"VIGILANT DOORKEEPING": POST-*KIOBEL* CORPORATE ACCOUNTABILITY UNDER THE ALIEN TORT STATUTE FOR NEGLIGENCE AND VIOLATIONS OF THE INTERNATIONAL PROHIBITION ON NONCONSENSUAL MEDICAL EXPERIMENTATION

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ABSTRACT

Twenty-first century experimental health care is inevitably advancing in the form of offshore clinical trials. As these trials become more profitable and popular with the nations that host them and the pharmaceutical companies that conduct them, research subjects are increasingly injured or killed in circumstances that cast doubt on whether trial administrators obtained informed consent or, in some cases, demonstrated outright negligence. This Note examines the legal framework under which non-U.S. citizens have brought tort claims against U.S.-based corporations for violations of customary international law, focusing on the prohibition on nonconsensual medical experimentation. In April 2013, the U.S. Supreme Court foreclosed the possibility of bringing claims against corporations under the Alien Tort Statute ("ATS") for activity that occurred outside the United States, except in narrow circumstances. This Note argues that in cases where foreign research subjects are injured or killed after participating in offshore clinical trials in which U.S. pharmaceutical companies fail to obtain informed consent or demonstrate negligence, those injured parties should be able to rely on the ATS for relief.

INTRODUCTION

According to the *Harvard Business Review*, an average-sized pharmaceutical company with 60,000 patients in clinical trials could save $600 million per year by moving half of its clinical trials from highly-regulated sites in the United States and Western Europe to India and South America.[1] In these less-regulated environments, companies have few incentives to overcome difficulties in communication with potential research subjects whose cultures often lack basic concepts such as "research," "hypothesis," and "randomization."[2] In addition, foreign resource-poor governments and physicians are often desperate to receive medical supplies and money from these companies in exchange for quickly producing citizen research subjects.[3] These structural deficiencies frequently result in pharmaceutical companies using inadequate informed consent language. Furthermore, policing these agreements is cumbersome

[1] Jean-Pierre Garnier, *Rebuilding the R&D in Big Pharma*, HARV. BUS. REV., May 2008, at 68.

[2] Bethany Spielman, *Offshoring Experiments, Outsourcing Public Health*, *in* THE GLOBALIZATION OF HEALTH CARE 286, 289 (I. Glenn Cohen ed., 2013).

[3] Shirley S. Wang, *Most Clinical Trials Done Abroad*, WALL ST. J., Feb. 18, 2009, http://www.wsj.com/article/SB123499424805316443.html; *see also* Seth W. Glickman et al., *Ethical and Scientific Implications of the Globalization*, 360 NEW ENG. J. MED. 816, 816 (2009) (finding that in some cases, individuals with the condition under study might only receive care by participating in a clinical trial).

and expensive.[4] According to one researcher, "it takes injury, scandal, or sustained patient advocacy to hold trial sponsors accountable. . . ."[5]

When individuals have been seriously injured or killed after participating in a clinical trial, they (or their beneficiaries) have been able to seek relief under the Alien Tort Statute ("ATS").[6] This statute gives U.S. district courts jurisdiction over a set of actions alleging violations of customary international law ("CIL"), colloquially known as the law of nations.[7] Under the ATS, claimants almost always need to demonstrate state action in collusion with the private action that brought about their harm because courts have held that, in most cases, only states can violate international law.[8] Article 38.1(b) of the Statute of the International Court of Justice ("ICJ") refers to "international custom" as a source of international law, and courts have therefore held that violations of CIL constitute violations of binding, international law.[9] In *Abdullahi v. Pfizer, Inc.*, the Second Circuit Court of Appeals held that the prohibition on nonconsensual medication experimentation on human beings constituted a universally accepted norm of CIL, and thus any alleged violation would fall within the jurisdiction of the ATS.[10]

The Supreme Court departed with decades of ATS interpretation in April 2013 when it decided *Kiobel v. Royal Dutch Petroleum*. The majority opinion, written by Chief Justice Roberts, applies the canon of statutory interpretation known as the presumption against extraterritoriality to the ATS, effectively barring the claim.[11] This presumption is founded upon the "commonsense notion that Congress generally legislates with domestic concerns in mind."[12] The Court concluded that absent clear congressional

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[4] Mwanamvua Boga et al., *Strengthening the Informed Consent Process in International Health Research through Community Engagement: The KEMRI-Wellcome Trust Research Programme Experience*, PLOS MED., Sept. 2011, at 1.

[5] ADRIANA PETRYNA, WHEN EXPERIMENTS TRAVEL: CLINICAL TRIALS AND THE GLOBAL SEARCH FOR HUMAN SUBJECTS 134, 136 (2009).

[6] *See generally* Abdullahi v. Pfizer, Inc., 562 F.3d 163 (2d Cir. 2009).

[7] Sosa v. Alvarez-Machain, 542 U.S. 692, 720, 723 (2004).

[8] Kadic v. Karadzic, 70 F.3d 232, 239 (2d Cir. 1995), *cert. denied*, 116 U.S. 2524 (1996) (finding only certain conduct violating the law of nations including piracy, slavery, war crimes, and genocide applies to private individuals); *see also Abdullahi*, 562 F.3d at 188 (quoting Kadic, 70 F.3d at 232) ("A private individual will be held liable under the ATS if he 'acted in concert with' the state, i.e., 'under color of law.'"); Jordan J. Paust, *The Other Side of Right: Private Duties Under Human Rights Law*, 5 HARV. HUM. RTS. J. 51, 51 (1992).

[9] Filártiga v. Peña-Irala, 630 F.2d 876, 883 (2d Cir. 1980).

[10] *Abdullahi*, 562 F.3d at 187.

[11] Kiobel v. Royal Dutch Petroleum Co., 133 S. Ct. 1659, 1669 n.5 (2013).

[12] Smith v. United States, 507 U.S. 197, 204 (1933) (holding that the Federal Tort Claims Act does not apply to claims arising in Antarctica). The Court has barred numerous

intent for statutory application beyond the territorial borders of the United States, claimants must demonstrate that their claims "touch and concern" the territory of the United States with sufficient force to displace the presumption against extraterritoriality.[13] The Court declined to expound upon the meaning of "touch and concern," and subsequent litigation in the lower courts has yielded conflicting definitions.

As a result of the *Kiobel* decision, lower courts have cited Chief Justice Roberts's majority opinion, noting the textual ambiguity of the phrase "touch and concern," and reached different conclusions as to the applicability of the ATS.[14] Furthermore, many legal commentators and human rights advocates criticized the decision, fearing that the Court shut its doors to human rights violations committed overseas by U.S.-based corporations.[15] Still others have focused on the splintered opinions of Justices Kennedy, Alito, and Thomas, which indicate that cases with a stronger connection to the United States might overcome statutory preclusion.[16] In either case, victims of negligent or nonconsensual medical experimentation at the hands of U.S. pharmaceutical companies face additional legal hurdles as lower courts reconsider the scope of ATS jurisdiction after *Kiobel*.

This Note argues that ATS claims brought by foreign plaintiffs injured or killed as a result of negligent or nonconsensual medical experimentation conducted abroad by U.S. pharmaceutical companies should meet the

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statutory claims under the presumption against extraterritorial application. *See, e.g.*, EEOC v. Arabian Am. Oil, Co., 499 U.S. 248, 249 (1991) (barring claims under Title VII of the Civil Rights Act of 1964 against employment practices of U.S. firms located abroad); Foley Bros., Inc. v. Filardo, 336 U.S. 281, 285-86 (1949) (holding labor statutes inapplicable to private contractors working with the United States but operating in foreign countries).

[13] *Kiobel*, 133 S. Ct. at 1659.

[14] *Compare, e.g.*, Sexual Minorities Uganda v. Lively, 2013 WL 4130756, at *15 (D. Mass. Aug. 14, 2013) (quoting *Kiobel*, 133 S. Ct. at 1669) ("Given that Defendant is a United States citizen living in this country and that the claims against him 'touch and concern the territory of the United States . . . with sufficient force to displace the presumption against extraterritoriality,' a cause of action is appropriate under the ATS."), *with* Al Shimari v. CACI Int'l, Inc., 2013 WL 3229720, at *9 (E.D. Va. June 25, 2013) (noting that "Plaintiffs' reading of Kiobel is a fair one," because Kiobel's 'touch and concern' language may be interpreted in many ways but nevertheless dismissing the plaintiffs' claims); *see also* Doe v. Exxon-Mobil Corp., 2013 WL 3970103 (D.C. Cir. July 26, 2013).

[15] Kiobel v. Shell: *Supreme Court Limits Courts' Ability to Hear Claims of Human Rights Abuses Committed Abroad*, CTR. FOR CONSTITUTIONAL RIGHTS (Apr. 17, 2013), http://ccrjustice.org/newsroom/press-releases/kiobel-v.-shell%3A-supreme-court-limits-courts%E2%80%99-ability-hear-claims-of-human-rights-abuses-committed-a.

[16] Ralph Steinhardt, *The ATS After Kiobel*, AM. SOC'Y OF INT'L LAW (Jan. 31, 2014, 4:49 PM), http://www.asil.org/blogs/ats-after-kiobel.

Supreme Court's "touch and concern" standard and overcome the presumption against extraterritoriality.[17] Part I explains the rapid emergence of offshore clinical trials, the history and purpose of the ATS, and the corporate accountability gap in the context of the Trovan Experiment conducted by Pfizer in the 1990s. Part I also examines the *Kiobel* decision and subsequent ATS litigation. Part II argues that ATS cases involving a U.S.-based defendant are not statutorily precluded; that the actions of U.S. pharmaceutical companies sufficiently "touch and concern" the United States; and that obtaining informed consent offers a sufficient liability shield to these companies while conducting offshore clinical trials. Additionally, Part II asserts that the state action requirement should be revisited in order to preserve ATS claims, and plaintiffs can seek remedies for their ATS claims in state courts as an alternative to pursuing federal claims. Finally, Part III proposes numerous potential solutions to the corporate accountability gap to ensure that the United States is not undermining the purpose of the ATS in the context of negligent or nonconsensual medical experimentation.

I. BACKGROUND

Before establishing that foreign research subjects who are injured or killed in negligent or nonconsensual medical experimentation should be able to rely on the ATS for relief despite the *Kiobel* decision, it is necessary to contextualize the issue. Section A of this Part explains the rise of offshore clinical trials and problems with obtaining informed consent. Section B introduces the ATS and explains the legal framework involved. Section C describes the evolution of ATS jurisprudence and examines the corporate accountability gap as revealed by the Trovan Experiment conducted by Pfizer and the resulting litigation in *Abdullahi v. Pfizer*. Section D connects the previous sections by examining the Supreme Court's landmark decision in *Kiobel v. Royal Dutch Petroleum* and its impact on subsequent ATS claims in the lower federal courts. Lastly, Subsection 1 of Section D distinguishes between "Foreign-Cubed" and "Foreign-Squared" cases.

A. The Rise of Offshore Clinical Trials

In 2014, global drug sales are forecasted to reach $1.1 trillion (up from $712 billion in 2007).[18] Multi-regional clinical trials to test those drugs have become common practice in an era of globalized health care. While

[17] *Id.*

[18] Bill Berkrot, *Global Drug Sales to Top $1 Trillion in 2014: IMS*, REUTERS, Apr. 20, 2010, http://www.reuters.com/article/2010/04/20/us-pharmaceuticals-forecast-idUSTRE63J35O20100420.

the Food and Drug Administration ("FDA") cannot identify all ongoing trials, the National Institutes of Health ("NIH") estimates that 178,158 clinical trials are currently being conducted in all fifty states and in 187 countries involving millions of people.[19] Forty to sixty-five percent of these trials are run in developing countries.[20] In fact, of the $39 billion spent by pharmaceutical companies on research and development in 2004, twenty-one percent was spent outside of the United States.[21]

These numbers are likely to rise because obtaining licenses for experimental drugs in developed countries involves considerable obstacles not faced in developing countries. First, since the 1970s, the FDA has heavily regulated clinical trials involving human subjects for what it calls Good Clinical Practice ("GCP") and Human Subject Protection ("HSP").[22] Second, the Environmental Protection Agency ("EPA") and all fifty states regulate the management of hazardous waste pharmaceuticals.[23] Third, the pool of human subjects from which to choose in the Western world is shrinking because of a phenomenon known as "treatment saturation."[24] The average Western adult takes four or five different medications for various health maladies, making them unusable for clinical drug testing because test results obtained from them are less likely to show the

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[19] U.S. NAT'L INST. OF HEALTH, http://www.clinicaltrials.gov (last visited Nov. 7, 2014).

[20] Kelly Hearn, *The Rise of Unregulated Drug Trials in South America*, NATION, Sept. 21, 2011, http://www.thenation.com/article/163547/rise-unregulated-drug-trials-south-america (finding that the FDA inspected less than one percent of foreign clinical trials in 2008). A 2004 report out of China found that only eighteen percent of published trials obtained informed consent from participants. *See* Dalu Zhang et al., *An Assessment of the Quality of Randomised Controlled Trials Conducted in China*, TRIALS 9:22, Apr. 24, 2008, http:///www.trialsjournal.com/content/9/1/22; *see also* Kris Hundley, *The Latest Industry Being Outsourced to India: Clinical Drug Trials*, TAMPA BAY TIMES, Dec. 14, 2008, http://www.tampabay.com/news/business/article934677.ece (finding that the FDA inspected only eight of thousands of trials in India from 2005-2008).

[21] CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2006), *available at* https://cbo.gov/sites/default/files/10-02-drugr-d.pdf; *see also* Julie Schmit, *Costs, Regulations Move More Drug Tests Outside USA*, USA TODAY, May 16, 2005, http://usatoday30.usatoday.com/news/health/2005-05-16-drug-trials-usat_x.htm?POE=click-refer. The twenty largest U.S. pharmaceutical companies conduct one third of their phase 3 trials outside the United States. *See* Glickman et al., *supra* note 3, at 816.

[22] *Clinical Trials and Human Subject Protection*, FOOD & DRUG ADMIN. (Sept. 9, 2014), http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/default.htm (last visited Dec. 29, 2014).

[23] *Management of Hazardous Waste Pharmaceuticals*, ENVTL. PROT. AGENCY (Sept. 12, 2014), http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm.

[24] PETRYNA, *supra* note 5, at 21.

effectiveness of a specific drug.[25] In short, pharmaceutical companies can save millions by moving their operations to developing countries.[26]

While substantive research is often conducted in developing countries, the potentially beneficial results are realized primarily in developed countries, at least in the short term. Spending is not proportional to the types of diseases that cause the greatest global burden since only one quarter of one percent of the total global disease burden occurs in the developed world, in which the pharmaceutical industry derives ninety-five percent of its revenue.[27] Despite the disproportionate benefit to the developed world in terms of spending and research, clinical trials yield other important benefits and incentives. The expansion of clinical research into developing countries augments the medical care options available to subjects who would otherwise be shut out.[28] Research investment benefits local scientific and medical communities by affording them access to more advanced technologies and the opportunity to develop technical expertise. Moreover, these trials provide drug companies in developing countries access to unused patient pools, and the partnerships bring state-of-the-art medications to local drug stores. In addition, many drug companies pay patients large lump sums for their participation and provide medications that are otherwise too expensive for most locals.[29]

These secondary benefits, however, do not come without risks to research subjects. Clinical trials involve medical experimentation, which can be extremely dangerous. Many research subjects are seriously injured or killed after participation in experiential drug trials, and very few are meaningfully compensated.[30] For example, in March 2006, eight healthy adult males participated in a phase I clinical trial conducted by PAREXEL, a Massachusetts-based, multinational contract research organization.[31] The study was the first human trial of a drug designed to mitigate autoimmune and immunodeficiency disorders.[32] Six men who received the drug developed rapid, catastrophic multisystem failure (while the remaining two

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[25] *Id.*

[26] Garnier, *supra* note 1, at 68.

[27] Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market & A Public-Health Policy Failure*, 359 LANCET 2188, 2189 (2002).

[28] Wang, *supra* note 3.

[29] *The Promise and Pitfalls of Clinical Trials Overseas*, 322 SCI. 214, 216 (2008), http://www.sciencemag.org/content/322/5899/214.full.pdf?sid=ca9e11b5-600c-4a05-8e8e-db30b4240206.

[30] Renuka Munshi & Urmila Thatte, *Compensation for Research Related Injury*, PERSP. CLIN. RES. (Jan.-Mar. 2003), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601709.

[31] *Id.*

[32] *Id.*

received a placebo).[33] The injured participants received very little compensation because PAREXEL claimed that it was not liable for unforeseen reactions caused by its drug.[34]

U.S. law does not require sponsors of clinical trials to provide compensation or free medical care to injured trial participants.[35] Only sixteen percent of academic medical centers provide free care to injured research subjects as a matter of policy, and no private pharmaceutical companies have announced a similar policy.[36] Furthermore, injured trial participants (or their beneficiaries) are often unable to pursue tort claims in their home countries. In many cases the host state's judicial system is dysfunctional, corrupt, unsafe, or without enforcement mechanisms.[37] Even in cases where there is a functioning judiciary, plaintiffs must rely on general tort law principles that are universally applicable, but often unreliable in court.[38] As a result, most injured trial participants fail to receive any meaningful compensation, leading one bioethicist, Carl Elliot from the University of Minnesota, to remark, "[t]he fact that an injured subject in an exploitative research study can be required to pay for his or her own medical bills is, quite frankly, a disgrace."[39]

In addition to compensation problems, many research subjects are children or have been misled about the risks associated with participating in clinical trials.[40] These risks are exacerbated when foreign resource-poor governments and physicians, desperate to receive money and supplies in

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[33] *Id.*

[34] *Id.* In a more egregious case, a clinic trial carried out in India in early 2010 resulted in twenty-five deaths. Only five families were compensated initially, and only for a meager amount. The Drug Controller General of India ("DGCI"), under pressure from the public, instructed ten pharmaceutical companies to reimburse twenty-two families. Most of these families received Rs 1.5-2.5 lakh, or the equivalent of $2,463.30 to $4,105.50. *See id*.

[35] Robert Steinbrook, *Compensation for Injured Research Subjects*, 354 NEW ENG. J. MED. 1871, 1871-73 (2006).

[36] *Id.*

[37] *How Can Lawyers Deal with Dysfunctional Systems of Justice?*, ASIAN HUMAN RIGHTS COMM'N (Dec. 5, 2011), http://www.humanrights.asia/resources/journals-magazines/article2/1101/how-can-lawyers-deal-with-dysfunctional-systems-of-justice?searchterm=dysfunctional.

[38] In ATS tort cases against corporations, the most common tort law principles involved are product liability and vicarious liability. Both principles are unreliable because they are often undermined by limited liability, which shields a parent company from liability for actions taken by its subsidiaries.

[39] *US Experts Demand Compensation for Injured Trial Participants*, NATURE MED. BLOG (July 6, 2012, 9:56 AM), http://blogs.nature.com/spoonful/2012/07/us-experts-demand-compensation-for-injured-trial-participants.html.

[40] Michelle M. Mello et al., *Ethical Considerations in Studying Drug Safety – The Institute of Medicine Report*, 367 NEW ENG. J. MED. 959, 959-64 (2012).

exchange for providing research subjects, fail to ensure that pharmaceutical companies are actually obtaining informed consent. Most informed consent processes occur in local languages.[41] Informed consent forms, however, are usually written in English by researchers and later translated into the appropriate language. The result is often overly-simplistic language that masks the experimental nature of the clinic trial.[42] In reality, preventing nonconsensual experimentation requires time and effort because among the cultures involved, there can be wide disparities in education, economic, and social standing.[43]

Collectively, host governments have generally failed to provide adequate compensation to injured clinical trial participants and to ensure that pharmaceutical companies obtained informed consent. In essence, they have outsourced their public health responsibilities to pharmaceutical companies who operate in what one scholar has called "[a regulatory] enforcement vacuum."[44] Therefore, when foreign research subjects have been injured or killed as a result of participating in negligent or nonconsensual clinical trials conducted outside the United States by a U.S. pharmaceutical company, the ATS has served as one of the only means of restoration and accountability by providing a jurisdictional hook to bring claims into U.S. courts.

B. The Alien Tort Statute and Customary International Law

The ATS is a provision in the Judiciary Act of 1789, which established the federal court system. Since the legislative record is completely silent on the ATS, the reasons for its inclusion in this act are unknown; however, many legal scholars contend that its enactment was the direct result of the occurrence of piracy and the mistreatment of U.S. ambassadors.[45] The ATS states, "The district courts shall have jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."[46] It therefore permits non-U.S. citizens to bring tort

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[41] Boga et al., *supra* note 4, at 1.

[42] *Id.*

[43] Suellen Miller et al., *How to Make Consent Informed: Possible Lessons from Tibet*, 29:6 IRB: ETHICS AND HUMAN RESEARCH 7, 7-14 (2007); Spielman, *supra* note 2, at 289; *see also* K. Moodley et al., *Informed Consent and Participant Perceptions of Influenza Vaccine Trials in South Africa*, 31 J. MED. ETHICS 727, 727-32 (2005).

[44] Stacey B. Lee, *Informed Consent: Enforcing Pharmaceutical Companies' Obligations Abroad*, 12:1 HEALTH & HUM. RTS.: INT'L J. 15, 22 (2010), http://www.hhrjournal.org/index.php/hhr/article/view/200/297; Molly McGregor, *Uninformed Consent: The United Nations' Failure to Appropriately Police Clinical Trials in Developing Nations*, 31 SUFFOLK TRANSNAT'L L. REV. 103, 118-20 (2007).

[45] Sosa v. Alvarez-Machain, 542 U.S. 692, 720, 723-24 (2004).

[46] 28 U.S.C. § 1350 (1948).

actions in U.S. courts for alleged violations of the law of nations, which the court has interpreted to mean international law.[47] Article 38 of the Statute of the ICJ, to which the United States is a party, identifies the sources of international law.[48] One of those sources is international custom.[49] The Restatement (Third) of Foreign Relations Law defines CIL as "a general and consistent practice of states followed by them from a sense of legal obligation."[50] The court has held that "where there is no treaty, and no controlling executive or legislative act or judicial decision, resort must be had to the customs and usages of civilized nations."[51] The law of nations for ATS purposes therefore refers to CIL.[52]

In 1980, the Second Circuit extensively examined the ATS in *Filártiga v. Peña-Irala*. There, Paraguayan citizens who sued in New York alleging that the defendant, Americo Peña-Irala, a state official, tortured their brother and son as a form of political repression.[53] The court held that conduct in violation of the law of nations is actionable under the ATS "where the nations of the world have demonstrated that the wrong is of mutual, and not merely several, concern, by means of express international accords. . . ."[54] This ruling effectively allowed claims brought under the ATS for violations of present-day CIL.[55] After *Filártiga*, the court extended liability under the ATS to private actors in addition to state actors when their conduct violated the prohibition against certain universal norms including piracy, slavery, genocide, and war crimes.[56] For all other violations by private actors, the court concluded that a claimant must show sufficient state action in collusion with the private actor.[57] This decision resulted in hundreds of claims filed against multinational corporations ("MNCs") which were connected to human rights abuses in the countries where they conducted business.[58] The defendants included oil companies, mining companies, textile companies, and pharmaceutical companies.[59]

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[47] *See generally* Flores v. S. Peru Copper Corp., 414 F.3d 233 (2d Cir. 2003).

[48] Statute of the International Court of Justice art. 38(1), June 26, 1945, 59 Stat. 1055, 33 U.N.T.S. 993.

[49] *Id.*

[50] RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW § 102(2) (1987).

[51] The Paquete Habana, 175 U.S. 677, 700 (1900).

[52] Flores v. S. Peru Copper Corp., 414 F.3d 233, 233 (2d Cir. 2003).

[53] Filártiga v. Peña-Irala, 630 F.2d 876, 878 (2d Cir. 1980).

[54] *Id.* at 888.

[55] *Id.* at 890.

[56] *See* Kadic v. Karadzic, 70 F.3d 232, 239 (2d Cir. 1995).

[57] *Id.*

[58] Luis Enrique Cuervo, *The Alien Tort Statute, Corporate Accountability, and the New* Lex Petrolea, 19 TUL. ENVTL. L.J. 151, 176-77 (2006).

[59] *Id.*

C. The Evolution of ATS Claims and the Trovan Experiment

In response to a wave of litigation, the Supreme Court finally weighed in and considered which standard to employ in determining torts actionable under the ATS. In *Sosa v. Alvarez-Machain*, Humberto Alvarez-Machain alleged that he was illegally captured and detained by a U.S. agent who suspected him of being a drug dealer.[60] He subsequently sued under the ATS for violations of CIL.[61] The government contended that the ATS was merely a jurisdictional statute and did not provide a cause of action.[62] The Court disagreed, however, and found that the ATS was not a "jurisdictional convenience to be placed on the shelf for the use by a future Congress or state legislature that might some day, authorize the creation of causes of action."[63] Instead, the Court found a cause of action in common law, but noted that the jurisdictional bar to claims was high because plaintiffs had to show a violation of norms with definitive acceptance in the international community.[64] While the Court found that a single illegal detention of less than a day did not violate any norm of CIL sufficient to create a federal remedy, it implied that other factual occurrences might.[65]

Since *Sosa*, plaintiffs initiated a new wave of claims against MNCs including Exxon-Mobil, Shell, Nike, and Coca-Cola.[66] In many of these cases, the lower courts held that these claims did not meet *Sosa*'s jurisdictional bar. For example, in *Vietnam Ass'n for Victims of Agent Orange v. Dow Chemical Co.*, Vietnamese nationals sued U.S.-based corporations for committing violations of the laws of war by manufacturing and supplying Agent Orange to U.S. and South Vietnamese troops. The Second Circuit concluded that the defendant manufactured Agent Orange primarily to destroy crops and not to poison human populations.[67] Accordingly, the plaintiffs failed to establish an actionable claim under the ATS.[68]

Conversely, in *Khulumani v. Barclay National Bank, Ltd.*, the plaintiffs sued nearly fifty MNCs, alleging that they had aided and abetted the South African apartheid regime's human rights violations in South Africa.[69] The

[60] Sosa v. Alvarez-Machain, 542 U.S. 692, 697 (2004).

[61] *Id.* at 698.

[62] *Id.* at 712.

[63] *Id.* at 719.

[64] *Id.* at 732.

[65] Sosa v. Alvarez-Machain, 542 U.S. 692, 738 (2004).

[66] Cuervo, *supra* note 58, at 220 n.19.

[67] Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co., 517 F.3d 104, 119-20 (2d Cir. 2008).

[68] *Id.* at 123.

[69] Khulumani v. Barclay Nat'l Bank, Ltd., 504 F.3d 254, 258 (2d Cir. 2007).

court determined that the plaintiffs' claim of aiding and abetting liability could proceed under the ATS because human rights violations overcame the jurisdictional bar.[70] Based on the earlier *Sosa* decision and subsequent interpretation by the circuit courts, it is clear that in order for victims of negligent or nonconsensual clinical trials to prevail under the ATS, they would have to demonstrate that nonconsensual medical experimentation violated a CIL norm sufficient to create a federal remedy.[71] After Pzifer's Trovan Experiment in Nigeria, the Second Circuit would consider ATS jurisdiction for precisely this issue.

In March 1996, residents of Kano, Nigeria faced dual epidemics of measles and cholera. Adding to the misery, an epidemic of bacterial meningitis broke out which threatened to devastate the population.[72] Along with Doctors without Borders, Pfizer, the world's largest research-based pharmaceutical company, arrived on the scene to administer medical aid.[73] Pfizer devised a plan to test an oral antibiotic called Trovan on infected children at a clinic in Kano.[74] The drug had not yet received FDA approval.[75] With the approval of the Nigerian government, Pfizer selected 200 infected children, aged one to thirteen, for participation in a clinical trial to test the experimental drug.[76] Pfizer divided the children into two groups, treating half with Trovan and half with a lower dosage of a standard treatment endorsed by the World Health Organization ("WHO").[77] Eleven children died during the testing and others suffered blindness, deafness, paralysis, and brain damage.[78]

On August 29, 2001, the parents of these children (collectively representing eighty aggrieved families) filed two class action lawsuits under the ATS alleging that Pfizer violated CIL that prohibited nonconsensual medical experimentation.[79] Specifically, the claimants alleged that Pfizer acted in partnership with the Nigerian government, failed to obtain the informed consent of the clinical trial participants, and inadequately disclosed the risks involved in the study.[80] Pfizer claimed immunity because it was a private organization. The plaintiffs argued that Pfizer engaged in state action when it partnered with the Nigerian government and

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[70] *Id.* at 260.

[71] Sosa v. Alvarez-Machain, 542 U.S. 692, 728 (2004).

[72] Abdullahi v. Pfizer, Inc., 562 F.3d 163, 169 (2d Cir. 2009).

[73] *Id*.

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] Abdullahi v. Pfizer, Inc., 562 F.3d 163, 169 (2d Cir. 2009).

[78] *Id*.

[79] *Id*. at 170.

[80] *Id.*

government employees to conduct its clinical trial.[81] In its analysis, the Second Circuit relied on the nexus test, which requires a sufficiently close nexus between the State and the private actor such that "seemingly private behavior 'may be fairly treated as that of the State itself.'"[82] The court determined that Pfizer and the Nigerian government sufficiently collaborated to meet the ATS's state action requirement. In particular, the court noted that the Nigerian government

> provided a letter of request to the FDA to authorize the export of Trovan, arranged for Pfizer's accommodation in Kano . . ., extended the exclusive use of two hospital wards [and staff] to Pfizer . . ., back-dat[ed] an "approval letter" that the FDA and international protocol required to be provided prior to conducting the medical experiment . . . and silenc[ed] Nigerian physicians critical of the test.[83]

Having met the state action requirement, the plaintiffs next had to demonstrate that nonconsensual medical experimentation on human subjects violated a norm of CIL sufficient to create an actionable claim under the ATS. To establish that obtaining informed consent was required by CIL, the plaintiffs relied on numerous international documents related to medical experimentation including the Nuremberg Code, the Helsinki Declaration, and the International Covenant on Civil and Political Rights ("ICCPR").[84] The Nuremberg Code is a set of legal and ethical standards developed during the trials of Nazi war criminals. For the first time, the Code mandated that research subjects "exercise the free power of choice" and have sufficient information relating to the experiment so as to allow an "enlightened decision."[85] Similarly, the ICCPR requires that "no one shall be subjected without his free consent to medical or scientific experimentation."[86] While the district court declined to find that any of these sources of CIL created a definitive CIL norm that was sufficient to create a federal remedy, the Second Circuit disagreed.[87]

The court referenced the increasing number of offshore clinical trials and asserted that companies who conduct experiential drug trials without obtaining informed consent threatened international peace and security.[88]

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[81] *Id.* at 170.

[82] Abdullahi v. Pfizer, Inc., 562 F.3d 163, 188 (2d Cir. 2009).

[83] *Id.*

[84] *Id.* at 175.

[85] 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 181 (1949), *available at* http://www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-II.pdf.

[86] *Abdullahi*, 562 F.3d at 175.

[87] *Id.* at 176.

[88] *Id.* at 185.

In support of this conclusion, the court noted that the continued development of new drugs was essential to combating the cross-border spread of contagious diseases.[89] Pharmaceutical companies that conduct experiential drug trials without obtaining informed consent undermine this objective because their conduct "fosters distrust and resistance to international drug trials, cutting edge medical innovation, and critical international public health initiatives in which pharmaceutical companies play a key role."[90] Furthermore, seven of the twelve largest pharmaceutical manufacturers are American companies, and are therefore more likely to sponsor clinic trials abroad.[91] According to the court, "the failure to secure consent for human experimentation has the potential to generate substantial anti-American animus and hostility."[92]

As a result of these determinations, the court held that the appellants sufficiently stated a cause of action under the ATS for a violation of CIL prohibiting nonconsensual medical experimentation.[93] Despite the fact that no single source recognizing the norm is legally binding upon the United States, the court determined that the critical inquiry was whether the norm was sufficiently universal, specific, and of mutual concern to the international community to create a federal remedy under the ATS.[94] Having decided that the norm against nonconsensual medical experimentation met this criteria, the court allowed the claim to move forward.[95]

After this finding and a rejection of Pfizer's petition for a writ of certiorari by the Supreme Court, four families settled with Pfizer for $175,000 each from a $35 million fund in February 2011.[96] The early settlement left many important legal issues unresolved which are crucial to victims' relief efforts. Four years later, the Supreme Court resolved many of these issues regarding the scope of the ATS in *Kiobel v. Royal Dutch*

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[89] *Id.* at 186.

[90] *Id.* As a result of this particular incident, Kano locals boycotted a polio vaccination campaign for eleven months. The *Associated Press* reported that the boycott caused an outbreak of polio that spread throughout Africa and the Middle East and set back global eradication efforts. Salisu Rabiu, *Pfizer Asks Nigeria Court to Dismiss Case*, ASSOCIATED PRESS, July 4, 2007, http://origin.foxnews.com/printerfriendlywires/2007Jul04/0,4675,NigeriaPfizer,00.html.

[91] Abdullahi v. Pfizer, Inc., 562 F.3d 163, 187 (2d Cir. 2009).

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Nigerians Receive First Payments for Children Who Died in 1996 Meningitis Drug Trial*, N.Y. TIMES, Aug. 11, 2011, http://www.nytimes.com/2011/08/12/world/africa/12nigeria.html?_r=0.

Petroleum.

D. "Vigilant Doorkeeping": The Kiobel Decision

The plaintiffs were residents of the Ogoni Region of Nigeria and members of an activist group that opposed oil exploration and production in their village because of its adverse environmental effects.[97] They brought a class action lawsuit against Royal Dutch Petroleum Company and Shell Transport and Trading Company, p.l.c., alleging that the defendants aided and abetted the Nigerian government in a number of human rights violations including extrajudicial killings, torture, arbitrary arrest and detention, forced exile, and property destruction.[98]

The Supreme Court did not reach the question of whether the petitioners stated an actionable claim under the ATS, but instead considered "whether a claim may reach conduct occurring in the territory of a foreign sovereign."[99] Chief Justice Roberts noted the dangers of unwarranted judicial interference in foreign affairs expressed in *Sosa*.[100] In addition, he cited the canon of statutory interpretation known as the presumption against extraterritorial application, stating that "[w]hen a statute gives no clear indication of an extraterritorial application, it has none."[101] Chief Justice Roberts then applied this canon to the ATS.[102] The Chief Justice emphasized that the Court's holding applied to a factual scenario where "all the relevant conduct took place outside the United States."[103] He explained that where conduct occurred solely abroad, "mere corporate presence [in the United States]" did not "touch and concern" the United States "with sufficient force to displace the presumption against extraterritorial application."[104]

Chief Justice Roberts's application of the presumption against extraterritoriality nearly shuts out all claims brought under the ATS except in cases where claims "touch and concern" the territory of the United States sufficiently to displace the presumption. His analysis does not require the claim to literally "touch" U.S. soil because, in that case, extraterritoriality would not be at issue. Therefore, whether the "touch and concern" standard is met substantially depends upon whether the case involves a foreign plaintiff, a foreign defendant, or foreign conduct.

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97 Kiobel v. Royal Dutch Petroleum Co., 621 F.3d 111, 123 (2d Cir. 2011).

98 *Id.*

99 Kiobel v. Royal Dutch Petroleum Co., 133 S. Ct. 1659, 1664 (2013).

100 *Id.*

101 Morrison v. Nat'l Austl. Bank Ltd., 130 S. Ct. 2869, 2878 (2010).

102 *Kiobel*, 133 S. Ct. at 1664.

103 *Id.* at 1669.

104 *Id.*

1. "Foreign-Cubed" vs. "Foreign-Squared"

The *Kiobel* case represents a paradigmatic "foreign-cubed" case because it involved a foreign defendant, a foreign plaintiff, and exclusively foreign conduct. While "foreign-cubed" cases are now almost entirely barred,[105] ATS claims involving U.S. plaintiffs, U.S. defendants, or conduct occurring within the United States (although demonstrating more than "mere corporate presence") might overcome the presumption against extraterritoriality in a construction known as a "foreign-squared" case.[106] Justice Breyer's concurrence expressly supports allowing "foreign-squared" cases to proceed under the ATS. He contends that jurisdiction should extend where "(1) the alleged tort occurs on American soil, (2) the defendant is an American national, or (3) the defendant's conduct substantially and adversely affects an important American national interest . . . including a distinct interest in preventing the United States from becoming a safe harbor (free of civil as well as criminal liability) for a torturer or other common enemy of mankind."[107] His analysis, therefore, permits "foreign-squared" cases (and possibly even "foreign-cubed" cases).

Justice Kennedy's concurrence reveals that the majority's logic leaves open the possibility that the ATS can apply extraterritorially in certain other contexts. He reveals that the Court "is careful to leave open a number of significant questions regarding the reach and interpretation of the Alien Tort Statute."[108] While he does not elaborate on this point, he explains that some claims may not be covered by the Torture Victim Protection Act ("TVPA") that involve allegations of serious violations of international law.[109] In those disputes, he explains, "the proper implementation of the presumption against extraterritorial application may require some further elaboration and explanation."[110]

Many lower courts stayed their rulings on ATS claims pending the outcome of *Kiobel*. After *Kiobel*, these courts reevaluated ATS claims in light of the new jurisdictional bar set by the Supreme Court. Specifically,

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[105] *But see* Mwani v. Laden, 947 F. Supp. 2d 1, 1 (D.D.C. 2013) (holding that a "foreign-cubed" case that involved a terrorist bombing in and around the grounds of the U.S. Embassy in Nairobi, Kenya "touched and concerned" the United States with sufficient force to displace the presumption against the extraterritorial application of the ATS).

[106] Recent Case, *International Law – Alien Tort Statute – Second Circuit Holds That* Kiobel *Bars Common Law Suits Alleging Violations of Customary International Law Based Solely on Conduct Occurring Abroad.* – Balintulo v. Daimler AG*, 727 F.3d 174 (2d Cir. 2013)*, 127 HARV. L. REV. 1493, 1497-1500 (2014).

[107] Kiobel v. Royal Dutch Petroleum Co., 133 S. Ct. 1659, 1671 (2013) (Breyer, J., concurring).

[108] *Id.* at 1669 (Kennedy, J., concurring).

[109] *Id.*

[110] *Id.*

lower courts struggled to interpret the Court's "touch and concern" standard. Some courts have barred ATS claims irrespective of whether one party is a U.S.-based defendant, citing the new hurdles erected by the Chief Justice, while others have weighed that factor heavily, citing the concurring opinions and allowing ATS claims to proceed.

Following the Chief Justice's interpretation in *Kiobel*, the District Court for the District of Connecticut dismissed an ATS claim brought in September 2013 by Chinese residents alleging that the defendant, Zhao Zhizhen, aided and abetted torture and other crimes against humanity.[111] The court concluded that the case was also a paradigmatic "foreign-cubed" case because the plaintiffs were all residents (or visitors) of the People's Republic of China, the defendant was a Chinese citizen, and the alleged violations of international law occurred exclusively in China.[112]

Similarly, in *Balintulo v. Daimler AG*, foreign plaintiffs sued Daimler AG, a German-based car manufacturer with multinational subsidiaries (including in the United States) for aiding and abetting the South African apartheid regime by providing financial and technological support to the government.[113] The plaintiffs relied on Justice Breyer's concurrence in *Kiobel* and argued that the ATS still reaches extraterritorial conduct when the defendant is an American national by way of corporate citizenship through a subsidiary.[114] The Second Circuit disagreed, proclaiming that "[t]he opinion of the Supreme Court in *Kiobel* plainly bars common-law suits, like this one, alleging violations of customary international law based solely on conduct occurring abroad."[115] Furthermore, in *Al Shimari v. CACI Int'l., Inc.*, the U.S. District Court for the Eastern District of Virginia barred an ATS claim brought by four Iraqi citizens against a U.S.-based military contractor for the alleged abuse and torture that they sustained while detained in Abu Ghraib, Iraq, as suspected enemy combatants.[116] Explaining its holding, the court concluded that *Kiobel* barred the claim because the acts giving rise to the claim occurred exclusively in the territory of a foreign sovereign.[117]

Conversely, in *Sexual Minorities Uganda v. Lively*, the U.S. District Court for the District of Massachusetts allowed an action brought under the

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[111] Chen Gang v. Zhao Zhizhen, 2013 WL 5313411, at *2 (D. Conn. Sept. 20, 2013).

[112] *Id.* at 3; *see also* Chowdhury v. Worldtel Bangladesh Holding, Ltd., 746 F.3d 42 (2d Cir. 2014) (barring ATS claims where all the relevant conduct occurred in Bangladesh).

[113] Balintulo v. Daimler AG, 727 F.3d 174, 182 (2d Cir. 2013).

[114] *Id.* at 189.

[115] *Id.* at 182; s*ee also* Tymoshenko v. Firtash, 2013 WL 4564646 (S.D.N.Y. Aug. 28, 2013) (holding that a foreign defendant's use of a New York office and bank accounts was insufficient to displace the presumption against the extraterritoriality of the ATS).

[116] Al Shimari v. CACI Int'l., Inc., 2013 WL 3229720, at *1 (E.D. Va. June 25, 2013).

[117] *Id.*

ATS to proceed where a foreign plaintiff alleged that a U.S. citizen, along with a number of others, took actions in both the United States and Uganda to create "an atmosphere of harsh and frightening repression against LGBTI people in Uganda."[118] The court looked to the location in which the actions in question took place and noted that "an exercise of jurisdiction under the ATS over claims against an American citizen who has allegedly violated the law of nations in large part through actions committed within this country fits comfortably within the limits described by *Kiobel*."[119] Therefore, despite the fact that some of the conduct at issue took place in Uganda, the court concluded that enough of the relevant conduct took place within the United States (over a period of years) such that the "touch and concern" standard was satisfied.[120] This decision represents a positive trend for those seeking relief under the ATS post-*Kiobel*.

In January 2014, the Supreme Court revisited corporate accountability under the ATS in *Daimler AG v. Bauman*.[121] The plaintiffs, Argentinian residents, brought claims under the ATS and the TVPA alleging that Daimler AG's wholly-owned Argentinian subsidiary aided and abetted state security forces in kidnapping, torturing, and killing the plaintiffs or their relatives during Argentina's "Dirty War."[122] The plaintiffs seized upon Daimler AG's subsidiary location in California as a jurisdictional predicate.[123] The Supreme Court disagreed, finding that California courts lacked general jurisdiction over Daimler AG.[124] In a separate concurring opinion, Justice Sotomayor explained that the case was a "foreign-cubed" case, involving "foreign plaintiffs suing a foreign defendant based on foreign conduct."[125]

One of the most recent corporate accountability cases brought under the ATS was decided in late February 2014 and had substantial foreign policy implications. In *Du Daobin v. Cisco Sys., Inc.*, Chinese plaintiffs alleged that Cisco Systems, Inc. ("Cisco"), a U.S.-based corporation, assisted the Chinese Communist Party ("CCP") in creating a nationwide surveillance program known as the "Golden Shield" that has been used to identify and torture political opponents.[126] All eleven counts asserted by the plaintiffs

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[118] Sexual Minorities Uganda v. Lively, 2013 WL 4130756, at *1 (D. Mass. Aug. 14, 2013).

[119] *Id.* at *14.

[120] *Id.*

[121] Daimler AG v. Bauman, 134 S. Ct. 746 (2014).

[122] *Id.* at 748.

[123] *Id.*

[124] *Id.* at 763.

[125] *Id.* at 764 (Sotomayor, J., concurring).

[126] Du Daobin v. Cisco Sys., Inc., 2014 WL 769095, at *1 (D. Md. Feb. 24, 2014).

were brought under the ATS.[127] The U.S. District Court for the District of Maryland concluded that it lacked jurisdiction over the ATS claims because the claims implicated both the political question and act of state doctrines.[128] The political question doctrine, announced in *Marbury v. Madison*, states that courts must defer to the other political branches and refrain from deciding inherently political questions.[129] In this case, the court noted that Congress allows the sale of Internet infrastructure to Chinese police agencies and that the technologies are inherently neutral because much of the equipment is used in non-offensive ways.[130] In declining to assert jurisdiction, the court explained that "[t]o adjudicate this question would require the Judiciary to determine whether the U.S. rules and regulations surrounding the export of products to China are sound."[131] Additionally, the court was concerned about the implications of judging official actions by the Chinese government.[132] Such judgments would necessarily violate the act of state doctrine, which is intended to protect state sovereignty and to ensure that "the courts of one country will not sit in judgment on the acts of the government of another, done within its own territory."[133]

While the court never reached the questions of corporate immunity under the ATS and the presumption against extraterritoriality in light of *Kiobel*, it responded in dicta to claims made by Cisco on these points. Regarding corporate immunity, the court expressed doubt that such immunity exists under the ATS, noting that the Fourth Circuit had not addressed the issue and that several other circuit courts had rejected the notion of corporate immunity under the ATS.[134] The court also noted two factual differences that distinguished this case from *Kiobel* as it relates to the presumption against extraterritoriality. First, unlike Royal Dutch Shell, Cisco is a U.S.-based corporation with offices throughout the United States.[135] Second, Cisco's developmental actions relevant to the alleged abuses in China

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[127] *Id.* at *2.

[128] *Id.* at *4-7.

[129] Baker v. Carr, 369 U.S. 186, 211 (1962).

[130] *Du Daobin*, 2014 WL 769095, at *6.

[131] *Id.*

[132] *Id.* at *7.

[133] Banco Nacional de Cuba v. Sabbatino, 376 U.S. 398, 416 (1964) (quoting Underhill v. Hernandez, 168 U.S. 250, 252, (1897)).

[134] Du Daobin v. Cisco Sys., Inc., 2014 WL 769095, at *8 (D. Md. Feb. 24, 2014); *see also* Doe v. Exxon-Mobile Corp., 654 F.3d 11, 57 (D.C. Cir. 2011), *vacated*, No. 09–7125, 2013 WL 39701013, at *1 (D.C. Cir. 2013) (vacating on the basis of *Kiobel*); Flomo v. Firestone Natural Rubber Co., 643 F.3d 1013, 1021 (7th Cir. 2011); Romero v. Drummond Co., Inc., 552 F.3d 1303, 1315 (11th Cir. 2008).

[135] *Du Daobin*, 2014 WL 769095, at *9.

occurred predominantly within the United States.[136] Consequently, the court reasoned that claimants could bring ATS claims against a defendant who has "taken certain actions within the United States with respect to products that might be primarily used for violations of the laws of nations."[137]

II. ANALYSIS

Section A of this Part argues that ATS claims brought by foreign plaintiffs injured as a result of negligent or nonconsensual medical experimentation conducted abroad by U.S. pharmaceutical companies are not statutorily precluded after *Kiobel*. Section B asserts that the actions of these companies sufficiently displace the presumption against the extraterritorial application of the ATS. Subsection 1 of Section B contends that courts should liberally construe the "touch and concern" standard with regard to U.S. pharmaceutical companies given the importance of the norm against nonconsensual medical experimentation and the unique dangers of public health exploitation. Subsection 2 of Section B argues that obtaining informed consent offers a sufficient liability shield to companies conducting offshore clinical trials. Section C asserts that the state action requirement should be revisited in order to preserve claims brought under the ATS. Lastly, Section D contends that plaintiffs can seek remedies for their ATS claims in state courts as an alternative to pursuing federal claims.

A. "Foreign-Squared" Cases Survive

The majority in *Kiobel* did not conclude that corporations are immune from liability under the ATS.[138] Instead, the Supreme Court erected a jurisdictional barrier to ATS claims that would be nearly impossible to overcome in cases involving foreign plaintiffs, foreign defendants, and exclusively foreign conduct. As subsequent case law demonstrates, "foreign-cubed" cases are almost certainly unable to displace the ATS's presumption against extraterritoriality.[139] Unlike these cases, however, lower courts have split over whether "foreign-squared" cases may overcome the presumption.

In both *Balintulo* and *Bauman*, foreign plaintiffs relied on the defendant's subsidiary location in the United States to meet *Kiobel*'s "touch and

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[136] *Id.*

[137] *Id.* (quoting Sexual Minorities Uganda v. Lively, 2013 WL 4130756, at *2 (D. Mass. Aug. 14, 2013)).

[138] *See generally* Kiobel v. Royal Dutch Petroleum Co., 133 S. Ct. 1659 (2013).

[139] *See, e.g.*, Daimler AG v. Bauman, 134 S. Ct. 746 (2014); Balintulo v. Daimler AG, 727 F.3d 174 (2d Cir. 2013); Chen Gang v. Zhao Zhizhen, 2013 WL 5313411 (D. Conn. Sept. 20, 2013); Tymoshenko v. Firtash, 2013 WL 4564646 (S.D.N.Y. Aug. 28, 2013).

concern" standard.[140] The Second Circuit and the Supreme Court each found this argument unpersuasive.[141] A subsidiary's grant of corporate citizenship and its contacts with the state in which it resides amount to "mere corporate presence" and fail to displace the presumption. These examples are not truly "foreign-squared" cases, which necessarily involve a U.S.-based corporation.

Unlike cases involving a corporate subsidiary based in the United States, cases involving U.S. pharmaceutical companies that injure foreign human research subjects in negligent or nonconsensual clinical trials conducted abroad do qualify as "foreign-squared" cases. For example, in *Abdullahi*, Pfizer represented a U.S.-based MNC, the Nigerian citizens suing on behalf of the injured or dead Nigerian children represented foreign plaintiffs, and the clinical trials conducted in Kano represented the relevant foreign conduct.[142] Admittedly, even in "foreign-squared" cases such as *Abdullahi*, a court is likely to weigh heavily how much relevant conduct occurred within the United States. In *Al Shimari*, for example, a Virginia district court found that *Kiobel* barred a "foreign-squared" ATS claim involving a U.S.-based military contractor. The court decided not to consider the nationality of the defendant in its analysis, instead focusing on the relevant conduct, which occurred exclusively in Iraq.[143] In *Sexual Minorities Uganda*, decided after *Al Shimari*, the Massachusetts District Court allowed a "foreign-squared" ATS case to proceed where the defendant was a U.S. citizen who committed tortious acts in both the United States and in Uganda.[144] As a result of this decision, a foreign plaintiff bringing an ATS claim against a U.S. pharmaceutical company that conducted a negligent or nonconsensual clinical trial would have a stronger case if she could show that at least some of the relevant conduct occurred within the United States.

B. The Actions of U.S. Pharmaceutical Companies Constitute More Than "Mere Corporate Presence"

After *Kiobel*, plaintiffs bringing ATS claims must show that a defendant's conduct constitutes more than "mere corporate presence" in the United States. In order to displace the presumption against extraterritoriality, a defendant's conduct must sufficiently "touch and concern" the United States. Lower courts have held that U.S. subsidiaries,

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[140] *See Balintulo*, 727 F.3d at 179-80; *see also Bauman*, 134 S. Ct. at 748.

[141] *See Balintulo*, 727 F.3d at 182; *see also Bauman*, 134 S. Ct. at 763.

[142] *See generally* Abdullahi v. Pfizer, Inc., 562 F.3d 163 (2d Cir. 2009).

[143] *See* Al Shimari v. CACI Int'l, Inc., 2013 WL 3229720, at *1 (E.D. Va. June 25, 2013).

[144] *See generally* Sexual Minorities Uganda v. Lively, 2013 WL 4130756 (D. Mass. Aug. 14, 2013).

office locations, and bank accounts do not overcome this threshold.[145] The decision in *Al Shimari* indicates that even maintaining corporate headquarters in the United States does not sufficiently "touch and concern" the United States.[146] The court in *Sexual Minorities Uganda* clarified that an American citizen who violated international law norms in large part due to his actions within the United States would meet the "touch and concern" standard.[147] In *Cisco*, the court announced in dicta that certain actions taken by a U.S.-based corporation within the United States could constitute more than "mere corporate presence" if those actions were "related to products that might be primarily used for violations of the laws of nations."[148]

A U.S. pharmaceutical company maintains much more than a "mere corporate presence" in the United States. If the company conducts clinical trials involving humans, it must maintain GCP and HSP as required by the FDA.[149] Additionally, it must properly dispose of its hazardous waste pharmaceuticals as required by the EPA and state law.[150] Furthermore, any pharmaceutical company intending to sell a new drug or medical device in the United States must submit all relevant data to the FDA for review before the drug can be marketed to American consumers.[151]

Unlike maintaining a subsidiary presence, a bank account, a corporate office, or even a corporate headquarters, the interactions between U.S. pharmaceutical companies and U.S. regulatory agencies are continuous and substantial. Arguably, they constitute the type of developmental actions that the court described in *Cisco* and *Sexual Minorities Uganda*. The defendant in *Cisco* took actions within the United States to develop infrastructure that would later be used by the CCP to violate international law.[152] In *Sexual Minorities Uganda*, the defendant took actions within the United States as a purported attorney, author, and evangelical minister to convince Ugandan politicians to discriminate against LGBTI individuals in violation of CIL.[153] Similarly, Pfizer, a U.S. pharmaceutical company, took actions within the United States to develop Trozan (in compliance with

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[145] *See Balintulo*, 727 F.3d at 182 (subsidiaries); Tymoshenko v. Firtash, 2013 WL 4564646, at *4 (S.D.N.Y. Aug. 28, 2013) (corporate offices and bank accounts).

[146] *See Al Shimari*, 2013 WL 3229720, at *2.

[147] *See Sexual Minorities Uganda*, 2013 WL 4130756, at *15.

[148] *See* Du Daobin v. Cisco Sys., Inc., 2014 WL 769095, at *9 (D. Md. Feb. 24, 2014).

[149] FOOD & DRUG ADMIN., *supra* note 22.

[150] ENVTL. PROT. AGENCY, *supra* note 23.

[151] *Development & Approval Process (Drugs)*, FOOD & DRUG ADMIN. (Oct. 27, 2014), http://www.fda.gov/drugs/developmentapprovalprocess.

[152] *See Du Daobin*, 2014 WL 769095, at *6.

[153] *See* Sexual Minorities Uganda v. Lively, 2013 WL 4130756, at *3-4 (D. Mass. Aug. 14, 2013).

FDA and EPA regulations), a drug that was later used in a negligently conducted, nonconsensual clinical trial.[154] Therefore, a foreign plaintiff who can demonstrate continuous and substantial interaction with U.S. regulatory agencies and show that a U.S. pharmaceutical company planned to market a drug in the United States that was later used in a negligently conducted or nonconsensual clinical trial would have a stronger case that a defendant's actions sufficiently "touched and concerned" the United States to displace the presumption against extraterritoriality.

1. The Importance of the Norm and the Unique Dangers of Public Health Exploitation Warrant a Liberal Construction of the "Touch and Concern" Standard

The international prohibition against nonconsensual medical experimentation on human subjects is a product of the Nuremberg trials and is enshrined in the ICCPR.[155] As the Second Circuit in *Abdullahi* remarked, "The administration of drug trials without informed consent on the scale alleged . . . poses a real threat to international peace and security."[156] In order to combat the spread of infectious disease effectively, pharmaceutical companies must continue to develop new drugs. Permitting these companies to conduct negligent or nonconsensual clinical trials with impunity erodes trust, increases resistance to global experiential drug trials, and impedes medical innovation and international public health initiatives.[157] Moreover, because most of the largest pharmaceutical manufacturers are American companies, failing to hold them accountable for negligent or nonconsensual medical experimentation could ignite anti-American sentiment.[158] Seen in this light, foreign plaintiffs could make a strong legal argument that the actions of U.S. pharmaceutical companies in this context sufficiently "touch and concern" the United States to overcome the presumption against extraterritoriality.

In addition to potentially endangering global health initiatives, the lucrative opportunities for pharmaceutical companies to conduct offshore clinical trials combined with desperate host nations willing to erode regulations, ignore informed consent requirements, and refuse to require victim compensation presents a unique danger to the international community.[159] As one scholar who studied international clinical trials in both wealthy and poor countries (mostly in Latin American and Eastern

[154] *See* Abdullahi v. Pfizer, Inc., 562 F.3d 163, 187 (2d Cir. 2009).

[155] *Id.* at 175.

[156] *Id.* at 185.

[157] *Id.* at 186-87.

[158] *Id.* at 187.

[159] Wang, *supra* note 3.

Europe) remarked, "pharmaceutical corporations feed upon public health systems and are adaptable, mobile, and parasitic."[160] Clinical trials are increasingly occurring in states with deficient state health infrastructure and with little to no bargaining power compared to U.S. pharmaceutical companies. The resulting relationships can be especially harmful to a population that is already facing a public health emergency, as was the case in Nigeria.[161]

Apart from the special problems of public health exploitation, victims of negligent or nonconsensual medical experimentation, like other victims of human rights abuses, are often unable legitimately to pursue claims in their own court systems. In many cases, the judicial system is dysfunctional; corruption is rampant; safety concerns abound; or one party reasonably believes that the other might not return to the host country. Courts have considered all of these factors in determining whether foreign courts provide an adequate forum.[162] In *Kodak v. Kavlin*, the District Court for the Southern District of Florida denied a motion to dismiss based on *forum non conveniens*, noting that comments by the Bolivian Minister of Justice and findings by the World Bank and the State Department revealed widespread corruption within the Bolivian justice system.[163] With host-nation court systems largely unreliable, U.S. courts should be more willing to hear ATS cases involving negligent or nonconsensual medical experimentation in order to combat the potentially deadly effects of interlocking corporate and host-nation interests.

2. A Sufficient Corporate Liability Shield: Informed Consent

Clinical trials are essential to the development of cutting-edge drugs to combat infectious diseases and contain deadly pandemics. Exposing the largest pharmaceutical companies to excessive liability admittedly threatens these objectives. Thankfully, U.S. pharmaceutical companies already possess a sufficient corporate liability shield. These companies need only to follow the informed consent procedures required by the FDA, which are posted on the agency's website.[164] These requirements are designed to provide potential research subjects with sufficient information about the clinical trial, published in their native language, to allow them to make an

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[160] Adriana Petryna, *Clinical Trials Offshored: On Private Sector Science and Public Health*, 2 BIOSOCIETIES 21, 23 (2007).

[161] FED. MINISTRY OF HEALTH, REPORT OF THE INVESTIGATION COMMITTEE ON THE CLINICAL TRIAL OF TROVAFLOXACIN (TROVAN) BY PFIZER, KANO, 1996 35-36 (2001).

[162] ASIAN HUMAN RIGHTS COMM'N, *supra* note 37.

[163] Kodak v. Kavlin, 978 F. Supp. 1078, 1086 (S.D. Fla. 1997).

[164] *A Guide to Informed Consent – Information Sheet*, FOOD & DRUG ADMIN. (June 25, 2014), http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm.

informed and voluntary decision about whether or not to participate.[165] If pharmaceutical companies simply comply with this ethical and legal requirement, they substantially limit their exposure to lawsuits except in cases of gross negligence.

C. State Action Revisited

In claims of CIL violations during clinical trials, the ATS requires plaintiffs to prove state action, which can be extremely difficult.[166] Despite the fact that the ATS was originally intended to respond to torts committed by non-state rather than state actors, courts have required state action in cases involving the norm prohibiting nonconsensual medical experimentation. Specifically, the Second Circuit cited its *Kadic* decision when it announced in *Abdullahi* that absent any demonstration of state action, the prohibition on nonconsensual medical experimentation as a norm would not apply directly to private individuals.[167] In addition, the court held that state action would be required to "transform" a private party into the State under 42 U.S.C. § 1983, which allows for civil lawsuits for the deprivation of rights by state officials.[168]

In order to demonstrate state action as required by the courts for ATS and § 1983 claims, a claimant must identify one of several state action tests derived from constitutional law including joint participation, nexus, or delegation of a public function.[169] Under the delegation test, a court determines whether the state has delegated a public function to a private entity. As many MNCs conduct business that involves public works and industrial projects that significantly affect regional development, public function is a reasonable factor to consider in ATS cases.[170] Despite its importance, however, no court has directly based a holding on this test; although many courts perceive all § 1983 tests as interchangeable.[171]

In *Abdullahi*, the court used the nexus test; therefore the plaintiffs did not need to prove that the Nigerian government knew Pfizer did not obtain informed consent.[172] The court held that participation by Nigerian

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[165] *Id.*

[166] *See generally* Kadic v. Karadzic, 70 F.3d 232, 239 (2d Cir. 1995).

[167] Abdullahi v. Pfizer, Inc., 562 F.3d 163, 188 (2d Cir. 2009).

[168] *Kadic*, 70 F.3d at 245.

[169] Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass'n, 531 U.S. 288, 296 (2001) (joint participation test); *Id.* at 295 (nexus test); Lee v. Katz, 276 F.3d 550, 554-55 (9th Cir. 2002) (delegation of a public function test).

[170] Richard Frankel, *Regulating Privatized Government through Section 1983*, 76 U. CHI. L. REV. 1449, 1452 (2009).

[171] *See, e.g.*, Doe v. Unocal Corp., 963 F. Supp. 880, 890 (C.D. Cal. 1997).

[172] Abdullahi v. Pfizer, Inc., 562 F.3d 163, 187 (2d Cir. 2009).

government officials with Pfizer at any stage of the clinical trials constituted state action.[173] Using the nexus approach to link the state and the violation, while effective in *Abdullahi*, could produce adverse results. Specifically, it might incentivize pharmaceutical companies to limit contact and communication with host governments that may be necessary to overcome linguistic and cultural barriers to obtaining informed consent.[174] Using this test, even minimal contact with a host government that is irrelevant to informed consent increases corporate liability because any such contact could be used as grounds for demonstrating state action in ATS suits. Because one of the best ways to counter negligent or nonconsensual medical experimentation is to increase collaboration between pharmaceutical companies and host nations, this test could undermine the ultimate goal of protecting research subjects.[175]

The court in *Abdullahi* could have used the delegation test to find state action and avoid the potential pitfalls of the nexus test. The Nigerian government effectively delegated some of its public functions to Pfizer during the meningitis epidemic. Therefore, Pfizer could have been described as a Nigerian government actor when it conducted clinical trials in its Trovan experiment.[176] For example, during the epidemic, Nigeria sought international help from Doctors without Borders and the International Red Cross.[177] It declared a public health emergency and empowered Pfizer to conduct medical experiments to combat the epidemic. Specifically, it delegated to Pfizer the decision of whether to treat patients within the state's own hospital, an exclusively public function.[178] The hospital where Pfizer conducted its clinical trials was a part of the Hospital Management Board of the Kano State Ministry of Health.[179] A state official gave written permission to Pfizer to treat patients in the hospital as it saw fit.[180] This action essentially constituted the state empowering Pfizer to run its hospital ward. Pfizer had the authority to decide which members of the public would receive treatment and its experiments prevented or delayed access to the general public that sought routine treatment because

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[173] *Id.*

[174] *See* PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, RESEARCH ACROSS BORDERS: PROCEEDINGS OF THE INTERNATIONAL RESEARCH PANEL OF THE PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (2011), *available at* http://www.bioethics.gov/cms/sites/default/files/IRP-Proceedings%20and%20Recommendations_0.pdf.

[175] Spielman, *supra* note 2, at 294.

[176] *Id.* at 295.

[177] *Id.*; *see also* Abdullahi v. Pfizer, Inc., 562 F.3d 163, 170 (2d Cir. 2009).

[178] Spielman, *supra* note 2, at 295.

[179] *Id.*

[180] *Id.*

they were not part of the study.[181] These examples would have likely convinced the Second Circuit to find state action under the delegation test.

Unlike the example of the Nigerian government in *Abdullahi*, most state actors outsource their public health responsibilities entirely to the corporations conducting clinical trials and have little to no interaction with those corporations. This situation presents an even greater danger to research subjects.[182] Because the nexus test hampers collaboration between pharmaceutical companies and host governments, courts should consider the delegation of a public function test to demonstrate state action in ATS claims involving clinical trials.

D. State Law Claims

In addition to the ATS, there are other legal avenues that aggrieved parties might pursue to receive compensation and force accountability. For example, they might pursue common law tort actions alleging violations of state law. While plaintiffs are severely restricted in their ability to raise ATS claims in federal court, they may find relief in state courts. Well before *Filártiga* was decided in 1980, plaintiffs have tried to enforce international human rights norms in state courts. Early cases involving human rights violations looked to the United Nations ("U.N.") Charter and the Universal Declaration of Human Rights ("UDHR") as sources of binding international law.[183] For example, in *Sei Fujii v. State*, a California court struck down the Alien Land Law, which prohibited Japanese nationals from owning property in the Golden State.[184] The court found that such discrimination violated the U.N. Charter, which as a treaty, amounted to a violation of U.S. law.[185] Similarly, in *Namba v. McCourt*, the Oregon Supreme Court invalidated a state statute that prevented Japanese Americans from owning agricultural land. While the court found that the statute violated the Fourteenth Amendment, it also found that the statute violated the general human rights provisions of the U.N. Charter.[186]

After *Filártiga*, international human rights cases that were not suitable for ATS litigation were brought under state law. For example, in *Linder v. Calero Portocarrero*, the plaintiffs asserted both federal question and diversity jurisdiction in a lawsuit on behalf of Benjamin Linder, who was

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[181] *Id.*

[182] Lee, *supra* note 44, at 22; McGregor, *supra* note 44, at 118-20.

[183] Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc A/RES/217 (III) (Dec. 10, 1948).

[184] Sei Fujii v. State, 217 P.2d 481, 488 (Cal. App. 1950).

[185] *Id.* This decision was later affirmed by the California Supreme Court on constitutional grounds. *See* Sei Fujii v. State, 242 P.2d 617 (Cal. 1952).

[186] Namba v. McCourt, 204 P.2d 569, 579 (Or. 1949).

killed by Nicaraguan Contra rebels in 1987 after being subjected to torture.[187] The U.S. citizen plaintiffs could not sue under the ATS because the statute is restricted to alien plaintiffs. Additionally, the Contras were private individuals whose actions did not constitute state action.[188] Nevertheless, the Eleventh Circuit allowed the case to go forward as a diversity jurisdiction suit for wrongful death in which the tort standard was violation of the customary laws of war.[189]

Similarly, in *Martinez v. City of Los Angeles*, a Mexican man and his spouse successfully sued the City of Los Angeles and two of its police officers for providing false information to Mexican authorities which led to his arrest and imprisonment for two months in Mexico.[190] While the court dismissed his claims of arbitrary arrest and detention under the ATS, it allowed his California tort claims of false arrest and false imprisonment to proceed.[191] This decision indicates that claimants may bring state common law tort claims for conduct occurring abroad in U.S. state courts even after a court dismisses the ATS claims.

After 1980, plaintiffs frequently filed parallel state tort law claims alongside their federal ATS claims. Accordingly, an ATS claim for arbitrary arrest and detention usually includes a state law claim for false arrest and false imprisonment.[192] Additionally, an ATS claim for summary execution usually includes a wrongful death claim, and an ATS claim alleging torture usually includes an assault and battery claim.[193] Occasionally, state law claims have taken precedence during the course of litigation.[194]

While these examples demonstrate that state courts present claimants with certain advantages under the ATS, there are also many disadvantages to pursuing ATS claims in state courts. First, the procedural rules governing state court litigation vary, creating a jurisdictional battle as both sides attempt to move the case to the most procedurally favorable forum.[195] In addition, ATS litigation would be based on state tort law, the elements of which also vary from state to state. Furthermore, while courts impose a ten-

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[187] Linder v. Calero Portocarrero, 963 F.2d 332, 333-34 (11th Cir. 1992).

[188] *Id.*

[189] *Id.* at 333.

[190] Martinez v. City of Los Angeles, 141 F.3d 1373, 1376-77 (9th Cir. 1998).

[191] *Id.* at 1381-82.

[192] *See id.* at 1382.

[193] *Id.*

[194] *See, e.g.*, Doe v. Unocal Corp., 963 F. Supp. 880 (C.D. Cal. 1997) (allowing the plaintiffs to assert all of their ATS claims as state common-law tort claims, arguably affecting the defendant's decision to settle).

[195] *See, e.g.*, Wiwa v. Royal Dutch Petroleum Co., 226 F.3d 88 (2d Cir. 2000) (denying the defendant's *forum non conveniens* motion).

year statute of limitations on ATS claims, state law claims will likely face a shorter timeframe.[196] Additionally, courts have held that ATS claims with strong foreign policy implications are barred from state courts despite the state's authority over its own tort law.[197] If claimants choose to pursue ATS claims in state courts, defendants will likely rely on this doctrine to preempt their claims.

III. RECOMMENDATIONS

The risk of negligent or nonconsensual medical experimentation increases when pharmaceutical companies have few incentives to communicate with research subjects or with foreign, resource-poor governments who are often chiefly concerned with receiving money, equipment, and supplies in exchange for making their citizens available for research. It takes injury, scandal, or consistent advocacy to hold pharmaceutical companies accountable. Because many pharmaceutical companies conduct clinical trials in developing countries to avoid stringent regulation by the FDA and the EPA, this further exacerbates the corporate accountability gap.

As a result of these harsh realities, litigation under the ATS may continue to be the only way to limit or prevent negligent or nonconsensual medical experimentation. We should discourage these practices and ensure that clinical trial participants are given sufficient information to consent voluntarily to experiential drug trials. If those individuals are injured, we should compensate them for the harm done, which is partly the intent of the ATS. Therefore, U.S. courts should adopt a liberal construction of the "touch and concern" standard as applied to ATS claims involving foreign plaintiffs injured or killed as a result of negligent or nonconsensual medical experimentation that U.S. pharmaceutical companies conduct abroad. Lastly, in order to hold both private actors and state actors who outsource their public health responsibilities accountable, courts should reconsider the ATS's state action requirement.

CONCLUSION

Offshore clinical trials are here to stay. Pharmaceutical companies will continue outsourcing experiments from the United States to the developing world as long as it remains profitable. Similarly, the leaders of those

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[196] Paul Hoffman & Beth Stephens, Note, *International Human Rights Cases Under State Law and in State Courts*, 3 U.C. IRVINE L. REV. 1, 19 (2013).

[197] *See* Mujica v. Occidental Petroleum Corp., 381 F. Supp. 2d 1164, 1187-88 (C.D. Cal. 2005) (finding that California's interest in the claims are trumped by the doctrine of foreign affairs preemption); *see also* Du Daobin v. Cisco Sys., Inc., 2014 WL 769095, at *1 (D. Md. Feb. 24, 2014).

nations will continue outsourcing some or all of their public health responsibilities to pharmaceutical companies as long as they derive benefits from the arrangement. These exchanges characterize the convoluted context and precarious environment in which negligent or nonconsensual clinical trials occur.

In a post-*Kiobel* world, it will be much more difficult for individuals who are injured in these trials to bring claims against U.S. pharmaceutical companies under the ATS. Yet, barring ATS claims by foreign research subjects who are injured or killed in negligent or nonconsensual clinical trials conducted by these companies undermines the spirit and purpose of the ATS and exacerbates the corporate accountability gap. U.S. pharmaceutical companies maintain more than a "mere corporate presence" in the United States and their actions significantly impact America's ability to combat the cross-border spread of contagious diseases and have a serious impact on our national reputation. Pharmaceutical companies already possess a sufficient liability shield when they obtain informed consent. Injured research subjects, by contrast, face unreliable or corrupt domestic court systems and inadequate or nonexistent compensation. For these reasons, courts should liberally construe the "touch and concern" standard imposed by the Supreme Court and reevaluate the state action requirement of the ATS. In this way, we can adequately guard against the violation of the universal norm prohibiting nonconsensual medical experimentation.