

CHAPTER THREE

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GLOBALIZATION AND CLINICAL TRIALS

Compensating subjects in developing countries

Globalization has contributed to fundamental changes within the biomedical research endeavor. Indeed, when considered in concert with the effects of commercialization, the transformation might be described as dramatic. With the ongoing consolidation of the pharmaceutical research industry into massive multinational corporations, the scope of the business of developing medical products has grown to unprecedented levels, spanning across national boundaries and affecting health care consumers throughout the world. The influence of the global pharmaceutical industry is both reflected in and strengthened by international treaties protecting drug patents and initiatives to harmonize regulatory requirements.¹ At the national level, industry has been shown to have a significant influence on setting research agendas, public health policy and the education and practices of health care professionals.² And as this chapter will argue, globalization of the pharmaceutical industry can also be felt on an individual level.

Specifically, we will address the problem that arises when a human subject from a developing country is injured or dies in a clinical trial conducted by a first-world sponsor. We submit that this scenario, which operates at the interface of developing world ethics, human rights advocacy and international law, is instrumental in examining how conflicts of laws may interfere with the goal of promoting global social justice.

Protecting human subjects in international clinical trials requires a range of solutions, including capacity building within developing countries to establish or improve regulatory oversight mechanisms, professional education to foster ethical conduct by investigators and political pressure to promote socially responsible corporate practices. As this chapter will contend, it is also vitally important that legal systems in first-world jurisdictions protect subjects from developing countries and permit access to justice in first-world courts to enable them to obtain compensation.

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THE NEED FOR HUMAN SUBJECTS: ENTER DEVELOPING COUNTRIES

Human subjects are, in a sense, an indispensable commodity for achieving commercial objectives in biomedical innovation. The continued profitability of pharmaceutical multinationals depends on maintaining a pipeline of new – or, in the case of ‘me-too’ drugs,³ somewhat-new – drugs and medical devices that can be brought to market. The clinical trial, with both animals and humans, remains an integral part of product development. Successful clinical trials involving human subjects proving safety and efficacy are likewise necessary in order to obtain regulatory approval before a product can be marketed. The profitability of pharmaceutical multinationals ultimately depends, therefore, on the availability of human subjects.

Fueling the development pipeline has led to a substantial increase in the volume and diversity of clinical trials over recent decades (NBAC 2001b, 4), with a corresponding increase in the demand for human subjects. Unsurprisingly, concomitant with the proliferation of international research, these trends are also evident in developing countries (OIG 2001, 6).

A number of reasons have been cited for this latter development, including: access to a larger pool of human subjects, clearer result yield and the need to accelerate approval for new drug marketing (*id.*, 8-9). Host governments and investigators in developing countries also appear eager to attract research (NBAC 2001a, 1). However, it has also been suggested that 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 on the occasion of an adverse event (Lurie and Wolfe 1999).

At first blush, one might consider that the selection of a developing country in the course of “jurisdiction shopping” in response to market forces is not inherently problematic. Adopting the most cost-effective course of action is, after all, good business. Even preferences for a less onerous regulatory environment (which can lead to bringing a product to market faster) and for jurisdictions with lower risk of litigation can translate into cost savings. Nevertheless, furthering commercial objectives at the expense of human rights, individual well-being and moral values should engender serious concern.

An ethical, regulatory or legal concern?

The conduct of clinical trials involving human subjects in developing countries by first-world sponsors presents a host of ethical, regulatory and legal dilemmas. As with human subject protection generally, the issues raised are interrelated. Engaging with the main legal focus of this chapter on access to justice by developing world plaintiffs, therefore, requires a preliminary discussion of these related issues.

An ethical concern

Absent an appropriate allocation of risks and benefits, first-world sponsored research in developing countries would seem intrinsically unethical.

The primary ethical concern relates to the problem of exploitation, which can be defined as occurring when wealthy or powerful agents “take advantage of the poverty, powerlessness, or dependency of others to serve their own ends, without a sufficient benefit for the less advantaged individuals or group” (NBAC 2001a, 10; see also Macklin 2004, 99-130). With regard to this issue, the recently revised *International Ethical Guidelines for Biomedical Research Involving Human Subjects* produced by the Council for International Organizations of Medical Sciences (CIOMS) pronounces squarely against the commercially motivated practice of selecting developing countries for first-world sponsored research mentioned earlier:

Sponsors of research or investigators cannot, in general, be held accountable for unjust conditions where the research is conducted, but they must refrain from practices that are likely to worsen unjust conditions or contribute to new inequities. Neither should they take advantage of the relative inability of low-resource countries or vulnerable populations to protect their own interests, by conducting research inexpensively and avoiding complex regulatory systems of industrialized countries in order to develop products for the lucrative markets of those countries. (CIOMS 2002, 11)

The guiding principle here is distributive justice, which requires the equitable distribution of risks and benefits arising from research. Research should have direct relevance to the local communities from which subjects are drawn, and those communities should enjoy the benefits derived from their collective sacrifice (see generally, Macklin 2004, 68-98). Unfortunately, it has been frequently observed that only a small fraction of pharmaceutical industry expenditure on research and development has resulted in approved drugs for tropical diseases, with the balance of industry funding having been dedicated to first-world illnesses (Shah 2003, 30).⁴

Even without direct benefits accruing to the country from which subjects are drawn, benefits can be gleaned from the establishment of a clinical trial infrastructure, including the training of local investigators. Presumably, this would translate into much-needed research on diseases specific to developing countries at a local level. Such potential economic, educational and health gains should not be discounted. However, as the concern with the impact on individual subjects remains, considerations extrinsic to subjects’ interests should not obviate the need for effective regulatory and legal frameworks that are geared to protect the rights of subjects, including with regard to securing their right to compensation.

A regulatory concern

Ethical concerns about distributive justice and exploitation lead to important regulatory considerations. It has been observed that developing countries often have limited capacity to evaluate and monitor clinical trials through lack of adequate regulatory infrastructure, or are faced with a substantial conflict of interest, given their strong desire to attract foreign research (NBAC 2001a, 82-3). The key

question, then, is: who should be responsible for the protection of human subjects in developing countries?

An obvious solution to this problem is for developing countries to address this concern themselves. However, it would be overly harsh to place the burden of establishing systems to regulate clinical trials squarely upon the shoulders of developing countries, considering that there are far more pressing problems facing such countries and limited resources with which to respond to these problems. Nevertheless, a substantive system of research governance entrenched at the national level would indeed be the ideal solution. To that end, the Nuffield Council on Bioethics (2002, para 8.16) made the following recommendation:

We recommend that all developing countries should have in place a properly constituted and functioning system for the independent ethical review of research. This will include the establishment of effective research ethics committees. Developing countries may determine that the most appropriate means of reviewing externally sponsored research is via an independent national research ethics committee. In such circumstances the establishment, funding and proper operation of independent national research ethics committees should be the responsibility of national governments. No research should be conducted without review at the national or local level.

Guidance for developing countries for the establishment of ethics committees has also been offered by the World Health Organization (WHO 2000; 2002), with further sources on convergent ethical principles available in the form of international guidelines, such as the World Medical Association's *Declaration of Helsinki*⁵ and CIOMS guidelines (2002).

Conversely, it would also be inappropriate to demand that the country of a first-world sponsor become the singular guardian of developing world subjects. Such an approach runs afoul of concerns about paternalism or, as will be discussed below, "ethical imperialism." More practically, there may be problems with the extraterritorial application of sponsor-country regulations (Dubois 2003). This latter concern would be even greater where reliance is placed on "soft" controls, such as professional ethical guidelines, rather than official regulations. In this respect, the proposal (made in the US context) that a system of accreditation of research institutions would be "the only workable means of ensuring that American medicine does not provide benefit at the expense of the inhabitants of developing nations" (Kelleher 2004-5, 106) ought to be held in reserve for the time being. The current initiative for accreditation of research ethics committees in the United States is in its early stages, and despite having strong proponents within the US research establishment (IOM 2001), its effectiveness for protecting human subjects is yet to be assessed at the local level, let alone for participants in foreign trials.⁶

The Nuffield Council did not, of course, simply recommend that research ethics oversight should be solely the responsibility of host jurisdictions in the developing world; it also made recommendations relating to the responsibilities of first-world sponsor jurisdictions. A balanced approach, advocated by both the Nuffield Council (2002, paras 8.22-8.29) and National Bioethics Advisory Commission in the United States (NBAC 2001, 82-91), would require oversight by both host and sponsoring jurisdictions. Both bodies also recommended that first-world sponsors should

contribute to capacity building in the host jurisdiction. Capacity building, which would “develop and implement strategies that assist in building local capacity for designing, reviewing, and conducting clinical trials in developing countries” (id., 91), would have the added benefit of decreasing the reliance by host jurisdictions on first-world oversight mechanisms and facilitate the pursuit of research priorities for the developing world.

Admittedly, first-world support for dual oversight is not wholly altruistic, as it would also serve to ensure compliance with standards of good clinical practice and thereby help to alleviate concerns by drug regulatory agencies about the quality of data obtained from foreign trials. Even the recommendation that first-world sponsors and researchers should participate in capacity building may also be rooted in practical considerations, as it would likewise serve to enhance the quality and reliability of foreign trial data. Such motives, however, should not be seen to detract from the benefits that dual review and capacity building might provide.

Based on a growing body of scholarship on international research ethics and thorough inquiries such as have been conducted by the Nuffield Council, National Bioethics Advisory Commission and other bodies,⁷ one can safely hold out as predominant the view that first-world jurisdictions have clear ethical and regulatory obligations with respect to clinical trials in developing countries. Nonetheless, even where these obligations are satisfied, further considerations will remain of a legal nature. Owing to the level of uncertainty inherent in biomedical research, adverse events can always eventuate, despite even the most stringent system of regulatory oversight. Subjects can be injured or die in the course of a clinical trial. Thus, while regulatory measures that uphold ethical principles of distributive justice will undoubtedly contribute to the aim of protecting the rights of human subjects, account needs to be taken of issues related to compensation for subjects and the corresponding legal liability of sponsors.

A legal concern

It is undisputed that subjects are entitled to compensation for injuries sustained in the course of their participation in a clinical trial or biomedical research protocol. Research sponsors, institutions, investigators, ethics committees and even committee members may all be liable. Recent litigation in the United States has demonstrated that researchers will indeed be held to account for injuries to subjects.⁸ Institutions have thus rightly been encouraged to guard against such liability by ensuring that external sponsors have “appropriate and sufficient insurance to meet [their] legal liability to research subjects for harm arising out of the particular research” (Legal Liability Working Group 1994; see also NHMRC 1999, 36). The investigator’s obligation to provide compensation for injured subjects is well stated in the CIOMS guidelines (2002, Guideline 19):

Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their

dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation.

The right to compensation and corresponding legal liability would also extend to subjects in developing countries. As the European Group on Ethics in Science and New Technologies of the Council of Europe advocated in relation to clinical trials in developing countries, “The standards of insurance, liability and indemnity insurance for the participants in a clinical trial and their families must provide the same kind of protection wherever a trial takes place” (EGE 2003, 15).

A major problem, however, from the perspective of developing world subjects, is that clear lines of international accountability and transnational mechanisms for enforcing a claim for compensation are generally lacking. As the following section will show, procedural and substantive obstacles in international law can operate to frustrate efforts to bring an action in first-world courts, effectively insulating first-world researchers from claims arising from their activities. The developing world plaintiff thus faces the difficult challenge of access to justice.

OBTAINING COMPENSATION: EXIT FIRST-WORLD SPONSOR

The quest for compensation by an injured subject from a developing country intersects with the areas of tort law and international human rights law (Fidler 2001; Todres 2000). The balance of this chapter is concerned with the latter, where the developing world plaintiff must overcome both procedural and substantive hurdles:

- (i) locating a mechanism to obtain a remedy under international law;
- (ii) establishing the existence of subjects’ rights under international law, which must occur prior to proving their breach; and
- (iii) overcoming barriers arising from the *forum non conveniens* doctrine.

The Trovan Trial litigation is ongoing at the time of writing, involving the families of child subjects in Nigeria and Pfizer, a multinational pharmaceutical company based in New York. Nevertheless, it provides an excellent case study through which to illuminate the problems caused by the systematic operation of jurisdictional rules on transnational access to justice.

The Trovan Trial litigation

In December 2000, the *Washington Post* ran an investigative series entitled, “The Body Hunters.” It raised concerns about foreign-sponsored clinical trials conducted in Africa, Latin America, China and Eastern Europe. The first article in this series featured the Trovan Trial that forms the basis of this case study. The article sparked outrage in both Nigeria and the United States, with official inquiries and litigation having been instituted in both countries (Shah 2003, 34).

The events leading up to this litigation can be summarized as follows.⁹

In early 1996, serious epidemics of bacterial meningitis and cholera broke out in northern Nigeria. Pfizer, a leading transnational pharmaceutical company based in the United States, took this opportunity to conduct a clinical trial to test the efficacy

of its new broad-spectrum antibiotic, Trovan,¹⁰ as an oral treatment for meningitis in children. A clinical trial was quickly organized and conducted with the cooperation of Nigerian authorities. The US Food and Drug Administration expedited 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.¹¹ It is alleged that a number of child subjects died or sustained permanent disabilities, such as paralysis, deafness or blindness, as a result of participation in the trial.

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 relied on a federal statute, the *Alien Tort Claims Act*.¹² They pleaded that Pfizer had violated the customary international law prohibition of non-consensual human experimentation, argued to be codified in Article 7 of the *International Covenant on Civil and Political Rights*: "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 plaintiffs allege that Pfizer failed to explain to the parents of child subjects that the treatment was experimental, that Trovan had the potential to cause serious side effects, that participation in the study could be refused, and that conventional treatments were available at the same site free of charge from other organizations.

Pfizer steadfastly maintains a contrary position:

The study was conducted in accordance with standard international legislation on clinical trials, and the verbal consent of family members of all treated patients...Working in countries where literacy is low, and in the middle of a life-threatening epidemic, it is not always possible to gain consent in writing, but the fact that the treatment was experimental was explained to family of every patient in two languages – English and Hausa – before the treatment was administered.¹³

The plaintiffs contended that 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 forum. The plaintiffs maintained that a US court should hear the case because Pfizer is based there. In September 2002, the US District Court (Southern District of New York) decided that it had jurisdiction to hear the case, but declined in its discretion to do so. The Court required the plaintiffs to attempt to sue Pfizer in Nigeria, which it saw as the natural or proper forum. Accordingly, with Pfizer's undertakings to facilitate an action in Nigeria, the motion to dismiss the action was granted on the basis of *forum non conveniens*.¹⁴

The parallel Nigerian proceedings¹⁵ had been withdrawn or dismissed in August 2002. It was reported in the *British Medical Journal* in early 2003 that the plaintiff families had lost confidence in the Nigerian judicial system, where the 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 blamed the plaintiffs for any delay.¹⁶

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 any impact on the District Court’s analysis of the proper forum.¹⁷

Assuming that a trial on the merits ever proceeds, it would raise complex evidentiary 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.

International law: Lack of forum

The first challenge faced by a developing world plaintiff is to locate a suitable forum in which non-state actors, such as corporations, can be held legally accountable for their activities. Corporations are not yet generally seen as having legal personality in international law,¹⁸ which focuses on systematic abuses of human rights and on the interests and duties of states. A breach of an international norm by a non-state actor will likely be unenforceable under an international human rights forum (Dubois 2003, 203-4). For example, the Trovan plaintiffs would have little chance of success in bringing their claim through mechanisms available under the *International Covenant on Civil and Political Rights* (ICCPR). After showing to have exhausted all available domestic remedies, an individual could conceivably bring a complaint to the Human Rights Committee under the First Optional Protocol to the ICCPR.¹⁹ However, as only states hold duties under the ICCPR, it would have to be shown that a corporation acted under state “direction, instigation or control” for that state to be held responsible (ILC 2001, 80; Crawford 2002).

It has been argued that a state could be indirectly responsible for failing to provide a remedy within its jurisdiction for wrongs by private actors committed in another state (Clapham 1993), such as by providing effective access to domestic courts (Clapham 2001; Addo 1999; Sornarajah 2001). This has been considered specifically with respect to a state’s failure to regulate, control or supervise new drug research as a violation of a fundamental norm, such as the right to life (Fidler 2001, 327-9). Such arguments would seek to make obligations under international human rights law meaningful, particularly in response to the call for setting out legal responsibilities of multinational corporations in such a way that reflects their increased level of influence in a global society (Addo 1999; Koh 1991; Dubois 2003, 203-6). An important aspect of this call for accountability under international human rights law has been to mobilize national law, specifically tort law (Anderson 2002).

The course taken by the Trovan plaintiffs in their US action was to plead their claim under the *Alien Tort Claims Act* (ATCA), which enables a federal court to

hear claims by non-US nationals for torts committed “in violation of the law of nations,” including outside the US (Steinhard and D’Amato 1999; Pettyjohn 2003). The District Court held that a breach of Article 7 of the ICCPR and its equivalent principles in the main biomedical conventions was adequate for the purpose of founding jurisdiction under the ATCA. However, it also held that alleged treatment with experimental drugs without informed consent, “however reprehensible,” fell short of a violation of “universal concern” for which a non-state party might be held responsible. Fortunately, from the plaintiffs’ perspective, the District Court held that a non-state actor can be held in 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 recognized as joint participants, which it held to be the case for Pfizer and the Nigerian government in relation to the Trovan trial. The question then became whether the US or Nigeria was the appropriate forum (which will be discussed below).

As the Trovan litigation illustrates, the major problem of enforceability of non-state actors in international forums can be avoided where a defendant is otherwise subject to US federal court jurisdiction and the requirements under the ATCA can be satisfied. Thus, a claim based on the rights of subjects in developing countries can be brought directly as an international human rights law claim in a domestic forum. The ATCA, however, is a *sui generis* statute, unique to the US. In addition, the future of the ATCA as a measure providing fairly wide extraterritorial civil jurisdiction is uncertain. In 2004, the constitutional validity of prevailing wide interpretations of the ATCA statute’s scope came before the US Supreme Court for the first time. It remains to be seen whether the Court’s decision that the ATCA was originally intended to cover only certain kinds of torts has the effect of narrowing the sorts of claims that might be brought²⁰

It is worth mentioning that a developing world subject might also bring what might be cast as an international human rights claim indirectly by invoking a recognized domestic private law category, such as the torts of battery or negligence (Scott 2001; Moran 2001, 668). Common law courts have always recognized their jurisdiction over torts committed in other countries where the defendant is subject to their control (Lowenfeld 1996). This possibility for plaintiffs such as in the Trovan trial is relatively unexplored (Swan 2001). The appeal of such an approach is that it would be unnecessary to argue the violation of a complex international human rights norm if the law of negligence, for example, would protect the same interests (Scott 2001). Apart from jurisdictional issues, it should not be overlooked that complex and country-specific rules concerning of choice of law – that is, which country’s substantive tort law is applied in resolution of the dispute – might still arise.

Norms under international law

In order to pursue a claim based in international human rights law, as opposed to a simple private law tort claim, there is a need to ground the rights of developing world subjects in an accepted international law norm. While a subject’s right to

informed consent, for example, might be successfully constructed under customary international law by drawing upon a collection of instruments, ethical guidelines and national practices, none of the current international treaties or conventions unequivocally provides such a norm.

The most oft-cited international instruments, the *Nuremberg Code* and *Declaration of Helsinki*, have yet to receive authoritative judicial consideration as a source of norms under customary international law. Arguments have been advanced both in favour (Orlowski 2003) and against (Meier 2002) whether the basic principles enunciated in these documents occupy this status. However, it must be recalled that the *Nuremberg Code* was merely part of a decision reached by a US military tribunal²¹ and has received limited attention to date in domestic courts, including in the United States (Annas 1992).²² The *Declaration of Helsinki*, while broadly endorsed, nevertheless remains a code promulgated by a professional association (the World Medical Association).

The principal international law instrument in this area is the Council of Europe's *Convention on Human Rights and Biomedicine*.²³ An Additional Protocol concerning Biomedical Research was opened for signature 25 January 2005.²⁴ The *Convention* is a landmark achievement towards the entrenchment of ethical principles in biomedicine within a multilateral framework. Consensus supporting its principles, however, is by no means absolute. Principles that would permit non-therapeutic research on vulnerable persons with surrogate consent, for example, attracted vehement resistance in Germany (de Wachter 1997). Indeed, at the time of writing, only thirty-two out of forty-six member states have signed the instrument with just nineteen ratifications. Notable absences among the latter include research-intensive nations such as the United Kingdom, France, Germany and Switzerland.²⁵ More fundamentally, enforcement mechanisms of the *Convention* are limited insofar as it contains no provisions establishing a forum or procedure for dealing with claims of those injured in the course of biomedical research. Rather, as stated in Article 31 of the Additional Protocol, "The person who has suffered damage as a result of participation in research shall be entitled to fair compensation according to the conditions and procedures prescribed by law." The Explanatory Report to the *Convention* notes 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" (Council of Europe 1997, para 146). However, this must be in relation to a decision or measure taken by an authority of a party to that convention.

Article 7 of the ICCPR, while relied upon by the plaintiffs in the Trovan case, is not necessarily of assistance. Indeed, the US Court of Appeal in the Trovan litigation hinted that this determination is critical to their claim; however, both the Court of Appeal and District Court glossed over the issue. Article 7 has not to date formed the basis of any human rights action in the context of human experimentation (Dubois 2003, 203). Fidler's (2001) recent study examining whether placebo-based drug trials in developing countries violated international human rights law norms suggests little promise for potential claimants. While

Article 7 of the ICCPR appears to be a stable fundamental norm at the heart of protecting the integrity and security of the person in international law,²⁶ it is nevertheless an open-textured norm, the content of which is subject to divergent interpretations (Swan 2001, 98; Fidler 2001, 337, 341), and thus lacks specificity. Plaintiffs will therefore face the challenge of demonstrating its breach by any particular drug trial. The matter is further confounded by the absence of definite accepted criteria relating to what constitutes a valid informed consent.²⁷

Brief expansion on the latter point is warranted. The requirement of a subject's voluntary informed consent is supposed to provide some protection against exploitation in research. It has been held out as a fundamental human right, being both an ethical and legal safeguard. A failure to obtain a valid consent may amount to a case of battery or negligence. Establishing the legal standard upon which to assess the validity of informed consent presents yet another challenge for developing world plaintiffs in pursuing their claims. But before one can address informed consent as a legal doctrine, one must wade through the quagmire that is the debate between "cultural relativists" and "universalists" concerning the validity of transplanting ethical principles derived from Western traditions to other cultures. Informed consent, in the Western tradition, is strongly rooted in the primacy of individual autonomy. It has been argued, however, that the consent requirement would be viewed differently in cultures where community-based rather than individual decision making is the norm. In such cases, does forcing a requirement for a Western conception of informed consent on cultures in the developing world amount to "ethical imperialism"? Or, should one adopt a position of "ethical pluralism," which holds that rules governing research practices might vary according to the country where it is carried out?²⁸ A satisfactory resolution of this debate cannot be provided here. However, it merits pointing out that a determination on the issue of the universality of ethical principles is a necessary prerequisite for any judicial consideration of the doctrine of informed consent as it relates to a claim for compensation by a developing world subject.

The forum non conveniens challenge

Regardless of whether a claim is pleaded under the US ATCA or as a private law tort action, a significant challenge to the developing world plaintiff lies in overcoming barriers thrown up by the common law doctrine of *forum non conveniens*. This doctrine allows a court the discretion to decline to hear a claim on the basis that a more appropriate forum exists elsewhere, irrespective of the fact that it could assert jurisdiction over the defendant (Fawcett 1995; Lowenfeld 1996; Bell 2002).

Firstly, the strong presumption in favour of domestic (US) plaintiffs for choice of forum does not apply to foreign plaintiffs.²⁹ The District Court in the New York Trovan proceedings held that it has "a duty to exercise restraint when assessing the sufficiency of other nations' courts and legal systems." While the Court did not deny the plaintiffs' claims of judicial corruption, it nevertheless took the view that Nigeria

is a nation “experiencing difficulties in its transition from a dictatorship to a democracy,” and held that Nigeria would be an adequate forum. For the Court, nothing in the plaintiffs’ submissions on the inadequacy of Nigerian justice reached “beyond the most general of characterizations.” It should be noted, however, that it is on this latter question that the Trovan litigation was returned to the District Court on appeal.

Secondly, the standard for deferring jurisdiction to an alternate forum is not high. A defendant seeking to dismiss an action on the grounds of *forum non conveniens* must demonstrate that an adequate alternative forum exists. As the District Court in the Trovan action explained, an alternative forum is “adequate” under ATCA jurisprudence if the defendants are subject to or amenable to service of process there and the forum permits litigation of the disputed subject matter. It does not have to be a perfect forum. A foreign forum will be considered inadequate where plaintiffs are unlikely to obtain basic justice, but arguments that the other forum is too corrupt to be effective, such as maintained by the Nigerian plaintiffs, have seldom succeeded.³⁰

Thirdly, a plaintiff’s choice of forum must satisfy a balance of public and private interest factors.³¹ A defendant, 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, courts should give weight to the injury having occurred outside the US. The District Court concluded that the public interest factors did not strongly support one forum over the other: Nigeria had a “very strong interest” in the litigation, given the location of the trial and residence status of the subject-plaintiffs; but there was also a strong public interest in having a US Court decide issues of Pfizer’s possible tortious conduct, as Pfizer had developed, produced and performed preliminary testing of Trovan and designed the Kano protocol in the US, all with the ultimate goal of marketing the drug domestically. However, the District Court did conclude that the balance of private interest factors “clearly weighs in favor 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.” On the basis of certain undertakings by Pfizer, including in relation to discovery of documents, the motion to dismiss the New York proceedings was thus granted.

A developing world plaintiff may have good reason to seek compensation from a first-world court: the first-world sponsor might have a subsidiary based in the developing country that is not worth suing, having insufficient assets to cover its liabilities;³² where the sponsor lacks a local presence, it might be difficult to enforce a local judgment abroad; and, as has been alleged in the Trovan litigation, plaintiffs may have concerns about the capacity for their legal system to deliver a judgment that is free from political bias or considerable delay. Unfortunately, the *forum non conveniens* doctrine has made it very difficult for developing world plaintiffs to sue a defendant corporation in its home forum, particularly in the United States. *Forum non conveniens* decisions are often determinative of the overall outcome (Robertson 1994), as the cost of litigation often exhausts the limited legal and financial

resources of plaintiffs who are unable to secure an early settlement (Meeran 2003). It is thus ironic that while new rules have evolved to support the global economy in order to facilitate investment and activities in developing countries, including in the area of biomedical research, a rather old legal doctrine continues to operate to restrict reciprocal access to justice (see also Rogge 2001, 317).

While the *forum non conveniens* doctrine may have rightly originated in order to prevent “forum shopping” in commercial and maritime disputes (van Lynden 1998), justifications based on convenience should not be applied equally to the context of personal injury litigation. Indeed, it would seem incongruous to prevent developing world plaintiffs from “forum shopping” in respect of their choice of jurisdiction to pursue a remedy when first-world corporate sponsors are themselves guilty of “forum shopping” when choosing a developing world venue for a clinical trial in the first place.

CONCLUSION

The debate surrounding the ethics of research on the transmission of HIV in developing countries served to heighten awareness about gross disparities in the availability and quality of health care resources between developing and affluent countries (de Zulueta 2001, 310). It is our hope this chapter has likewise helped to stimulate debate not only on the issues relating to justice in international research canvassed here, but on the broader problem of access by citizens of developing countries to affordable medications, which represents perhaps the most poignant current global health concern.³³

In examining the case of injured subjects from Nigeria and their action against Pfizer, we have argued that a number of obstacles exist for plaintiffs from developing countries seeking to demonstrate that their injuries were wrongfully caused and obtain compensation. While the issues canvassed in the second part of this chapter relate to substantive entitlements and procedural hurdles under international human rights law, they of course translate into problems that can be addressed ultimately only through ethical practices of investigators, sponsors and states (both developing and first-world) that are supported by properly conceived legal and regulatory frameworks.

Many of the issues raised in this chapter are neither new (e.g. Veatch 1971), nor unique to developing countries, as they represent problems that otherwise exist in first-world jurisdictions but are exacerbated by circumstances of limited resources, both in terms of regulatory infrastructure and expertise, prevalent in developing countries. In short, the problem of access to justice by developing world subjects is at once an ethical, regulatory and legal dilemma, as conveyed in the first part of this chapter. Resolving the procedural and substantive problems relating to access to justice for developing world subjects entails a two-tiered response: firstly, it requires locating a balance between the needs for improved accountability of multinational corporations for harmful conduct abroad; and secondly, it requires what may very amount to a paradigmatic shift in the legal, regulatory and ethical foundations

buttressing the global research endeavour. As Benetar, Daar and Singer (2003, 138) aptly noted:

Achieving human development globally requires more than economic growth. It also requires confronting the current challenging context of global health, developing a global mindset, basing a response on shared values, and adopting transformational approaches in governance, global political economy and capacity strengthening.

Correcting legal impediments to access to justice by injured developing world subjects would, we submit, be a small albeit important step towards achieving this goal.

NOTES

The chapter is based on a paper presented at the 28th International Congress on Law and Mental Health in Sydney, Australia (2003), and is an expanded and revised version of: J. Ford and G. Tomossy, "Clinical Trials in Developing Countries: The Plaintiff's Challenge" 2004 (1) Law, Social Justice and Global Development Journal (LGD), available at: <http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/ford/> (Last accessed: 7 April 2005).

¹ On the issue of treaties and drug patents, see Chapter 7 in this volume. On the trend towards harmonization of drug regulation and the promotion of mutual acceptance of clinical trial data across jurisdictions, see the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, which is discussed by Dominguez-Urban (1997). The role of industry bias in this process is critiqued by Abraham and Reed (2003).

² Public Citizen, a non-profit public interest organization in the United States, has been on the record for a number of years regarding the incompatibility between the commercial interests of pharmaceutical companies. See, for example, a range of reports published by Public Citizen at <http://www.citizen.org/congress/reform/drug_industry/> (Last accessed: 20 April 2005), including in particular "The Other Drug War 2003: Drug Companies Deploy an Army of 675 Lobbyists to Protect Profits" (23 June 2003) and "Addicting Congress: Drug Companies' Campaign Cash and Lobbying Expenses" (7 June 2000). Such concerns appear to now have been vindicated in the recent report by the House of Commons Health Committee of the United Kingdom (2005).

³ For a discussion on the justifiability of "me-too" drugs, see Garattini (1997).

⁴ The disproportionate allocation of risk and benefit was the focus of an award-winning series of investigative reports in the *Washington Post* between 17-21 December 2000, entitled "The Body Hunters," and various follow-up articles available at: <<http://www.washingtonpost.com/wp-dyn/world/issues/bodyhunters/>> (Last accessed: 13 April 2005).

⁵ The World Medical Association *Declaration of Helsinki* was last amended in Edinburgh 2000, available at: <<http://www.wma.net/e/policy/b3.htm>> (Last accessed: 13 April 2005).

⁶ While it is conceded that arguments for accreditation do have merit, a proper critique of this issue and of the larger debate surrounding internal versus external controls of conduct in biomedical research go beyond the scope of this chapter.

⁷ A clear statement of the ethical considerations for first-world jurisdictions arising from globalization was clearly enunciated by the European Group on Ethics in Science and Technology (EGE 2003, para 2.5):

In the context of globalisation of research, the optimal protection of the participant must be a priority no matter where a clinical trial is performed: thus, it should only be carried out in countries with a less adequate healthcare environment, if very strict justification can be given. The more evident ones would be:

- The trial aims at addressing specific health conditions of the countries, for instance tropical diseases;
- The trial aims at addressing diseases existing also in industrialised countries but with a specifically high incidence in developing countries.
- The trial aims at developing treatments having a specific interest for the country (for instance, a new treatment cheaper than those already existing).

And in respect of the regulatory requirement of ethics committee review (id., para 2.8):

The scientific and ethical evaluation of the research protocol should be carried out by ethical committees from all countries involved. Host countries need to have a legal and ethical framework in order to take part in the clinical trial evaluation effectively and independently. The Group strongly supports EU initiatives to build local ethical committees in the host countries. It should be considered as a priority in terms of capacity building. When no local ethics committee exists, then the evaluation should be done by a mixed committee involving representatives from both EU Member States and host countries. It is essential that the members of this committee are independent and include persons representing patients' interests. If it is not possible to involve such an independent local representative in the evaluation, then no clinical trial should be implemented in the country.

⁸ For a discussion of some of the recent US cases, including the highly publicized Gelsinger litigation, see De Ville (2002).

⁹ It should be noted that this summary is based on the plaintiffs' statement of claim and does not constitute judicial findings of fact. The US District Court was 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 favor, 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.

¹⁰ Trovan (trovafloxacin), an oral antibiotic also available in an intravenous formulation (alatrofloxacin or Trovan-IV), was first approved by the US Food and Drug Administration in December 1997 and first became available on the market in February 1998. A public health advisory was issued on 9 June 1999, by the Center for Drug Evaluation concerning the risks of liver toxicity associated with use of the drug and its recommended use was restricted to patients fitting specific criteria. See: <<http://www.fda.gov/cder/news/trovan/default.htm>> (Last accessed: 25 April 2005). The drug was suspended from the European market by the European Medicines Evaluation Agency in June 1999. See: <<http://www.emea.eu.int/pdfs/human/press/pus/1804699EN.pdf>> (Last accessed: 25 April 2005).

¹¹ Plaintiffs also alleged 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, though it has been observed that this statistic might have been higher had Pfizer conducted follow-up visits to monitor the health of the subjects after completion of the study (Shah 2003, 33). Bacterial meningitis is fatal in one in ten cases and one in seven survivors is left with severe handicap, such as deafness or brain injury: see National Meningitis Association website at <www.nmaus.org> (Last accessed: 30 September 2003).

¹² 28 USC at 1350.

¹³ The statement by Pfizer was made in response to a television documentary, "Dying for Drugs", that had been aired recently in the UK. See <<http://www.pfizer.co.uk/template4.asp?pageid=196>> (Last accessed: 25 April 2005).

¹⁴ *Abdullahi v Pfizer Inc.* 2002 WL 31082956 (SDNY), 17 September.

¹⁵ In Nigeria's Kano Federal High Court: *Zango & Others v Pfizer* (FHC/K/CS/204/2001).

¹⁶ See: *British Medical Journal*. 2003. News. 899: 326.

¹⁷ *Abdullahi v Pfizer Inc* 77 Fed Appx 48; 2003 US App (2d Cir) LEXIS 20704, 8 October.

¹⁸ *Kadic v Karadzic* [1995] 70 F 3d 232 confirmed the potential ATCA liability of individuals for violations of public international law. Then, in *Doe v Unocal Corporation* [1997] 963 F Supp 880, the court in an ATCA case did not rule out the possible liability of corporations for violations of public international law. In 2002, the Court of Appeals held that allegations of the Unocal corporation's close connection to Burmese governmental acts in violation of human rights were sufficient to give a court ATCA jurisdiction: *John Doe I v Unocal Corp* (2002) WL 31063976. The US District Court for the Southern District of New York recently ruled, after an extensive discussion of authority including *Doe*, that a corporation is capable of being liable under international law – at least for gross human rights violations, and for purposes of the ATCA. See: *The Presbyterian Church of Sudan & Others v Talisman Energy Inc & The Republic of Sudan* [2003] 244 F Supp 2d 289 (SDNY 2003).

¹⁹ See Article 5(2). It is also worth noting that 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.

²⁰ *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. The Supreme Court confirmed (*Sosa v Alvarez-Machain* USSC No 03-339, 29 June 2004) that the ATCA did not itself create a cause of action, so that an existing recognized tort cause of action needed to be alleged. The Court noted that while nothing prevented federal courts from developing the originally limited categories of torts recognized under the ATCA, ATCA recognition would only be given to allegations of the violation of “a norm of international character accepted by the civilized world and defined with a specificity comparable to the features” of the originally recognized but limited categories of torts.

²¹ The *Nuremberg Code* constituted part of the judgment resulting from *US 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), 181-2.

²² A recent decision by the Maryland Court of Appeals is a notable exception. See: *Grimes v. Kennedy Krieger Institute, Inc* [2001] 366 Md 29, 782 A 2d 807.

²³ *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*. Council of Europe Treaty Series No. 164 <<http://conventions.coe.int/treaty/en/treaties/html/164.htm>> (Last accessed: 4 May 2005).

²⁴ *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*, Council of Europe Treaty Series No. 195. Available at: <<http://conventions.coe.int/Treaty/EN/Treaties/Html/195.htm>> (Last accessed: 25 April 2005).

²⁵ For information about the *Convention on Biomedicine*, including information about signatories and ratifications, see the Council of Europe website at: <http://www.coe.int/T/E/Legal_affairs/Legal_cooperation/Bioethics/> (Last accessed: 25 April 2005).

²⁶ *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).

²⁷ *Forti v Suarez-Mason* [1987] 672 F Supp 1531 (ND Cal 1987), 1543; *Wiwa*, n26. 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).

²⁸ On these debates, see the exchange between Macklin (1998), Baker (1998a; 1998b) and Beauchamp (1998), and generally Macklin (1999a; 1999b). Ensuring that consent is voluntary is a related ethical concern as it can be compromised by offering undue inducements – of particular concern in developing countries where otherwise minor inducements, such as a basic medical exam or minor financial compensation, may seem exploitative (CIOMS 2002, principle 7).

²⁹ The District Court in the Trovan litigation held that the plaintiffs, as foreign nationals with no significant ties to the district, would not to be afforded a presumption in favor of their choice of forum.

³⁰ 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).

³¹ See: *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.

³² 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 also: Baxi and Paul (1986).

³³ On the “10/90 gap”, which deals squarely with this issue, see the discussion by Schüklenk and Braimo in Chapter 2 of this volume. See also the inaugural issue of *Developing World Bioethics* (2002): “Drugs for the Developing World.”

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