



Law, Social Justice & Global Development
(An Electronic Law Journal)

**Clinical Trials in Developing Countries: The Plaintiff's
Challenge**

Jolyon Ford and George Tomossy,
Faculty of Law,
University of Sydney, Australia

jolyonf@law.usyd.edu.au
georget@law.usyd.edu.au

This is a **refereed article** published on: 4 June 2004

Citation: Ford, J and Tomossy, G 'Clinical Trials in Developing Countries: The Plaintiff's Challenge', 2004 (1) *Law, Social Justice & Global Development Journal (LGD)*.
<<http://elj.warwick.ac.uk/global/issue/2004-1/fordtomossy.html>>

Abstract

Current debate surrounding clinical trials in developing countries has served to heighten awareness about global inequalities in healthcare, particularly distribution of the benefits of research. The bioethics literature has not generally addressed the issue of distribution of the risks involved: the practical and legal challenges faced by subjects in developing countries who are wrongfully injured in the course of drug trial participation and would seek compensation. These individuals represent new entrants into a broader category of plaintiffs facing transnational 'access to justice' barriers when wronged in the course of the activities of multinational corporations in developing countries. This article examines the challenges faced by such plaintiffs, using as a case study the ongoing legal action commenced in the United States by the families of Nigerian children who had participated in a clinical trial sponsored by a leading US-based multinational pharmaceutical company.

Keywords: Access to Justice, Bioethics, Clinical Trials, Forum Non Conveniens, Remedies, Transnational Corporations

Authors' Note

The article is based on a conference paper presented at the 28th International Congress on law and Mental health (Globalisation and Health Panel) on 3 October 2003, Sydney, Australia.

1. Introduction – Globalisation and Clinical Trials

The volume of research conducted in developing countries has increased substantially over recent decades.ⁱ First world sponsors conduct clinical trials in developing countries for a number of reasons: access to a larger pool of human subjects, clearer result yield, and to accelerate approval for new drug marketing (Office of the Inspector General, 2001). Market forces drive trial sponsors to shop around for the least expensive, least onerous regulatory environment with the lowest liability exposure, including for the purpose of avoiding potential litigation in the event of adverse effects (Lurie and Wolfe, 1999). Host governments in developing countries appear on the whole eager to attract such research. Contributing to this trend are ongoing efforts to harmonise drug regulation and promote mutual acceptance of clinical trial data across jurisdictions, such as through the work of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (Dominguez-Urban, 1997).

Clinical trials in developing countries conducted by first-world sponsors, however, raise a host of ethical, regulatory and legal issues.

The principal *ethical* concern relates to distributive justice: the equitable distribution of risks and benefits arising from biomedical research.ⁱⁱ International health research undertaken in developing countries is meant to be both locally relevant and to benefit local communities. But while the US, Europe and Japan comprise 80 percent of the global consumer drug market, just 0.3 percent of the industry's research and development spending has resulted in approved drugs for tropical diseases (Shah, 2002). A common metaphor in media reports on international research is that of 'human guinea pigs' in one (poorer) country enduring risks for the benefit of citizens of another (wealthier) country.ⁱⁱⁱ The debate surrounding such trials has contributed to heightened awareness about gross disparities in the availability and quality of health care resources between developing and affluent countries (de Zulueta, 2001).

International research also poses significant *regulatory* challenges. Developing countries generally do not possess the sophisticated regulatory infrastructure required to evaluate and monitor clinical trials being conducted in their country (Office of Inspector General, 2001). There may be problems with the extraterritorial application of sponsor-country regulations (Dubois, 2003). The resulting regulatory vacuum means that developing countries are hard-pressed to verify compliance with standards of good clinical research practice and are reliant on foreign data or review processes to accomplish these aims.^{iv} Some direction on appropriate conduct can be deduced from international ethical guidelines, such as the World Medical Association's *Declaration of Helsinki* (2000)^v and those promulgated by the Council for International Organizations of Medical Sciences (2002); both provide a good indication of international consensus on key ethical questions. World Health Organisation Guidelines (2001) are also available for the establishment of effective research ethics review processes. However, such guidelines are no substitute for a substantive system of research governance entrenched at the national level, which most developing countries continue to lack.

Internal professional compliance with ethical standards and external regulation of researchers is certainly the most effective way to protect subjects while enabling necessary research. However, when protective and regulatory systems fail the subject and an adverse event occurs, the need for access to a forum to obtain compensation draws in broader *legal* concerns and challenges. International ethical guidelines rest on a foundation of respect for fundamental human rights, and there is an increasing interest in seeing these trials as raising questions not only of tort law but of international human rights law (IHL) (Fidler, 2001, pp 304, 352; Todres, 2000).

The legal problem with international research in developing countries – from the perspective of the aggrieved human subject – is that local remedial and compensatory structures might be wholly inadequate, with clear lines of international accountability and mechanisms for seeking compensation transnationally lacking. In bringing any claim for compensation in the jurisdiction of the first world trial sponsor, the subject/plaintiff faces a two-level problem. Firstly, there are procedural problems relating to the nature of available forums, coupled with rules that operate to insulate first world researchers from claims relating to their third world conduct. Secondly, even if procedural access to justice is obtained, injured subjects may struggle to demonstrate the existence of an accepted substantive norm applicable in medical trials, let alone prove its breach.

The topic of this Special Issue relates to the place and operation of law in relation to global health concerns. In our conclusion we argue that the need for biomedical research in developing countries, often critical to solving global health issues, should not preclude justice for individuals wronged in the course of globalising drug trials. While globalisation has resulted in the spread of clinical trials, and while it is commonly said that globalisation *erodes* borders, legal borders and barriers remain, preventing access to justice for third world claimants first world home of defendants.

2. Case Study: The Trovan Trial Litigation

In 2001, claimants from Nigeria initiated class action lawsuits alleging the following facts.^{vi} In early 1996, serious epidemics of bacterial meningitis and cholera broke out in and around the city of Kano, in northern Nigeria. This presented Pfizer, a leading transnational pharmaceutical company based in the United States, with an opportunity to conduct a clinical trial to test the efficacy of its new broad-spectrum antibiotic, Trovan, as an oral treatment for meningitis in children. A clinical trial was quickly organised and conducted with the cooperation of Nigerian authorities, the US Food and Drug Administration expediting approval for export of the experimental drug on the basis of an apparent invitation to Pfizer from the Nigerian Government. Trovan was tested against the approved treatment that used a competitor's product. A number of child subjects died or sustained permanent disabilities, such as paralysis, deafness or blindness.^{vii}

In 2000, the *Washington Post* ran an investigative series entitled 'The Body Hunters', questioning the ethics of foreign-sponsored clinical trials conducted in Africa, Latin America and China and Eastern Europe. The first article in this series featured the Trovan study, raising serious concerns about the process of ethics review of the protocol and quality of informed consent from trial subjects (Stephens, 2000). The report sparked outrage in both Nigeria and the United States, with official inquiries and litigation having been instituted in both countries (Shah, 2002).

In March and August 2001, plaintiffs representing the affected children or their families brought actions against Pfizer in Kano and New York respectively. In the US action, plaintiffs have relied on a US federal statute (the *Alien Tort Claims Act* 28 USC at 1350, hereafter 'the ATCA', discussed below), pleading a violation by Pfizer of the customary international law prohibition on non-consensual human experimentation said to be codified in Art. 7 of the *International Covenant on Civil and Political Rights* 1966 (ICCPR, in force 1976): 'No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. *In particular, no one shall be subjected without his free consent to medical or scientific experimentation*'. The alleged violation is Pfizer's failure to explain to parents of trial children that the treatment was experimental (knowing that Trovan had the potential to cause serious side effects), could be refused, and that other organisations offered conventional treatments at the same site free of charge.

Assuming that a trial on the merits ever takes place, such a case would raise complex evidential and legal issues relating to subjects' rights under international law, standards of conduct, informed consent and causation. However, as the preliminary phases of this litigation have demonstrated, the primary obstacle faced by the plaintiffs is convincing a US court to hear the case at all.

The plaintiffs have argued that a US court should hear the case because Pfizer is based there, and because an action in Nigeria would be bound to be decided adversely to the plaintiffs, as it alleged Nigerian government complicity in the Trovan trial. They argued that the Nigerian court system was subject to improper influence from the executive and so was too corrupt to be considered an adequate alternative forum. The US District Court (Southern District of New York) decided in September 2002 that it had jurisdiction to hear the case, but declined in its discretion to do so, requiring the plaintiffs to attempt to sue Pfizer in Nigeria, which the Court saw as the natural or proper forum. Accordingly, with Pfizer's agreement to various undertakings to facilitate an action in Nigeria, Pfizer's motion to dismiss the action was granted on the basis of *forum non conveniens*.^{viii}

The parallel Nigerian proceedings^{ix} had been withdrawn or dismissed in August 2002. The *British Medical Journal* reported in early 2003 that the plaintiff families said that they had lost confidence in the Nigerian judicial system, where their case had been stalled since March 2001. They had withdrawn

their action after 'it became clear that they were not likely to get justice in Nigeria after their case was adjourned more than 14 times'. Pfizer blames the plaintiffs for any delay.^x

In October 2003, the US Court of Appeals for the Second Circuit vacated the 2002 New York decision on the motion to dismiss and remanded the matter to the District Court to determine whether it was corruption or delay of the sort alleged by the plaintiffs that precipitated the dismissal or withdrawal of the Nigerian action, and to evaluate whether this impacts on the District Court's analysis of the proper forum.^{xi}

3. The Plaintiff's Challenge

Our interest in the Trovan Trial litigation is in the systemic operation of jurisdictional rules on transnational access to justice in international biomedical research. The plaintiff's challenge is presented in three parts: Firstly, establishing the existence of norms protecting subjects' rights in international research; secondly, locating a mechanism to obtain a remedy under international law; and thirdly, overcoming barriers arising from the *forum non conveniens* doctrine.

While we focus in this paper on procedural rules, it is useful to bear in mind that even if there is sufficient self-awareness of rights, the primary challenge faced by developing country plaintiffs in bringing any international or transnational claim to vindicate injured interests is likely to be the practical one of lack of funding and legal resources. This lack is compounded by the use by defendant researchers of procedural devices that drag out any litigation over a long period (von Freyhold 1996; Meeran 2003).^{xii}

3.1 Norms Under International Law?

A discussion of procedural barriers to justice cannot proceed without brief consideration of the fact that even if a suitable forum can be found where a private actor might be liable, a major hurdle for plaintiffs adopting a claim based in IHRL – as opposed to a simple private law tort claim – will be establishing the existence of an accepted international law norm, with a justiciable (specific enough) content prohibiting the conduct alleged.

First of all, the principal international law instrument in this field – the Council of Europe's *Convention on Human Rights and Biomedicine*^{xiii} – is only a regional regime and contains no provision establishing a forum and procedure for dealing with claims of those injured in the course of biomedical research. The enforcement mechanisms of the *Convention* are limited. Article 24 purports to entitle a person who has suffered 'undue damage resulting from an intervention' to 'fair compensation according to the conditions and procedures prescribed by law'.^{xiv} However, the *Convention* does not itself specify those conditions or procedures; they are those prescribed by national law (Explanatory Report, 1997).^{xv} This would appear to leave plaintiffs in transnational claims to the nationally specific procedures of private international law (which are insufficient, as discussed below).

More fundamentally, while the *Convention* is a landmark achievement towards the entrenchment of ethical principles in biomedicine within a multilateral framework, the consensus supporting those principles is by no means absolute. For example, research on vulnerable persons within the framework set out by the *Convention* attracted vehement resistance in Germany. The heart of German opposition was that it would permit non-therapeutic research with surrogate consent, thus breaching a strict interpretation of the *Nuremberg Code* that an individual's consent was an absolute requirement for ethical research (de Wachter, 1997). Indeed, the degree to which the *Convention* has been embraced is disappointing. At the time of writing, only 31 out of 45 member states have signed the instrument with 17 ratifications. Notable absences among the latter include research-intensive nations such as the United Kingdom, France, Germany and Switzerland.^{xvi}

An ongoing process that merits close attention in the near future is the harmonisation of clinical trials regulation, particularly in the European Union.^{xvii} Pursuant to a May 2001 directive of the European Parliament and Council of the European Union, Member States of the European Union are required to take legislative, regulatory or administrative action to harmonise clinical trials governance in their national systems by July 2004.^{xviii} The impact on advancing the cause of human subject protection by

the Clinical Trials Directive is thus, ironically, at least in the immediate future, more significant than that of the *Convention*. But notwithstanding the positive effect of the Clinical Trials Directive, it must be recalled that the main purpose of the directive is recognised to be to ‘simplify and harmonise the administrative provisions governing clinical trials,’ not to advance human subject protections.^{xix}

Article 7 of the ICCPR is not necessarily of assistance. Where non-consensual medical experimentation is not systematic or in the context of imprisonment, and falls short of torture, there has been no authoritative determination of what standards are universally accepted as binding.^{xx} Article 7 has not (in the human experimentation context) formed the basis of any other human rights action to date (Dubois 2003: 203). The US Court of Appeal in the *Trovan* litigation noted – hinting at the significance of this for the eventual outcome – that the customary international law status and content of the Art. 7 norm was an issue merely glossed over before both it and the District Court. David Fidler’s recent study (examining whether placebo-based drug experimentation in developing countries has violated any IHRL norms), suggests little promise for potential claimants (Fidler, 2001). For example, the Art 7 prohibition appears to be a stable, fundamental norm at the heart of protecting the integrity and security of the person. However, while it is true that the general prohibition is clearly secure in international law,^{xxi} the plaintiff faces a challenge showing that any particular drug trial was a breach of the norm, because it might be said to lack specificity: it is an open-textured norm, the content of which is subject to wide interpretive differences of view (Swan 2001: 98; Fidler 2001: 337, 341). In determining what suffices as adequate informed consent to trials, for example, insufficiently definite accepted criteria exist to determine whether any one given act amounts to a prohibited act.^{xxii}

Arguments have been advanced both in favour (Orlowski, 2003) and against (Meier, 2002) whether the basic principles of human subject treatment in the *Nuremberg Code* and the *Helsinki Declaration*^{xxiii} have the status of norms of customary international law, so as to be binding irrespective of whether the actors were bound by the terms of any given treaty. Nevertheless, the *Nuremberg Code* has to date received limited attention in domestic courts (eg Annas, 1992) and it must be recalled that the *Declaration of Helsinki*, while broadly endorsed, remains a code promulgated by a professional association (the World Medical Association). The status of either document as a source of customary law has yet to receive authoritative judicial consideration.

3.2 International Law: Lack of Forum

Before analysing the primary procedural doctrinal barrier – the *forum non conveniens* principle – facing groups such as the *Trovan* plaintiffs, it is necessary to explain why these plaintiffs have formulated and brought their action in the manner described above. Simply put, very few international or transnational avenues exist for obtaining justice in such situations. This reflects, again, a broader lack of forums and procedures for the legal accountability of (first world) non-state actors, such as corporations, for their conduct in third world countries.

While the *Trovan* claim is expressed as an IHRL claim, much of the international law system offers little prospect of relief to such a class. This system focuses on systematic abuses of human rights and on the interests and duties of States (rather than on the rights of individuals or the duties of corporations). In particular, for procedural reasons, the International Covenant on Civil and Political Rights (ICCPR) regime would not be an appropriate avenue. A class such as the *Trovan* complainants might conceivably bring an individual complaint to the Human Rights Committee under the First Optional Protocol to the ICCPR.^{xxiv} However, as only the state holds duties under the ICCPR, the action would not be useful against a corporate trial sponsor and would require that the subject’s own state (assuming it is even a signatory to the Protocol) was sufficiently involved in the drug trial.^{xxv}

Moreover, a ‘remedy’ as a result of the Protocol Committee’s response would almost certainly not include compensation, notwithstanding what is stated in Article 2 of ICCPR about obligations to adopt measures to ensure that an effective remedy exists. It may become arguable that indirect State responsibility (or, breach of its IHRL obligations) might arise in a State failing to ensure a remedy for wrongs by private actors within its jurisdiction for rights violations taking place in another State (Clapham, 1993). The argument is that, for IHRL obligations to be meaningful, States should be obliged at least to provide effective access to domestic courts (Clapham, 2001, also Addo, 1999; Sornarajah, 2001). David Fidler has considered whether, on existing authority and instruments, a State’s failure to regulate, control, or supervise new drug research (by its actors abroad), to reduce risks, might be seen as a violation by it of a norm such as the right to life (Fidler, 2001, pp 327-329).

However, the International Law Commission's *Draft Articles on State Responsibility* indicate that presently the general rule is that the only case where the conduct of private actors will be attributable to the State is where the actors have acted under the direction, instigation or control of the State (Crawford, 2002).

State responsibility aside, the corporations conducting such research are not yet generally seen as having legal personality in international law, thus rendering them largely incapable of 'suit' in international law. There are of course loud calls for setting out the legal responsibilities and procedural status of multinational corporations in a way that reflects their increased level of influence in global society (see Addo (ed), 1999; Koh, 1991; Dubois, 2003, pp 203-206). These include calls to mobilise national law – including tort law – to address the transnational activities of corporations (Anderson, 2002). This is not the place for a full discussion of international legal personality of non-state actors, save to note that the US District Court for the Southern District of New York recently ruled – after an extensive discussion of authority – that a corporation is capable of being liable under international law (at least for gross human rights violations, and for purposes of the ATCA): *The Presbyterian Church of Sudan v Talisman Energy Inc.*^{xxvi}

The challenge facing plaintiffs who pursue a public international law remedy is, therefore, that even if the norm requiring informed consent to medical experimentation has some status and certain content under international law, its breach is likely to be unenforceable in IHRL forums, since most violations will be by non-state actors (see also Dubois, 2003, pp 203-204). The *Trovan* class established jurisdiction in a US domestic forum by pleading their action under the ATCA. This statute founds jurisdiction in federal courts, against a defendant over which US courts have personal jurisdiction, to hear claims by a non-US national for a tort committed 'in violation of the law of nations' including outside the US (see generally Steinhardt and D'Amato (eds) 1999; Pettyjohn, 2003). The Court took the allegation that the Art 7 ICCPR prohibition and its equivalent in the main biomedical conventions is a well-established, universally recognised norm of customary international law (independent of the instruments themselves), as an adequate pleading of a 'violation of the law of nations' for the purposes of founding jurisdiction.

The District Court held that alleged treatment with experimental drugs without free consent (in the circumstances), 'however reprehensible,' fell short of a violation of an offence of 'universal concern' for which a non-state party may be held liable. However, the Court held, non-state activity can be a breach of international law when the government has so far insinuated itself into a position of interdependence with the private actor that they must be recognised as joint participants in the challenged activity. The Court held that the pleadings revealed a sufficient allegation that the Nigerian government and Pfizer were 'joint participants' for the purposes of jurisdiction under the ATCA. The question then became whether the Court should decline to exercise this jurisdiction, on the basis that Nigeria was the proper forum. We discuss this below.

The enforceability problem of international forums can be avoided, then, in cases where a defendant is otherwise subject to US federal court jurisdiction, and the ATCA pleading requirements can be met. A claim based on the medical experimentation norm might thus be brought directly as an IHRL claim in a domestic forum. However, the ATCA is a *sui generis* statute, unique to the US. In addition, the future of ATCA as a measure providing extraterritorial civil jurisdiction is uncertain: the US Supreme Court decided in December 2003 to reconsider the constitutional validity of prevailing wide interpretations of the statute's scope.^{xxvii} It is however also open to wrongfully injured drug trial subjects to bring what might be cast as an IHRL claim *indirectly*: a recognised domestic private law category is invoked, such as the tort of battery (see Scott, 2001a; also Moran, 2001, p 668). It is trite that Courts of general jurisdiction (at least in common law countries) have always recognised a jurisdiction over torts committed in other countries where the defendant is subject to their control (see generally Lowenfeld, 1996). This possibility for plaintiffs such as the *Trovan* class is relatively unexplored (see Swan, 2001). There would be no need to show a complex IHRL norm if tort (negligence) law protects the same interests (cf Scott, 2001a). For plaintiffs alleging wrongs in the context of medical experimentation, municipal negligence law adequately captures the wrong even if it is not as symbolic as bringing an action based on IHRL. The action is simply an ordinary tort one, albeit a transnational action seeking to access a forum in the researchers' first world residence.

3.3 The Forum Non Conveniens Challenge

Our discussion has so far proceeded on the assumption that developing country subjects of an international biomedical trial would seek justice abroad, rather than in the country where the trial took place. First, such plaintiffs may feel that they cannot obtain an adequate local private law remedy free from political influence or considerable delay in the relevant developing country. (This is not of course to suggest that legal systems in developing countries generally are inadequate. Instead, as we suggest below, it might be seen as proper and reflective of broader social justice and accountability concerns that the suit follow the first world researcher to their resident jurisdiction.) Second, the research sponsor's local presence might not have sufficient assets to attach if a judgment is obtained.^{xxviii} Third, where the researcher lacks a local presence, the plaintiffs might doubt their ability to have a local judgment recognised and enforced abroad.

A considerable barrier facing subjects in a situation where the research sponsor has a local subsidiary which was at least *prima facie* the relevant actor in the events, but is not worth suing, is to persuade a court in the (first world) jurisdiction of the parent corporation why it should not respect the separate legal personality of the subsidiary and decline to proceed against the parent company. This is not the place for a full discussion of the 'novel, complicated and hugely expensive challenge' in holding parent multinationals legally accountable for the conduct of their subsidiaries abroad (so-called 'foreign direct liability') (Meeran, 2003; see eg Addo, 1999). But such actions are certainly possible, most famously in the English cases of *Thor Chemicals*, *Connelly v RTZ Corporation Plc*, and *Lubbe v Cape PLC*.^{xxix}

Whether the US ATCA or a private law remedy is selected, a considerable barrier operating, like separate legal personality, to insulate researchers and other actors in relation to tortious conduct abroad is the common law doctrine of *forum non conveniens*. This is a discretionary device permitting a court (supposedly in rare instances) to decline to hear a claim even though it is a permissible venue with proper jurisdiction over the claim, on the basis that a more appropriate forum exists (see generally Fawcett, 1995; Lowenfeld, 1996; Bell, 2002).

Given that it is likely to be their primary doctrinal challenge, we here briefly analyse the doctrine's operation from the perspective of plaintiffs in developing countries, conscious that the field it occupies is 'one of the most baffling subjects of legal science.'^{xxx} For our purposes it is not necessary to engage fully the difficult policy considerations surrounding the merits of the *forum non conveniens* doctrine and its operation (cf Weintraub *et al*, 2002). If we accept, for argument, the disputed view that the doctrine's balancing process allows an overly wide discretion to judges (Robertson, 1994), the doctrine can be understood to have generally made it very difficult for developing country plaintiffs to sue, particularly in US courts (at least in federal courts), even in the home forum of the defendant corporation, for negligent actions abroad. Not only are *forum non conveniens* decisions very often determinative of the overall outcome (Robertson, 1994), the extensive procedural litigation about where to litigate often defeats plaintiffs of the sort under consideration, given their limited legal and financial resources and if unable to secure an early settlement (Meeran, 2003).

Our broader point is that while the rules supporting the global economy have evolved very rapidly to enable direct investment and activity in developing countries – including in the area of international biomedical research – ironically, the extended operation of the rather old doctrine of *forum non conveniens* restricts reciprocal legal accountability for such activities (see also Rogge, 2001, p 317).

Where a US federal court has jurisdiction,^{xxxi} a defendant seeking *forum non conveniens* dismissal must demonstrate that an adequate alternative forum exists.^{xxxii} An obstacle to foreign plaintiffs is that while strong presumption is given in favour of domestic plaintiffs' (US nationals') choice of forum, this presumption is weaker in respect of foreign plaintiffs.^{xxxiii} The Trovan court held that it has 'a duty to exercise restraint when assessing the sufficiency of other nations' courts and legal systems.' Although the Court accepted that the plaintiffs' claims of judicial corruption indicated that Nigeria is a nation 'experiencing difficulties in its transition from a dictatorship to a democracy,' it held that a Nigerian court would be an adequate forum. For the Court, nothing in the plaintiffs' submissions on the inadequacy of Nigerian justice 'reaches beyond the most general of characterizations.'^{xxxiv}

Drug trial defendants such as Pfizer, if successful in showing the existence of an adequate alternative forum, will argue that, in determining which forum will be most convenient and best serve the ends of justice (by reference to the *Gilbert* public and private interest factors^{xxxv}), courts should give weight to the injury having occurred outside the US.

The Trovan Court held that Nigeria undeniably had a ‘very strong interest’ in the litigation since the Trovan test occurred there and all the plaintiffs are Nigerian residents. However, the Court conceded that there was a strong public interest in having a United States court decide issues concerning Pfizer’s possible tortious conduct – the citizens of the New York forum ‘share a compelling interest in this litigation as well,’ since Pfizer developed, produced, and performed preliminary testing of Trovan (and the Kano treatment protocol) within the US, with the ultimate goal of selling the drug domestically.

The Trovan Court concluded that the *Gilbert* public interest factors did not strongly support one forum over the other. Instead, as evidence of numerous elements essential to the plaintiffs’ claim would be much more accessible in the Nigerian forum, the balance of the private interest factors ‘clearly weighs in favour of granting Pfizer’s motion to dismiss because the vexation that it would incur in pursuing the relevant Nigerian discovery while litigating in this forum, is grossly disproportionate to any convenience that the plaintiffs may experience’. Pfizer’s motion to dismiss the New York proceedings was thus granted, on the basis of certain undertakings (including as to discovery of documents) by Pfizer.

One example suffices to show the often arbitrary, unpredictable operation of the *forum non conveniens* doctrine. In *Presbyterian Church of Sudan v Talisman Energy Inc*, the US District Court recently held that the US and public interest in hearing claims of corporate complicity in genocide in Sudan was much greater than its interest in hearing the Trovan case, since the violations alleged in the Trovan case were not of norms of ‘universal concern.’^{xxxvi} However, in contrast to the Canadian corporate defendant in *Talisman*, Pfizer resided in the Trovan Court’s very own jurisdiction.

The unfair exclusionary potential of the doctrine has been eased in England in cases where a ‘justice exception’ is recognised. It was recognised in the leading English case *Spiliada* that while in English courts a stay will be granted where the court is satisfied that there is another available forum with jurisdiction (which is the more appropriate forum ‘in the interests of all the parties and the ends of justice’), if a plaintiff can establish objectively by cogent evidence that he will not obtain justice in the foreign forum, then a stay of the English proceedings should not be granted.^{xxxvii} The fact that impecunious South African plaintiffs before the House of Lords in *Lubbe v Cape PLC*^{xxxviii} would not have had funding to pursue their asbestosis claim in South Africa – otherwise the natural forum for the dispute – enabled them to pursue the parent company in London in respect of past negligent workplace practices. Such an approach, while it has not been received without criticism (see generally Morse, 2002), is at least encouraging to plaintiffs of the sort we are discussing.

The approach of Australian courts would represent considerably less difficulty to plaintiffs in the position of the Trovan class. Australia holds to the traditional *forum non conveniens* doctrine that even if another possible forum exists, where a plaintiff properly invokes the jurisdiction of an Australian court, the court must not decline to hear the case unless of the opinion it is a ‘clearly inappropriate forum’ in the sense that the choice by the plaintiff to sue there is ‘vexatious and oppressive’ to the defendant: *Voth v Manildra Flour Mills*.^{xxxix} There is an extensive literature on the merits of the Australian approach against the *Spiliada* one, which it is not necessary to cover here (see Bell, 2002: 164; Prince, 1998).^{xl} The Australian approach makes it difficult for companies based in Australia to escape accountability if sued by a foreign plaintiff. From the perspective of transnational tort plaintiffs in developing countries, the Australian doctrine is thus preferable. It is also arguably more globally responsible, and acts as an incentive to Australian companies to adopt good environmental and safety standards in their overseas operations (Prince, 1998), although perhaps to their competitive disadvantage.

The US version of the doctrine is now routinely used to block personal injury plaintiffs from developing countries seeking a remedy in US courts. Arguably, the doctrine was developed primarily in relation to commercial transactions and disputes: the concern over forum shopping relates almost entirely to commercial and especially maritime disputes (Prince, 1998; Van Lynden, 1998). It is arguable that the implications of the doctrine are quite different in the personal injury (non-market tort) context. This is not the place to attempt a reconciliation of the debates on the wider aims of tort law. However, it is at least not obvious or universally accepted that the primary policy objective to be reflected in the content of the rule is systemic efficiency rather than justice in any one case. As a general matter, a defendant’s home jurisdiction should only rarely be considered an inconvenient forum. While problems of evidence-taking in foreign personal injury class actions give support to defendants’ stay applications, it is difficult to accuse injured subjects (facing no real prospect of a

satisfactory local remedy) of inconvenient ‘forum shopping’ where they seek to sue a defendant research corporation in its home jurisdiction, where that defendant might itself have been shopping around for a foreign trial site holding the least likelihood of homing legal accountability.^{xii}

The European system is also instructive. Article 2 of the 1968 *Brussels Convention* precludes application of the doctrine where the defendant is domiciled in the EU.^{xiii} Ideally, in a system of ‘equal’ legal systems, a globalised version of the 1968 *Brussels Convention* might decrease the uncertainty associated with *forum non conveniens*. However, the Hague Conference negotiations on a universal convention on jurisdiction have somewhat stalled in recent years.^{xiiii} And legal systems in developing countries where drug trials take place are not generally the equals (in terms of resources, efficiency and independence) of first world systems. While comity and avoiding judicial chauvinism are traditionally given as reasons for declining to hear cases relating to events in other countries, observers have seldom referred to the comity implications of deciding *not* to hear cases about the allegedly wrongful conduct of one’s private corporations abroad (cf Prince, 1998, p 580).

The wider barrier that plaintiffs face in relation to *forum non conveniens* may be the isolation of the field to which the doctrine belongs – private international law. Feminist critiques have of course demonstrated how the public/private distinction in IHRL excludes private actors and action from scrutiny, to the disadvantage of victims (Chinkin, p 1999). Joel Paul has shown, in the context of the struggle of Bhopal gas disaster victims to sue US company Union Carbide in the US in the 1980s, how even as economic globalisation and integration transforms all our experiences, it does not seem to touch the rigid separation of the two branches – public and private – that we use to describe international law fields. He argued that the separation is in fact only recent, and – like the development of the *forum non conveniens* doctrine – driven by market forces, for the purposes of ensuring that commercial or private transnational conduct is insulated from public regulation (Paul, 1988). Thus, the use of the *forum non conveniens* doctrine in the *Union Carbide* decision illustrated, according to Paul, an implicit acceptance by the Court that neither the company nor the US and its courts were ultimately responsible for the acts of Union Carbides’ subsidiary abroad (Paul, 1988; see also Baxi and Paul, 1986; and Baxi, 2001; cf Cummings, 1986).

4. Conclusion

Public (and global) health and human rights are powerful approaches to advancing human well-being and change (Mann 1994). But there is a need to conceive of injured trial subjects’ rights not only as substantive entitlements, but also to examine the procedural notions, patterns and forces that limit subjects’ rights of access to forums where they can realise or at least articulate those rights.

We have argued that a number of major obstacles exist for plaintiffs seeking to demonstrate that their injuries were wrongfully caused and require compensation. The barriers may be more practical than legal (Meeran, 2003). Aside from the problem of legal resources and practical capacity to maintain transnational claims, the plaintiff must convince a court or forum (at a domestic or international level) that it has jurisdiction to hear a claim, where research corporations do not have full personality in international law. Further undermining a claim will be the uncertain, imprecise content of those norms pertaining to the rights of subjects in clinical trials. There are available private law actions, based on tort, which can be brought transnationally; however, even if the plaintiff can reach the corporate sponsor in its first world base, the *forum non conveniens* device remains a major hurdle – at least in the US.

Procedural and substantive access to justice for wronged trial subjects is part of the wider issue of balancing the need for accountability of multinational corporations for harmful conduct abroad with the value of limited liability and separate corporate personality, which provide incentives for transnational investment and global economic growth.

Another delicate balance requires noting. There is no doubting the need for large-scale drug trials in developing countries directed at locally prevalent diseases.^{xliv} Would increased legal exposure lead to an excessively defensive mindset in researchers, so that strengthening legal remedial mechanisms for adverse events might discourage or undermine effective research? As Article 24 of the *Biomedicine Convention* attempts to articulate, a remedy is called for as a matter of justice where ethical

mechanisms for subject protection have failed. It might be argued that the interests of individual injured subjects should not trump the public health imperatives of research. Fidler has asked whether the longer-term result of increasing the profile of rights in this area might be to prevent tangible progress on treating disease (Fidler, 2001, p337).

It is not clear, however, that rationalising compensation avenues would have such serious effects. There is, rather, a danger that the perception of a lack of (effective or accessible) remedy will discourage people from taking part in useful and proper research. Moreover, this topic must be seen against the backdrop of global disparities in health and health care. It is not then difficult to imagine the resentment, and the feeling of exploitation and impotency, that subjects in developing countries would feel, perceiving a lack of remedy when exposed to the risks of research without enjoying its benefits. Principle, evident rational self-interest and long-term interdependence in pursuing global health solutions (Singer and Benatar 2001) thus suggest that remedial avenues require attention.

Endnotes

ⁱ For example, in 1994, the United States liberalised rules on new drug research, allowing the use of foreign data. The number of requests for foreign drug trial approvals from the US Food & Drug Administration (FDA) increased by sixteen times between 1990 and 1999 (Dubois, 2003).

ⁱⁱ Another major ethical debate is between ‘cultural relativists’ and ‘universalists’ concerning the validity of transplanting to other cultures ethical principles derived from Western traditions (see Macklin, 1999a; 1999b).

ⁱⁱⁱ Ethical and regulatory concerns associated with international research in developing countries were covered in a detailed series of investigative reports in *The Washington Post* in December 2000, entitled ‘The Body Hunters’ (<<http://www.washingtonpost.com/wp-dyn/world/issues/bodyhunters/>>) [2 April 2004].

^{iv} In the absence of effective review mechanisms in the host country, the National Bioethics Advisory Commission in the United States (2001) recommended that clinical trials be approved by ethics committees in both the host jurisdiction as well as an American Institutional Review Board.

^v *World Medical Association Declaration of Helsinki* 1964 (last amended Edinburgh 2000)

(<<http://www.wma.net/e/policy/b3.htm>>) [2 April 2004].

^{vi} The summary of facts is based on the plaintiffs’ statement of claim in the US District Court proceedings n viii, below. The Court was there bound by rules of procedure (for the purposes of a motion to dismiss) to typically accept the material facts alleged in the complaint as true and construe all reasonable inferences in the plaintiff’s favour: see *Grandon v Merrill Lynch & Co* 147 F.3d 184, 188 (2nd Cir. 1998). In the same way, our discussion can proceed from some assumption of the facts, since our purpose is to show the systemic operation of the doctrines that affect plaintiffs in these situations.

^{vii} Plaintiffs’ also allege that subjects in the control group (treated with an existing, approved treatment) were purposefully ‘low-dosed’, in order to improve the comparative results of Trovan, and that this caused further avoidable injury and death. Pfizer claimed that it lost only 6% of patients in both the Trovan and Control groups (Shah, 2002). Bacterial meningitis is fatal in one in 10 cases and one in 7 survivors is left with severe handicap, such as deafness or brain injury: see National Meningitis Association website at <www.nmaus.org> [30 September 2003].

^{viii} *Abdullahi v Pfizer Inc.* (01-Civ.8118, 2002 WL 31082956 (SDNY), 17 September 2002). A class of Nigerian plaintiffs is also currently suing in Connecticut, where Pfizer’s huge research and development complex is located.

^{ix} In Nigeria’s Kano Federal High Court: *Zango & Others v Pfizer* (FHC/K/CS/204/2001).

^x News, *British Medical Journal* 2003, pp 326;899, (26 April 2003).

^{xi} *Abdullahi v Pfizer Inc* [2003] (02-9223 (2d Cir. 8 October 2003)).

^{xii} See *Lubbe v Cape PLC* [2000] 1 WLR 1545; Morse, 2002.

^{xiii} *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. European Treaty Series No. 164 <<http://conventions.coe.int/treaty/en/treaties/html/164.htm>>

^{xiv} There is also little indication of what the drafters of the *Biomedicine Convention* mean by ‘undue damage’ in Art. 24.

^{xv} The Explanatory Report comments that ‘on the topic of fair compensation, reference can be made to Article 50 of the *European Convention on Human Rights* which enables the Court to afford just satisfaction to an injured party’. However, this must be in relation to a decision or measure taken by an authority of a party to that convention.

^{xvi} For information about the *Convention on Biomedicine*, including information about signatories and ratifications, see the Council of Europe website at: <<http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=8&DF=02/04/04&CL=ENG>>

^{xvii} Also of interest is the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, which has the aim of harmonising drug regulatory standards between the United States, European Union and Japan. Guidelines promulgated by this body have also been formally adopted in other countries, such as by the Therapeutic Products Directorate of Health Canada. See: <http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/goodclin_e.pdf>

^{xviii} European Union Directive on Clinical Trials (Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use) *Official Journal of the European Communities* L

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121/34 (1.5.2001) (<http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf>

^{xxix} Medicines Control Agency (UK). Consultation letter on the *Medicines for Human Use (Clinical Trails) Regulations 2003* (MLX 287) (Feb. 21, 2003) <<http://www.doh.gov.uk/clinicaltrialsconsult/clintrials-consultation.pdf>>

^{xxx} A 2001 decision by a Maryland Court of Appeal specifically invoked the *Code* to fill a gap in domestic law on non-therapeutic paediatric research: *Grimes v. Kennedy Krieger Institute, Inc* [2001] 366 Md. 29, 782 A.2d 807.

^{xxxi} *Xuncax v. Gramajo* [1995] 886 F.Supp. 162 (D.Mass. 1995); *Wiwa v Royal Dutch Petroleum Co* [2000] 226 F.3d 88 (2d Cir. Ct App, 2000).

^{xxxii} *Forti v Suarez-Mason* [1987] 672 F.Supp 1531 (ND Cal 1987), 1543; *Wiwa* n xxi above. On the difficulty perceived by courts in giving content to ‘amorphous’ international law standards, see *Tel-Oren v Libyan Arab Republic* [1984] 726 F.2d 774 (DC Cir. 1984).

^{xxxiii} *Helsinki Declaration* n v above; the *Nuremberg Code* constituted part of the judgment resulting from *U.S. v. Karl Brandt et al., Trials of War Criminals Before the Nuremberg Military Tribunal Under Control Council Law No. 10*, Vol. 2, Nuremberg, October 1946 - April 1949. (Washington, DC: US Government Printing Office, 1949), p 181-182.

^{xxxiv} Article 25 of the *European Convention on Human Rights* 1950 (ECHR) would not appear to preclude a non-EU citizen developing national country from bringing an individual petition to the relevant commission, and thence possibly to the European Court of Human Rights, where the trial sponsor is a State signatory to the ECHR.

^{xxxv} A claimant would face other significant hurdles, most importantly the requirement under Article 5(2) to show exhaustion of all available domestic remedies.

^{xxxvi} *The Presbyterian Church of Sudan & Others v Talisman Energy Inc & The Republic of Sudan* [2003] 244 F.Supp. 2d 289 (SDNY 2003).

^{xxxvii} *Sosa v Alvarez-Machain* [2003] 266 F. 3d 1045 (9th Cir. 2001), *reheard en banc*, 331 F. 3d 604 (9th Cir. 2003), *certiorari granted* 1 December 2003.

^{xxxviii} Famously, in the Bhopal Gas Disaster litigation, suing in the US was seen as necessary because the local Indian Union Carbide entity implicated in the negligence suit was in effect an empty shell: *Re Union Carbide Corporation* 634 F. Supp 842 (1986); see eg Baxi 1986; Paul 1988.

^{xxxix} *Ncgobo v Thor Chemicals* and *Sithole v Thor Chemicals*, unreported, *Times Law Review*, 10 November 1995 and 15 February 1999; *Connelly v RTZ Corporation Plc and Ors* [1997] 3 WLR 373; [1998] AC 854; and *Lubbe v Cape PLC* [2000] 1 WLR 1545; cf *Adams & Others v Cape PLC* [1990] Ch. 433.

^{xxx} Kirby J, High Court of Australia in *Renault v Zhang* [2002] 187 ALR 1, [86], quoting Cardozo J.

^{xxxxi} The doctrine has a wide array of formulations and operations in different US state jurisdictions: see Weintraub *et al* 2001.

^{xxxii} As the *Trovan* Court explained, ATCA jurisprudence maintains that an alternative forum is ‘adequate’ if the defendants are subject or amenable to service of process there and the forum permits litigation of the disputed subject matter. It need not be a perfect forum. A forum foreign will be considered inadequate where conditions in the forum demonstrate that plaintiffs are unlikely to obtain basic justice there, but arguments that the other forum is too corrupt to be effective have seldom succeeded in fact. See for example *Aguinda v Texaco Inc* [2001] 142 F.Supp 2d 534 (SDNY 2001) (World Bank report and US government statements on Indonesian judicial corruption did not render that other forum inadequate).

^{xxxiii} The *Trovan* court held that as foreign nationals with no significant ties to the district, the plaintiffs were not to be afforded a presumption in favour of their choice of forum.

^{xxxiv} It was on this question that the *Trovan* litigation has been returned to the District Court by the Court of Appeals for the Second Circuit: see n xi above.

^{xxxv} *Gulf Oil Corp. v Gilbert* [1947] 330 US 235 (1947). Those factors include court congestion, unfairness of imposing jury duty on a community ‘with no relation to the litigation’, the interest in having localised controversies decided at in that locality, avoiding problems in the conflict of laws and the application of foreign law. Private factors include ease of access to evidence, cost and convenience of witnesses attending trial, availability of compulsory process and other factors that might shorten the trial or make it less expensive. From those factors, the court must determine whether a trial would either create oppressiveness and vexation for the defendants out of proportion to plaintiff’s convenience, or be inappropriate because of considerations affecting the court’s own administrative and legal problems.

^{xxxvi} See n xxvi, above.

^{xxxvii} *Spiliada Maritime Corp v Cansulex Ltd* [1987] AC 460, 478. See also *Connolly v RTZ Corp Plc* [1998] AC 854, 872. English courts look at factors similar to the *Gilbert* private interest factors, while public interest factors operate under the surface.

^{xxxviii} *Lubbe v Cape Plc* [2000] 1 WLR 1545.

^{xxxix} *Voth v Manildra Flour Mills* [1990] 171 CLR 538; *Renault SA v Zhang* [2002] 187 ALR 1.

^{xl} The Australian approach has been criticised as ‘mistaken’ in Australia’s leading text on the field, the *Spiliada* balancing doctrine being seen as more appropriate to contemporary circumstances and more harmonious with international law and comity: Nygh & Davies 2002; see also comments of Kirby J in *Renault SA v Zhang* [2002] 187 ALR 1, [94].

^{xli} See Evans LJ’s related critical comments on ‘reverse forum shopping’ in the Court of Appeal in *Lubbe v Cape PLC* [1998] CLC 1559; the ‘forum shopping’ label was unwarranted in the *Lubbe* case, where the alternative to suing in London was an inability to pursue the claims at all: Meeran, 2003.

^{xlii} *The Brussels Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters* 1968. Also EC Council Regulation 44/2001. See *Group Josi Reinsurance SA v Universal General Insurance* [2000] All ER (EC) 653, July 2000. It appears likely that this includes the United Kingdom: *Owusu v Jackson* [2002] ECWA Civ 877 (referred to the ECJ; cf *Harrods (Buenos Aires) No 1* [1994] 4 All ER 334).

^{xliii} See progress at <www.cptech.org/ecom/jurisdiction/hague.html#cptdocs>

^{xliiv} We do not here comment on whether international drug trials, the results of which have no intended or likely local application, can ever be justified. The situation is complicated where developing countries positively welcome such research. Apart from hard cash or other incentives, an incident of the presence of a first world medical research team might be better basic medical attention in the area. Of course, one cannot assume that the interest of local decision-makers in the trial can be taken to represent that of the population at large. See generally inaugural issue of *Developing World Bioethics* vol 1:1 (2002) Symposium: ‘Drugs for the Developing World’.

References

Addo, M (ed) (1999) *Human Rights Standards and the Responsibility of Transnational Corporations* (Boston: Kluwer).

Anderson, M (2002) ‘Transnational Corporations and Environmental Damage: is Tort Law the answer?’ *Washburn Law Journal* 41(3), p 399.

Annas, G J (1992) ‘The Nuremberg Code in U.S. Courts: Ethics versus Expediency’, in Annas, G J and Grodin, M A (eds) (1992) *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (New York: Oxford).

Annas, G J and Grodin, M A (1992) *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (New York: Oxford).

Baxi, U and Paul, Y (1986) *Mass Disasters and Multinational Liability: the Bhopal Case* (Bombay: Sweet & Maxwell (Indian Law Institute)).

Baxi, U (2001) ‘Geographies of Injustice: Human Rights at the Altar of Convenience’, in Scott, C (ed) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Oxford: Hart Publishing), p 197.

Bell, A (2003) *Forum Shopping and Venue in Transnational Litigation* (Oxford: Oxford University Press).

Chinkin, C (1999) ‘A Critique of the Public / Private Dimension’, *European Journal of International Law* 10, p 387.

Clapham, A (1993) *Human Rights in the Private Sphere* (Oxford: Oxford University Press).

Clapham, A (2001) ‘Using the *European Convention on Human Rights* to Protect the Right of Access to the Civil Courts’, in Scott, C (ed) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Oxford: Hart Publishing), 513.

Crawford, J (2002) *The International Law Commission's Articles on State Responsibility: Introduction, Text and Commentaries* (Cambridge, Cambridge University Press).

Cummings, S (1986) 'International Mass Tort Litigation in the Light of the Bhopal Disaster', *Georgia Journal of International and Comparative Law* 16, p 109.

de Zulueta, P (2001) 'Randomised placebo-controlled trials and HIV-infected pregnant women in developing countries: ethical imperialism or unethical exploitation?' *Bioethics* 15(4), p 289.

De Wachter, M A (1997) 'The European Convention on Bioethics' *Hastings Center Report* 27(1), p 13.

Dubois, W (2003) 'New Drug Research, the Extraterritorial application of FDA Regulations, and the Need for International Cooperation', *Vanderbilt Journal of Transnational Law* 36, p 161.

Dominguez-Urban, I (1997) 'Harmonization in the regulation of pharmaceutical research and human rights: the need to think globally' (1997), *Cornell International Law Journal* 30, p 245.

Council of Europe (1997) *Explanatory Report to the Biomedicine Convention*, <<http://www.legal.coe.int/bioethics/gb/pdf/rapport.pdf>>

Fawcett, J (ed) (1995) *Declining Jurisdiction in Private International Law* (Oxford:Oxford University Press).

Fidler, D (2001) "'Geographic Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries', *Harvard International Law Journal* 42, pp 2, 299.

Koh, H (1991) 'Transnational Public Law Litigation', *Yale Law Journal* 100, p 2347.

Lowenfeld, A (1996) *International Jurisdiction and the Quest for Reasonableness: Essays in Private International Law* (Oxford: Oxford University Press).

Lurie, P and Wolfe, S M (1999) 'Proposed Revisions to the Declaration of Helsinki. Paving the way for Globalization in Research', *Western Journal of Medicine* 171(1), p 6.

Macklin, R (1999a) 'International Research: Ethical Imperialism or Ethical Pluralism?' *Accountability in Research* 7(1), p 59.

Macklin, R (1999b) *Against relativism: Cultural Diversity and the Search for Ethical Universals in Medicine* (New York, Oxford University Press).

Mann, J *et al* (2003) 'Health and Human Rights', *Health and Human Rights* 1, p 8.

Meeran, R (2003) 'Corporations, Human Rights and Transnational Litigation' Lecture, Castan Centre for Human Rights Law, Melbourne, 29 January 2003 at (<www.law.monash.edu.au/castancentre/events/2003/meeranpaper.html>)

Meier, B (2002) 'International protection of persons undergoing medical experimentation: Protecting the right of informed consent', *Berkeley Journal of International Law* 20, p 513.

Moran, M (2001) 'An Uncivil Action: The Tort of Torture and Cosmopolitan Private Law', in Scott, C (ed) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Oxford: Hart Publishing).

Morse, C (2002) 'Not in the Public Interest? *Lubbe v Cape PLC*', *Texas International Law Journal* 37, p 541.

Nygh, P and Davies, M (2002) *Conflict of Laws in Australia* (Sydney, Butterworths).

Office of Inspector General (2001) *The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects*. Rep. No. OEI-01-00-00190.

Orlowski, V (2003) 'Promising Protection Through Internationally Derived Duties', *Cornell International Law Journal* 36.

Paul, J (1988) 'The Isolation of Private International Law', *Wisconsin International Law Journal* 7 (1), p 149.

Pettyjohn, M (2003) 'Bring me your tired, your poor, your egregious torts yearning to see the green: the Alien Tort Statute', *Tulsa Journal of Competition and International Law* 10, p 513.

Prince, P (1998) 'Bhopal, Bougainville and *OK Tedi*: Why Australia's *Forum Non Conveniens* Approach is Better', *International and Comparative Law Quarterly* 47, p 573.

Roberston, D (1994) 'The Federal Doctrine of *Forum Non Conveniens*: An "Object Lesson in Uncontrolled Discretion"', *Texas International Law Journal* 29, p 353; cf Weintraub, R (1994) 'International Litigation and *Forum Non Conveniens*', *Texas International Law Journal* 29, pp 323 – 352.

Rogge, M (2001) 'Towards Transnational Corporate Accountability', *Texas International Law Journal* 36, p 299.

Scott, C (ed) (2001) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Oxford: Hart Publishing).

Scott, C (2001a) 'Translating Torture into Transnational Tort', in Scott, C (ed) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Oxford: Hart Publishing), p 47.

Shah, S (2002) 'Globalising Clinical Research', *The Nation*, 1 July 2002.

Singer, P A and Benatar, S R (2001) 'Beyond Helsinki: A Vision for Global Health Ethics', *British Medical Journal* 322(7289), p 747.

Sornaraja, M (2001) 'State Responsibility for Harms by Corporate Nationals Abroad' in Scott (ed) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Oxford: Hart Publishing), p 491.

Steinhardt, R and D'Amato, A (eds) (1999) *The Alien Tort Claims Act: An Analytical Anthology* (New York: Transnational).

Stephens, R (2000) 'Where Profits and Lives Hang in the Balance: Big Drug Companies Test Offshore to Speed Products to Market', *The Washington Post*, 17 December 2000.

Swan, M (2001) 'International Human Rights Tort Claims and the Experience of United States Courts', in C. Scott (ed) *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Oxford: Hart Publishing).

Todres, J (2000) 'Can Research Subjects of Clinical Trials in Developing Countries Sue Physician-Investigators for Human Rights Violations?', *New York Law School Journal of Human Rights* 16, p 373.

Baron van Lynden, C (ed) (1998) *Forum Shopping* (London: LLP).

von Freyhold, H (1996) 'Cross-Border Legal Interactions in New York Courts' in Volmar Gessner (ed) *Foreign Courts: Civil Litigation in Foreign Legal Cultures* (Aldershot: Dartmouth Publishing Company).

Waldmeir, P (2001) 'The Guinea Pigs demand Justice', *Financial Times*, 18 October 2001.

Weintraub, R *et al* (2002) 'International Forum Shopping' (Symposium) *Texas International Law Journal* 37, pp 463-588.