z. Kmietowicz, 'Incidence of severe disability among very premature babies has not changed for a decade' *British Medical Journal* 345 (2012)e8264.

<sup>94</sup> T. Weir, *supra* note 92.

<sup>95</sup> J.K. Mason, *supra* note 51, pp. 204-213.

<sup>95</sup> T. Weir, *supra* note 92.

<sup>96</sup> *ibid.*; A. Whitfield, *supra* note 74.

Although both the Trial Regulations 2004 and the new EU Regulation require proof of insurance to cover the potential liability of clinical investigators and sponsors<sup>97</sup> both Regulations only concern trials for medicinal products rather than other types of investigational treatments such as for example fetal surgery. Interestingly, while both Regulations require transparency regarding any insurance or indemnity arrangements covering the liability of the sponsor and investigator,<sup>98</sup> they do not make it obligatory to compensate the trial participant unless legally liable to do so. The focus of the Regulations is on the requirement for transparency as to the arrangements that exist in the event of injury or death of a trial subject, and of any insurance or indemnity arrangements covering the liability of the sponsor and investigator.<sup>99</sup> Under both Regulations details of the insurance or indemnity arrangements that cover the liability of the investigator and sponsor have to be submitted either to the REC in the research ethics application form<sup>100</sup> or to the Member State's legal representative.<sup>101</sup>

With chances of succeeding in a fault-based action so low, one would have expected, at least on ethical grounds,<sup>102</sup> that rather than only mandating insurance arrangements the new EU Regulation 2014 might impose an obligation on the sponsor to compensate a trial participant for no-fault harm sustained when participating in a trial. After all, there is a benefit to society for people to agree to participate in clinical trials, so that it would be only fair that society should compensate them should harm occur.<sup>103</sup> The mere fact that they consented to trial participation should not overlook the fact that research subjects are being used for the benefit of others.<sup>104</sup> People who volunteer for clinical trials and are harmed should receive compensation for their injuries and such compensation should be a major consideration for all those involved in clinical research. In the end, compensation in a no-fault-based action will also only be forthcoming if they can go the arduous route of proving the causative link to the injury suffered. As the Pearson Commission<sup>105</sup> which was charged to consider the issue of compensation for death or personal injury (including antenatal injury) in a clinical trial stated:

We think it is wrong that a person who exposed himself to some medical risk in the interest of the community should have to rely on ex gratia compensation in the event of injury. We recommend that any volunteer for medical research or clinical trials who suffers severe damage as a result should have a cause of action, on the basis of strict liability, against the authority to whom he has consented to make himself available.<sup>106</sup>

The case for no-fault compensation of children who are born disabled because of their mothers being enrolled in a clinical trial is even stronger because of the need for financial provision for these children with current welfare support for the disabled and those who care for them being inadequate.<sup>107</sup> However, the inroads which have been made into the fault-based system in England for clinical trial injuries are negligible despite the fact that trial participants are more likely to be

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<sup>97</sup> CTR 2004, sch. 1, part 2 para. 14.

<sup>98</sup> *ibid.*, sch. 2, part 2(16); EU Regulation 2014, chapter XII, Article 76(1).

<sup>99</sup> CTR 2004, sch. 3, part 1 (1)(g)(iv) and (3)(c) and sch. 1, part 1 (15) (5) (i) and sch. 3, part 1 (1)(g) (iii).

<sup>100</sup> *ibid.*, sch. 1, part 2 para. 16 and sch. 3, part 1 (3) (c) and part 3 (15) (5) (j).

<sup>101</sup> EU Regulation 2014, chapter XI, Article 74; see also J.V. McHale, *supra* note 33.

<sup>102</sup> R. Steinbrook, 'Compensation for injured research subjects', *New England Journal of Medicine* 354 (2006) 1871-1873.

<sup>103</sup> J.M. Barton et al, 'The compensation of patients injured in clinical trials', *Journal of Medical Ethics* 21(3) (1995) 166-169.

<sup>104</sup> S. Guest, 'Compensation of subjects of medical research: the moral rights of patients and the power of research ethics committees', *Journal of Medical Ethics* 23(3) (1997) 181-185.

<sup>105</sup> The Royal Commission on Civil Liability and Compensation for Personal Injury (Cmnd 7054, 1978).

<sup>106</sup> *ibid.*, para. 1341.

<sup>107</sup> *The Guardian*, 'Welfare Reforms a Further Blow to Families with a Disabled Child' on 16 September 2011, at <http://www.theguardian.com/society/joepublic/2011/sep/16/cost-raising-child-with-disability>.

injured for reasons which are attributable to the trial treatment but in respect of which negligence cannot be established on part of the clinical investigator or sponsor.<sup>108</sup>

### **5.1 The Consumer Protection Act 1987**

This Act which implemented EU Directive 85/374/EC provides an exception to the need for proof of fault imposing strict liability for drug related injuries<sup>109</sup> including pre-natal injuries to the fetus involving defective products.<sup>110</sup> Despite the strict liability of the producer and supplier of products for defective medicinal products<sup>111</sup> it is, however, still necessary to establish causation in relation to the defective product. A defective product is defined as a product which does not measure up to that degree of safety which 'persons are generally entitled to expect'.<sup>112</sup> One of the problems with this definition is that it is circular since deciding what persons are entitled to expect is the question that the definition of defect ought to answer.<sup>113</sup> The objective of early phase clinical drug trials is, amongst others things, to discover possible side effects of the investigational medicine on the trial participants. Therefore, it may be difficult for them to argue that they were entitled to expect greater levels of safety.<sup>114</sup> Clearly, trial participants cannot be entitled to expect that investigational drugs will never cause adverse effects. Quite the contrary, they are not necessarily entitled to expect that these drugs will not have adverse effects. However, as safety is a relative concept, the seriousness of the potential injury will be a relevant factor in the assessment of what persons are entitled to expect.<sup>115</sup> Moreover, liability is difficult to establish under the Act in that the drug manufacturer can raise the 'state of the art' or 'development risk' defence.<sup>116</sup> This means that the manufacturer will not be liable if the state of scientific knowledge, at the time the drug was put in circulation, was such that the defect could not have been discovered.<sup>117</sup> The obvious conclusion therefore seems that this defence undermines the general aspiration of the Act to introduce no-fault liability into this area.<sup>118</sup>

### **5.2 Insurance for no-fault claims**

Where the sponsor of the trial is a member of the Association of the British Pharmaceutical Industry (ABPI) no-fault compensation payments to the injured trial participant will ordinarily be made in accordance with the guidelines of the ABPI. However, the guidelines themselves are not legally binding but form a self-regulated approach. In any event, pharmaceutical companies which are not members of the ABPI do not need to honour these recommendations.<sup>119</sup> Furthermore the guidelines are not always interpreted without qualifications by the companies.<sup>120</sup> The guidelines make a

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<sup>108</sup> J.M. Barton et al, *supra* note 103.

<sup>109</sup> CPA 1987, pt 1 s 2.

<sup>110</sup> CDA 1976 as amended by the CPA Act 1987, s.3.

<sup>111</sup> *ibid.*, pt 2 s.7(e).

<sup>112</sup> *ibid.*, pt 1 s.3.

<sup>113</sup> E. Jackson, *supra* note 60, p. 544 citing J. Stapleton, *Product Liability* (London: Butterworths, 1994) p. 234.

<sup>114</sup> P.R. Ferguson, 'Clinical Trials and Healthy Volunteers', *Medical Law Review* 16(1) (2008) 23-51.

<sup>115</sup> M. Jones, *supra* note 83, p.858.

<sup>116</sup> CPA 1987, pt 1 s 4 (1)(e).

<sup>117</sup> *ibid.*; P.R. Ferguson, *supra* note 114 stating that the original draft of the EU Directive was changed to include the 'development risk' defence as the pharmaceutical industry claimed that innovation would be inhibited if this defence was not provided.

<sup>118</sup> C. Newdick, 'The Development Risk Defence of the Consumer Protection Act 1987', *Cambridge Law Journal* 47(3) (1988) 455-476 who suggests that showing that the defect could not have been discovered in the current state of scientific knowledge is basing liability on the conduct of the producer, which is similar to the test in negligence where liability is not imposed for unforeseeable risk.

<sup>119</sup> ABPI, 'Clinical Trial Compensation Guidelines' (2015) [http://www.abpi.org.uk/our-work/library/guidelines/Documents/compensation\\_guidelines\\_2014.pdf](http://www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf), accessed 15 March 2015; J.M. Barton et al, *supra* note 103.

<sup>120</sup> J.M. Barton et al, *supra* note 103.

distinction between the compensation of phase I trial participants and all others, i.e. those enrolled in phase II, III or IV trials with the most recent amendment of the guidelines removing the distinction between the compensation arrangements of healthy volunteers in phase I trials that do not have the target disease and those in phase I trials that do have the target disease but where there is *no reasonable prospect of direct benefit*.<sup>121</sup> The ABPI guidelines provide for a legally binding obligation regarding no-fault compensation made with phase I trial participants. In contrast there is no legal commitment regarding patients in phase II, III or IV trials as they have some prospect of therapeutic benefit;<sup>122</sup> the commitment only involves an assurance given to clinical investigators and RECs that compensation will be paid in the case of harm.<sup>123</sup>

Since even healthy volunteers in phase I trials have experienced problems with obtaining compensation,<sup>124</sup> a harmed trial participant will find even less support in a non-legally binding commitment. Thus the guidelines for compensation in phase II, III or IV clinical trials recommend that, notwithstanding the absence of a legal commitment,<sup>125</sup> patient volunteers suffering bodily harm (including death) *should* be compensated where, on the balance of probabilities, the injury was attributable to the drug being studied or to any clinical intervention which is part of the trial protocol.<sup>126</sup> The amount of compensation to be paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English court in cases where legal liability is admitted.<sup>127</sup> Compensation may thus be withheld depending on the particular patient's circumstances regarding the level of risk the patient can reasonably be expected to accept<sup>128</sup> so that patients with already life threatening conditions will receive a lesser amount.

Pharmaceutical sponsors are likely to impose further limitations on claims.<sup>129</sup> As explained initially, pregnant women are unlikely to be enrolled in pure phase I trials unless it is foreseeable that there are minimal risks and burdens and research of comparable effectiveness cannot be carried out in women who are not pregnant. They are more likely to be enrolled in phase I/II trials. Since there are no compensation guidelines for participants in phase I/II trials they may be classified by the industry as falling either under the looser drafted phase II, III and IV compensation guidelines or under the stricter phase I guidelines. This would of course be disingenuous since the guidelines of the latter do not mention the fetus and by definition therefore exclude compensation being paid to a child injured in utero if the child's mother has participated in a clinical trial.<sup>130</sup> The guidelines of the former on the other hand, which are without legal commitment, specifically exclude injuries arising from phase I trials which involve 'patient volunteers' with no prospect of receiving direct benefit but refer to compensation being paid to a child injured in utero.<sup>131</sup>

The ABPI recommendations envisage a number of further exclusions which equally point to a less than generous intent. Thus, compensation should only be paid for more serious injuries of an

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<sup>121</sup> ABPI, 'Clinical Trial Compensation Guidelines' (2015).

<sup>122</sup> *ibid.*; S. Guest, *supra* note 104.

<sup>123</sup> ABPI, 'Clinical Trial Compensation Guidelines' (2015); see also J.V. McHale, *supra* note 23.

<sup>124</sup> See P.R. Ferguson, *supra* note 114 regarding the difficulties of receiving compensation in the aftermath of the TGN1412 trials concerning the severe adverse reactions experienced by the healthy volunteers.

<sup>125</sup> ABPI, 'Clinical Trial Compensation Guidelines' (2015), para. 1.7 stating that this means regardless of whether the patient can prove negligence by the sponsor or that the product is defective.

<sup>126</sup> *ibid.*, para. 1.2.

<sup>127</sup> *ibid.*, para. 4.1.

<sup>128</sup> *ibid.*, para. 4.2.

<sup>129</sup> J.M. Barton et al, *supra* note 103.

<sup>130</sup> ABPI, 'Clinical Trial Compensation Guidelines' (2015), para. 2.2; see also S. Guest, *supra* note 104, disputing that the distinction drawn between healthy volunteers and patient volunteers is valid as all research ought to be subject to the same principles.

<sup>131</sup> ABPI, 'Clinical Trial Compensation Guidelines' (2015), para. 1.3.

enduring and disabling character and not for less serious or curable complaints.<sup>132</sup> Compensation is also excluded where the injury has arisen through a significant departure from the agreed protocol<sup>133</sup> or through the wrongful act of a third party, including the clinical investigator's failure to deal adequately with an adverse reaction.<sup>134</sup> This would require trial participants to bring an action in negligence against the clinical investigator which, as discussed, has limited chance of success.

### 5.3 *Ex gratia* payments

Where the sponsor is a commercial entity but not a member of the ABPI the disabled child injured in utero during the course of a clinical trial may seek an *ex gratia* payment for her disabilities but there is no automatic right.<sup>135</sup> The adverse publicity of an action against a pharmaceutical company may be an incentive to agree to such a payment but pharmaceutical companies do not always move quickly to compensate even injured healthy volunteers. This became all too apparent in the Northwick Park case.<sup>136</sup> All the same, with the lack of legal enforceability of the industry's moral undertaking, an *ex gratia* payment may be the only means to receive compensation where the trial participant has been injured in a trial sponsored by a pharmaceutical company which is not a member of the ABPI.

Similarly, an *ex gratia* payment may be the only recourse for the research subject where the non-negligent injury occurred in a trial which was not commercially sponsored. According to the European Medicines Agency, approximately 40% of clinical trials in the European Economic Area are not sponsored by the pharmaceutical industry but by non-commercial sponsors, mainly academia.<sup>137</sup> As the Royal College of Physicians notes, the legal situation for compensation for non-negligent injury in research funded by public sector bodies such as universities, NHS trusts or the Medical Research Council (MRC) is not satisfactory.<sup>138</sup> Generally, public sector bodies cannot agree in advance to non-negligent injury compensation and have difficulty in implementing an insurance policy for no-fault claims. They tend to accept only liability for negligent harm but will, in exceptional circumstances, consider whether an *ex-gratia* payment could be offered.<sup>139</sup> Besides, there is no legal requirement under the CTR 2004 and the EU Regulation 2014 for a no-fault compensation scheme for injury resulting from participation in a clinical trial. That this is so is not conducive to the greater harmonisation of the protection of research subjects amongst EU Member States with some countries having adopted a no-fault compensation system for research-related injuries.<sup>140</sup>

## 6. Discussion and conclusion

All new therapies, whether non-drug or drug treatments, whether aimed at the pregnant woman, or the fetus with developmental abnormalities, need to be tested for their safety and efficacy in clinical trials before they can become generally available. Because existing and future children and pregnant women and the public at large will benefit from that clinical research it is only fair to

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<sup>132</sup> *ibid.*, para. 1.4.

<sup>133</sup> *ibid.*, para. 3.4.1.

<sup>134</sup> *ibid.*, para. 3.4.2.

<sup>135</sup> Royal College of Physicians, *supra* note 20, para. 4.14; see also J.V. McHale, *supra* note 23.

<sup>136</sup> *ibid.*; P.R. Ferguson, *supra* note 114.

<sup>137</sup> See European Medicines Agency, 'Clinical Trials in Human Medicines'

<[http://www.ema.europa.eu/ema/index.jsp?curl=pages/special\\_topics/general/general\\_content\\_000489.jsp&mid=WC0b01ac058060676f](http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000489.jsp&mid=WC0b01ac058060676f)> accessed 10 August 2014.

<sup>138</sup> Royal College of Physicians, *supra* note 20, para. 4.22; see also S. Guest, *supra* note 104.

<sup>139</sup> Royal College of Physicians, *supra* note 20, para. 4.23; see also MRC which provides a standard form for *ex gratia* payments and offers the assurance that it will give sympathetic consideration to claims in respect of non-negligent harm arising from an MRC funded trial.

<sup>140</sup> M.A.R. Aviles, *supra* note 39.

compensate children for injuries sustained in utero due to the participation of their pregnant mothers in clinical trials. However, there is currently not only a lack of fairness but also considerable legal uncertainty surrounding the compensation of the child, born disabled as a result of an injury sustained in utero.

Thus although the CDA 1976 was passed to deal with civil liability for prenatal harm very few actions have ever succeeded the Act. This is despite the fact that the Law Commission on Injuries to Unborn Children in 1974 was set up in the aftermath of the thalidomide tragedy. Clearly some of the problems of the CDA could be remedied if it recognised the fetus as a legal person to which a duty of care can be owed during pregnancy and which, if injured, would therefore be able to bring an action, once born. However, attributing legal personality to the fetus would open up a myriad of legal problems and is not necessary to achieve the compensation of a child for pre-natal injury in consequence of her pregnant mother's participation in a clinical trial. Rather it is suggested that it would be possible to make amendments to the Act to bring it in line with the developments in the common law of England and other common law jurisdictions in such a way as to allow a child who sustained injuries in utero during a clinical trial to obtain damages.

By making the defendant only answerable to the child if liable in tort to the parent<sup>141</sup> the CDA 1976 takes an antagonistic approach to a child injured in utero and claiming compensation. Any duty is owed to the 'father' or 'mother' of the child at the time of the occurrence for which the defendant may be liable, thereby leaving out of account that the 'mother' is the woman's pregnant self. In a clinical trial any duty by the defendant to the female parent should therefore be viewed not as a duty to the woman but to the pregnant woman in her duality as woman and fetal container. While derivative liability to the child is a relatively simple concept when it refers to the liability owed to the father, it is more demanding when it refers to the liability owed to the 'mother' or the dual unit of woman and fetus. A duty owed to the 'mother' ought to include a duty to any part of that dual unit which might be foreseeably affected by the act of carelessness. Such an interpretation would neither abrogate the pregnant woman's right over her body nor would it ascribe legal rights to the fetus. This reading of the defendant's duty would be more in line with the law as it has developed in Canada and Australia. In a Canadian case the judge held that the duty was owed to both mother and child because 'finding that there was a duty owed by the defendant doctor to the infant plaintiff is not conferring upon the fetus the status of legal personhood. It did not put the defendant in the impossible situation of owing a duty to one person to determine the existence of another.'<sup>142</sup> In the Australian case of *Watt v Rama* Gillard J, in a minority judgment, expressed the duty in terms of the duty owed to an unborn child as a member of a foreseeable class of victims likely to be affected by the act of carelessness. The injury is part of the chain of causation leading to the damage suffered by the child at birth.<sup>143</sup> Again this would restrict the damage suffered from the breach of duty to the damage sustained by a legal person, i.e. the child when she achieves legal personality at birth.

A further problem with the principle of liability under the CDA 1976 is that it turns on the wrongful act by the defendant or 'the occurrence' before the child's birth<sup>144</sup> and is therefore concerned with the injury which was occasioned to the fetus in utero rather than the subsequent damage suffered by the child at birth (or rather, under the Act, 48 hours after birth). However, the cause of action arises when the damage is suffered by the child rather than when the wrongful act is committed. After all, if the child is not born alive such as when the woman miscarries or her child is still-born, no damage is suffered from the disability and no rights would accrue. It is in order to avoid the attribution of legal personality to the fetus and a duty to the fetus itself that the Act does not separate the concepts of injury and damage. It would not be beyond the bounds of possibility to re-

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<sup>141</sup> CDA 1976, s 1(3)

<sup>142</sup> *Cherry v Borsman* (1991) 75 D.L.R (4<sup>th</sup>) 668 (British Columbia Sup. Ct) 677.

<sup>143</sup> [1972] V.R. 353, 373.

<sup>144</sup> CDA 1976, s 1(1).



write the Act in such a way that it is recognised that the injury occurs to the fetus as a part of the pregnant woman's self but that the damage is suffered and the right to compensation comes into existence when the child is born alive with the disability caused by the injury. Thus Gillard J in *Watt v Rama* had thought it unhelpful to consider the question as to the existence of a duty of care in isolation from the elements of breach of duty and damage: '...if the act or omission by which the damage was caused is identifiable it may put one on the trail of a possible duty of care of which the act or omission would be a breach.'<sup>145</sup> In this light the judge suggested to start with the damage and work back through the cause of it to the possible duty which may have been broken and concluded that the injury was to be regarded part of the chain of causation leading to the damage suffered by the child at birth.<sup>146</sup>

A statutory amendment of the CDA 1976 would not only follow the development in other common law jurisdictions. The arguments advanced by Gillard J has also been accepted by the English courts. Thus in the joint cases of *Burton v Islington Health Authority* and *de Martell v Merton and Sutton H.A.*<sup>147</sup> in 1993<sup>148</sup> the English Court of Appeal upheld the decisions in favour of the claimants and accepted the reasoning of the High Court in *de Martell* which was based on Gillard J's minority judgment: 'A careless act carrying foreseeable risk of harm to another is not, of itself, a breach of duty owed under the law of negligence. The breach occurs at the moment that the act causes the harm.'<sup>149</sup> As Dillon LJ opined 'it is not open to the health authority to deny liability on the ground that the organism that they injured was not in law the plaintiff and yet to deny responsibility for the defects with which the plaintiff was born on the ground that they inflicted them before birth.'<sup>150</sup> Thus the argument is not that the damage is caused to the claimant before the claimant exists; rather the argument is that the damage is suffered at the moment when she achieves legal personality. The negligent act does not have to be contemporaneous with the resulting damage

A further criticism regarding the lack of fairness and uncertainty of the CDA 1976 is that it withholds rights from the newly-born for 48 hours.<sup>151</sup> The Act provides that the child must live for at least 48 hours before the parents may recover damages for her loss of expectation of life,<sup>152</sup> the greatest head of loss in the case of an early neonatal death. As the child's personal representatives they are in effect denied bringing an action for such compensation on behalf of the deceased child on the basis that she would not have had a right of action for the first 48 hours. This seems illogical when a child generally acquires legal personality at birth and when the Act itself provides that liability for injury sustained prenatally is to be regarded as 'liability sustained by the child immediately after its birth'.<sup>153</sup> After all, the Act defines birth or born as meaning 'born alive' or 'the moment of a child's birth... when it first has a life separate from its mother'.<sup>154</sup> Since the newly born child under the Act has, however, no right of action for the first two days of her existence it is necessary to determine the exact moment of time she acquires legal rights. To do so one would need to pinpoint the child's exact time of birth. But this will more often than not rest on the accuracy of the clocks in the delivery room or, in the hurly burly of delivery complications, on the guess-work of everyone involved in the birth. It would surely be more logical and satisfactory to make the child's legal

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<sup>145</sup> [1972] V.R. 353, 371-372.

<sup>146</sup> [1972] V.R. 353, 374.

<sup>147</sup> [1993] Q.B. 204.

<sup>148</sup> As the birth of both claimants preceded the CDA 1976, the common law was applicable, see CDA 1976, s 4(6).

<sup>149</sup> *Burton v Islington Health Authority* and *de Martell v Merton and Sutton H.A* [1993] Q.B. 204, 219.

<sup>150</sup> *ibid.*, 220.

<sup>151</sup> I. Kennedy and R.G. Edwards, *supra* note 71.

<sup>152</sup> CDA 1976, s. 4 (4).

<sup>153</sup> *ibid.*, s. 4 (3).

<sup>154</sup> *ibid.*, s. 4 (2)(a).

standing dependant on being born alive even though in some circumstances problems deciding whether a child is still-born or born alive can be envisaged.<sup>155</sup>

However, the major criticism of the CDA 1976 is that compensation is based on the fault principle since the general principle ought to be that where prenatal injury occurs in the course of a clinical trial compensation should be paid to the child born disabled. Since the Act was passed before the Pearson Committee had reported it did, however, not take into account its recommendations for a no-fault, state-funded compensation scheme for injury occasioned in clinical trials.<sup>156</sup> Because of the public benefit from clinical trials a publicly funded scheme to compensate disabled children for research-related injuries would have been the fair approach at least in trials conducted by non-commercial sponsors. It is more questionable whether compensation should be borne by the public in the case of clinical trials sponsored by pharmaceutical companies because the public benefit element is outweighed by the large profit element involved in commercial research.

The drafting of the new EU Regulation 2014 was a missed opportunity for mandating no-fault compensation in all EU Member States rather than leaving the compensation system to be determined by national law. However, both the CTR 2004 and the EU Regulation 2014 only require evidence of sponsor insurance. For a child injured in utero in a clinical trial having to rely on the interpretation of the terms of the ABPI guidelines by a commercial sponsor regarding the compensation for her disablement is not satisfactory. Pharmaceutical companies are not all members of the ABPI, do not necessarily adhere to the ABPI guidelines and are not averse to stretching the definition of the guidelines. Self-regulation by the pharmaceutical industry can rarely be claimed to be in the interest of those left injured in clinical trials. Therefore, an argument can be advanced that the ABPI guidelines for compensation for injury in hybrid phase I/II, phase II, III and IV trials ought to be the same as those for trial participants in phase I trials. Otherwise children born disabled due to their mother's participation in a clinical trial sponsored by the industry may have to rely on the generosity of a pharmaceutical company's ex gratia payment with its lack of precedent setting and its lack of transparency. The establishment of a clinical trial injury compensation fund to which both commercial sponsors and the public contribute might be a solution.

Children who have sustained injuries in utero in clinical trials should be able to rely on a no-fault compensation scheme since such injuries will have financial consequences for the child born disabled with her whole life ahead adversely affected by her disabilities. Incorporating the recommendations of the Pearson Committee regarding clinical trial injuries into the CDA 1976 would provide greater certainty for pregnant women participating in these trials knowing that there will be adequate financial provision in the case of mishaps, and it might also encourage more pregnant women willing to become enrolled in clinical trials. Greater certainty of the legal position would not only benefit the child injured in utero during the trial, it would have the added benefit of encouraging public and commercial sponsors to conduct more trials with potential teratogenic effect in pregnant women to the benefit of current and future children.

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<sup>155</sup> Still-Birth Definition Act 1992 s 1(1) defining a still-born child as a child who did not breathe at any time or show any other signs of life; Infant Life (Preservation) Act 1929, s.1 and the definition of 'capable of being born alive' in *C and another v S and others* [1987] 1 All ER 1230 as not 'incapable of ever of breathing either naturally or with the aid of a ventilator'.

<sup>156</sup> The Royal Commission on Civil Liability and Compensation for Personal Injury (Cmnd 7054, 1978) para. 2.