

A Look Back and
a Look Forward

By James V. Aiosa
and Paul V. Majkowski

The history of these cases allows us to identify lessons learned and issues yet unresolved, as well as contemplate new legal standards that might develop.

Thirty Years of Agent Orange Litigation

The various claims arising from the use of the chemical defoliant “Agent Orange” during the Vietnam War collectively comprise one of the seminal and most diverse mass toxic tort cases in United States judicial history.

The Agent Orange litigation has involved several phases over the past 30 years, from 1979, when the original veterans’ class action complaint was filed, through 2009, when the United States Supreme Court denied certiorari to review the dismissal of a third wave of veterans’ claims based on the “government contractor defense” and also denied review to dismissed claims asserted by Vietnamese nationals under the Alien Tort Claims Act.

Looking back over the history of the Agent Orange cases and at the future of mass toxic torts, we can identify lessons that have been learned, issues with which we are still grappling, and new legal standards that might develop. In this article, we will address several of these lessons, issues, and legal standards through the prism of the Agent Orange cases: use of class actions in mass toxic torts; evidentiary standards for causation; the application of the government contractor defense and derivative immunity principles; international

toxic tort claims based on the Alien Tort Claims Act; and the pleading of mass toxic torts under the recently articulated *Iqbal/Twombly* standards.

Overview of Agent Orange History

During the Vietnam War, the U. S. armed forces utilized a number of chemical herbicides “to reduce foliage behind which the enemy might lurk.” *In re Agent Orange Prod. Liab. Litig.*, 304 F. Supp. 2d 404, 407 (E.D.N.Y. 2004), *aff’d*, 517 F.3d 76 (2d Cir. 2008), *cert. denied*, 129 S. Ct. 1523 (2009). Agent Orange, a 50-50 mixture of high-concentration 2,4-D (2,4-Dichlorophenoxyacetic acid) and 2,4,5-T (2,4,5-Trichlorophenoxyacetic acid), was used in the greatest volume and was applied to foliage through aerial spraying. The 2,4,5-T component of Agent Orange contained trace amounts, often less than one part per million, of the dioxin congener 2,3,7,8 tetrachlorodibenzo-p-dioxin (TCDD), which is alleged to cause adverse health effects. The use of Agent Orange



■ James V. Aiosa is a partner with Rivkin Radler LLP, in Uniondale, New York, where he heads the toxic tort group. Mr. Aiosa is a member of DRI’s Toxic Torts and Environmental Law Committee. Paul V. Majkowski is also a partner in Rivkin Radler’s Uniondale, New York, office, and focuses his practice on toxic tort litigation. Mr. Aiosa and Majkowski would like to thank Steven Sachs, an associate with the firm, for his assistance in preparing this article.

was discontinued in 1970, after an animal study suggested an association between large doses of 2,4,5-T and possible teratogenic effects.

The original wave of Agent Orange cases, including a class action filed in New York federal court in 1979, were consolidated. Judge Jack B. Weinstein in the Eastern District of New York presided over and ultimately certified a class in this multidistrict litigation. *In re Agent Orange Prod. Liab. Litig.*, 304 F. Supp. 2d 404, 410–21 (E.D.N.Y. 2004) (recounting history of original litigation). The plaintiffs alleged that the veterans' exposure to herbicides used in Vietnam that contained trace amounts of dioxin resulted in a number of cancers and other diseases, as well as miscarriages and birth defects. As the United States had discretionary function immunity, the plaintiffs named as defendants the chemical manufacturers that had produced the herbicides pursuant to the government's contracts and specifications.

A class settlement was reached on the eve of trial in 1984, for a total of \$180 million. As recognized by the Second Circuit Court of Appeals in affirming Judge Weinstein's approval of the settlement, this amount reflected a "nuisance value" and was appropriate, given the deficiencies of the plaintiffs' case with respect to causation and other issues and the strength of the manufacturers' defenses, which included the government contractor defense. *In re Agent Orange Prod. Liab. Litig.*, 818 F.2d 145 (2d Cir. 1987), *cert. denied sub nom. Pinkney v. Dow Chem. Co.*, 484 U.S. 1004 (1988) and *Krupkin v. Dow Chem. Co.*, 487 U.S. 1234 (1988).

Subsequent to the settlement, the claims of class members who had opted-out were dismissed on summary judgment for lack of causation and on government contractor defense grounds. *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom. Lombardi v. Dow Chem. Co.*, 487 U.S. 1234 (1988).

Reflecting the difficulties inherent in dealing with future claims in mass toxic torts, there have been additional waves of Agent Orange litigation after the 1984 settlement. First, plaintiffs challenged the 1984 settlement in two overlapping class actions filed in 1989 and 1990, in which

they argued that the 1984 class settlement did not bind them "because the latency of their injuries prevented them from knowing whether or not they were included in the class at the time of the first deadline for opting out of the [original] class action." *In re Agent Orange Prod. Liab. Litig.*, 304 F. Supp. 2d 404, 421 (E.D.N.Y. 2004), *aff'd*, 517 F.3d 76 (2d Cir. 2008). The courts found that the plaintiffs were bound by the settlement and dismissed their claims. *Ryan v. Dow Chem. Co.*, 781 F. Supp. 902 (E.D.N.Y. 1991), *aff'd sub nom. In re Agent Orange Prod. Liab. Litig.*, 996 F.2d 1425 (2d Cir. 1993).

Beginning in 1998, plaintiffs filed another wave of lawsuits in which they contended that their diseases became known to them only after the fund created from the 1984 settlement had been exhausted and that they could, therefore, file suit. Judge Weinstein dismissed the claims as constituting an improper collateral attack on the 1984 settlement; however, the Second Circuit reversed, finding that individuals whose claims manifested after exhaustion of the settlement fund had not been adequately represented in the 1984 settlement. *Stephenson v. Dow Chem. Co.*, 273 F.3d 249 (2d Cir. 2001), *aff'd in part, vacated in part*, 539 U.S. 111 (2003). That ruling was affirmed by a 4–4 Supreme Court, with Justice Stevens recusing himself from the case because his son had served in Vietnam.

On remand, the manufacturers were granted summary judgment dismissing these third-wave claims, based on the government contractor defense, which holding was affirmed on appeal and denied review by the Supreme Court. *In re Agent Orange Prod. Liab. Litig.*, 304 F. Supp. 2d at 407.

In addition to the U.S. veterans actions, in January 2004, a putative class of Vietnamese nationals brought suit in federal court for personal injuries and damage to the Vietnamese environment allegedly resulting from Agent Orange use. The gravamen of the claims was that the Agent Orange manufacturers violated the Alien Tort Claims Act by conspiring with and aiding and abetting the U. S. government in waging chemical warfare in contravention of international legal norms. The courts rejected these claims. *Vietnam Association for Victims of Agent Orange v. Dow Chem. Co.*, 373 F. Supp. 2d 7 (E.D.N.Y. 2005), *aff'd*,

517 F.3d 104 (2d Cir. 2008), *cert. denied*, 129 S. Ct. 1524 (2009).

Mass Toxic Tort Class Actions

The Agent Orange class action has proved unique among mass toxic torts inasmuch as courts have frequently refused to certify such classes, whereas the Agent Orange plaintiffs received class certification. Over

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the past 30 years, courts have refused to certify classes in actions alleging toxic torts, including those seeking classwide medical monitoring, because the individual issues have predominated over the common issues. *See In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 209 F.R.D. 323, 347–48 (S.D.N.Y. 2002) ("[T]he overwhelming majority of state and federal courts have denied certification of environmental mass tort classes, even in single source cases."). These results somewhat predictably follow from the fact that the causation element in toxic tort actions becomes highly individualized because of the need to show a dose-response relationship, which will almost always be peculiar to the particular class member, as well as that a court must examine alternate causes of a plaintiff's injuries on an individualized basis as very few diseases are characterized as signature diseases.

Looking back at Agent Orange, however, the court certified the class, reversing the paradigm, even though the same considerations applied with respect to causation and perhaps, even more so, due to the difficulty in adducing competent evidence quantifying exposure). Judge Wein-



stein offered a partial explanation when he expressed the belief that class actions are “useful in very complex cases that often involve political as well as economic and scientific issues.” Jack B. Weinstein, *Preliminary Reflections on Administration of Complex Litigations*, CARDOZO L. REV. DE NOVO 1, 9 (2009). Judge Weinstein recently observed in a law review essay

Focus on what a manufacturer knew about risks associated with a product’s operational use and whether the government also knew about them.

that, “When settled, [class actions] provide a method of sound utilization of available funds, with minimal transaction costs, to assist persons who believe they were, or are, injured; they permit defendants to limit their exposure and get on with their productive work without huge continuing litigations hanging over their heads.” *Id.* Yet, as Judge Weinstein further noted, the use of class actions in mass toxic tort cases, which involve unknown future claimants, is thwarted under the *Agent Orange* precedent, which did not bind future claimants to the original class settlement. *Id.* at 10 (“*Stephenson* helped cripple class actions. It meant that a defendant could not be sure it was buying full piece.”).

Notably, the court based class certification in *In re Agent Orange* on the commonality of the defendant manufacturers’ affirmative defenses and issues regarding general causation, on which the U.S. courts consistently ruled in the manufacturers’ favor. Moreover, due to sufficiently strong defenses the court characterized the settlement as having nuisance value in approving it. So, in some circumstances, might it be better to take on the entire class at once, rather than piece-meal?

As Judge Weinstein observed, the inability to bind future claimants defeats the effi-

cacy of the class action from the defendant’s perspective, because the defendant can never conclusively buy its peace. A possible solution to this dilemma, through tort legislation, would reform class action settlements involving toxic exposure and latent injury claims by adopting an appropriate statute of repose on these claims. This would provide a settling defendant with the necessary protection against open-ended, future claims.

Government Contractor Defense

The U.S. Agent Orange cases have had an element not common to all mass toxic tort actions—the government contractor defense, also referred to as the “military contractor defense” in some decisions. The government contractor defense provides a contractor that is “getting the government’s work done” and acting in accord with government specifications with immunity derived from the sovereign immunity reserved for the government under the Federal Tort Claims Act. Most frequently, the government contractor defense has precluded claims alleging defects in military aircraft, and the seminal United States Supreme Court decision articulating the elements of the defense, *Boyle v. United Techs. Corp.*, 487 U.S. 500 (1988), involved an allegedly defective escape hatch on a military helicopter.

Over the past 30 years since *Boyle*, the government contractor defense has been raised in a variety of other contexts, including a number of alleged mass tort or toxic tort exposures. For example, the government contractor defense has been at issue in cases involving asbestos exposure during naval shipbuilding, exposure to benzene in military jet fuel, lead paint in housing built for civilian workers engaged in WWII wartime production efforts, and exposure to wastes disposed at plant producing chemical material for the military. See *Harris v. Rapid Am. Corp.*, 532 F. Supp. 2d 1001, 1004 (N.D. Ill. 2007) (cataloging cases approving and rejecting removal of asbestos cases against shipbuilders); *Lambert v. B.P. Prods. N. Am., Inc.*, 2006 U.S. Dist. LEXIS 16756 (S.D. Ill. 2006) (involving benzene in military jet fuel); *State of Ohio, ex rel. Dann v. Sherwin-Williams Co.*, 2008 U.S. Dist. LEXIS 85427 (S.D. Ohio 2008) (involving lead paint in civilian produc-

tion worker housing); *Anderson v. Hackett*, 2009 U.S. Dist. LEXIS 66651 (S.D. Ill. 2009). Comparable derivative immunity principles have been at issue in the World Trade Center cases alleging toxic exposures. Government contractor defense principles have also been recognized as applicable to non-military products. See, e.g., *Carley v. Wheeled Coach*, 991 F.2d 1117 (3d Cir. 1993), cert. denied, 510 U.S. 868 (1993).

Most recently, the D.C. Circuit ruled that, based on the government contractor defense principles set forth in *Boyle*, tort claims against contractors providing services in a military theater may be subject to “battlefield preemption.” *Saleh v. Titan*, 580 F.3d 1 (D.C. Cir. 2009). The court did not delineate the precise contours of this new standard, but it represents an important development for the realm of toxic and environmental torts that courts will likely grapple with in the future. As an ever-increasing number of private contractors perform services in military theaters in accordance with the “total force concept,” because the modern military theater includes a variety of potentially toxic substances, the possibility of toxic tort lawsuits against contractors will arise. We have recently seen lawsuits alleging toxic exposure from waste disposal practices in Iraq and Afghanistan, the “burn pit” cases for which consolidation as a multidistrict litigation is pending, and to hexavalent chromium. *In re KBR, Inc. Burn Pit Litig.*, MDL No. 2083, D. Md.) (Iraq/Afghanistan waste disposal practices); e.g., *McManaway v. KBR, Inc.*, No. 3:08-cv-0186-RLY-WGH (S.D. Ind. Third Amended Complaint filed Sept. 25, 2009, *Gallaher v. KBR, Inc.*, No. 5:09-cv-69 (N.D. W. Va. Complaint filed June 25, 2009) (hexavalent chromium).

Under the requisite circumstances, a defendant might find the government contractor defense a vital tool to employ in a toxic tort action. Not only will the defense immunize the contractor, a colorable government contractor defense will permit removal to federal court based on federal officer removal. 28 U.S.C. §1442.

The defense must pass a three-pronged test that shows that:

- (1) the United States approved reasonably precise specifications (for the allegedly defectively designed equipment);
- (2) the equipment conformed to those

specifications; and (3) the contractor warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States.

The first and third elements are typically the most contentious parts of the test.

In the context of a product claim, addressing the first part of the test, a plaintiff will argue that the government did not determine the product specifications. In addressing this aspect of the test, the Second Circuit's 2008 *In re Agent Orange* decision that affirmed the applicability of the government contractor defense to Agent Orange held that the pertinent inquiry is whether the government was the "agent of decision" regarding the composition of a product. 517 F.3d at 91. In sum, while part of the decision-making process might involve the government's "reliance on [the] manufacturers' expertise in making a fully informed decision on what to order," if the government "independently and meaningfully reviews the specifications" and "approves" them, responsibility for the specifications belong to the government for purpose of the government contractor defense. *Id.*

In the case of services, the issue is the degree to which the government exercised control over the manner in which a contractor provided services, and a plaintiff will seek to show that the contractor exercised its own discretion. The case law involving services is less developed than in the products context. The D.C. Circuit's recently articulated standard is that "[d]uring wartime, where a private service contractor is integrated into combatant activities over which the military retains command authority, a tort claim arising out of the contractor's engagement in such activities shall be preempted." *Saleh v. Titan*, 580 F.3d at 9. This holding reversed the earlier district court's conclusion that for preemption to occur, a contractor needed to meet a heightened standard, proving that it operated "under the direct command and exclusive operational control of the military chain of command." *Ibrahim v. Titan Corp.*, 556 F. Supp. 2d 1, 5 (D.D.C. 2007).

The third element of the test, which addresses the relative states of knowledge of a manufacturer and the government and a manufacturer's disclosure of known

risks, presents some unique inquiries, inasmuch as toxic injury risks depend on anticipated dose-response relationships associated with intended use of products, if the risks are even known. Additionally, while a manufacturer might understand risks associated with occupational exposure, those risks might differ significantly from the foreseeable risks involved in operational use of a product in a different context. A plaintiff will seek to show that a manufacturer had knowledge of toxic risks to defeat this prong of the defense.

The defense must, therefore, focus on what a manufacturer knew about risks associated with a product's operational use and whether the government also knew about them. In the 2008 *In re Agent Orange* decision, the Second Circuit found that the government possessed the same knowledge as the manufacturers, and that there was no showing that the manufacturers "had knowledge of a danger that might have influenced the military's conclusion that 'operational use' of Agent Orange posed 'no health hazard... to men or domestic animals,'" or that the manufacturers possessed some "never-disclosed knowledge of a sort that might have influenced the government's decision-making process regarding Agent Orange as it was used in Vietnam." *In re Agent Orange Prod. Liab. Litig.*, 517 F.3d at 101-02 (emphasis added).

Causation: A Move toward Evidence-Based Toxicology

Throughout the history of toxic tort litigation, the issue of causation has presented a dilemma because epidemiology and toxicology, the disciplines typically utilized to prove causation within the exposure-dose-response-disease paradigm, has a limited ability to meet traditional legal and evidentiary standards of proof. Epidemiology is defined as "the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations." Michael D. Green, D. Michael Freedman & Leon Gordis, *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 335, 335 (Fed. Jud. Ctr. 2d ed. 2000). The "statistical analysis" generated by epidemiology infers "associations" between exposure and disease, but, fundamentally, "it should be emphasized that *an association is not equivalent to cau-*

sation." *Id.* at 336. On the other hand, toxicology does not offer definitive results for a given toxic exposure scenario because we cannot use human subjects to test scenarios. *Id.* at 339 n.14 ("Experimental studies in which human beings are exposed to agents known or thought to be toxic are ethically proscribed.").

In the Agent Orange cases, causation

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was not tried, although Judge Weinstein did consider the issue on summary judgment with respect to the plaintiffs who opted out of the 1984 class settlement. Judge Weinstein held that the plaintiffs could not sustain their burden on causation. Agent Orange was again unique among mass toxic torts, insofar as scientists have conducted specific health studies of the Vietnam War veterans, including the "Ranch Hand" study of those veterans directly involved in Operation Ranch Hand, allowing Judge Weinstein to conclude that "[n]o acceptable study to date... concludes that there is a causal connection between exposure to Agent Orange and the serious health effects claimed by plaintiffs." *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. at 1231.

Most frequently, toxic tort plaintiffs will rely on studies that involve causation issues that differ from those involved in their cases. Defendants should challenge and courts should reject this type of evidence. See, e.g., *Knight v. Kerby Inland Marine, Inc.*, 363 F. Supp. 2d 859, 864-66 (S.D. Miss. 2005) (rejecting testimony of a plaintiffs' expert who "relied on a variety of relatively dissimilar epidemiological studies to conclude that specific chemicals cause specific cancers," in which the studies, rather than



analyzing the particular exposure-disease scenario at issue, “lump[ed] numerous high-grade solvents together,” identified “only a broad category of exposure,” and failed to isolate “particular exposures,” or failed to document “the level of exposure”). Indeed, close to 25 years ago, Judge Weinstein specifically admonished against such evidence: “A number of sound epidemio-

Consistent with *Iqbal* Twombly, in the future courts should require toxic tort plaintiffs to present scientifically plausible bases for their claims at the outset in initial complaints.

logical studies have been conducted on the health effects of exposure to Agent Orange. These are the only useful studies having any bearing on causation. All the other data supplied by the parties rests on surmise and inapposite extrapolations from animal studies and industrial accidents.” *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. at 1231. This fundamental approach has not changed over the past 25 years, and defense attorneys should remember it and address deficient causation evidence.

Another approach in contesting a plaintiff’s evidence that defense attorneys should consider is to emphasize the necessity of evidence-based toxicology to prove toxic torts, rather than relying on statistical evidence. See generally Philip S. Guzelian, et al., *Evidence-Based Toxicology: A Comprehensive Framework for Causation*, 24 Human & Experimental Toxicology 161 (2005). Notably, in the context of presumptive disability decision-making for veterans benefits, the National Academy of Sciences’ Institute of Medicine has likewise explained that the process should result in “evidence-based decisions,” that “association” is not the appropriate criterion for benefit determinations, and that

decisions “should be grounded in a scientific evaluation of the full range of evidence that the exposure of interest causes the disease or disability.” See Paul V. Majkowski and James V. Aiosa, *Using Statistical Analysis in Mass Toxic Tort Cases: Are the Courts a Century Behind Science?* MASS TORTS (Am. Bar Ass’n, Chicago, Ill.), Fall/Winter 2009, at 12.

Causation issues will continue to be both a linchpin and a dilemma in the toxic tort realm. From the defense perspective, as Judge Weinstein recognized 25 years ago, we must oppose the “surmise and inapposite extrapolations from animal studies and industrial accidents,” and as good science dictates, we must carefully monitor statistical evidence use and advocate for the use of evidence-based toxicology.

Environmental Alien Tort Statute Claims

Another uncommon aspect of the Agent Orange cases was the Vietnamese nationals’ reliance on the Alien Tort Claims Act (ATCA) as a theory for relief. 28 U.S.C.A. §1350. An ATCA claim is predicated on violation of the “law of nations” or “customary international law.” As discussed below, to date, a number of cases brought under the ATCA have alleged toxic injuries and environmental contamination. Plaintiffs in these cases have generally failed due to the lack of definitive international legal norms concerning environmental risk and protection and handling hazardous, toxic wastes. Such cases might become more prevalent as international consensus develops concerning toxic exposures, if aggressive United States and European regulators identify additional toxic risks and standards, and other international entities, such as the Stockholm Convention on Persistent Organic Pollutants and the United Nations Human Rights Council, continue to emphasize environmental and hazardous waste issues.

Although “courts have recognized that [the ATS] may be applicable to international environmental torts,” many ATCA toxic tort claims have been rejected by the courts, as noted above, because plaintiffs failed to show that international legal norms exist regarding environmental matters. *Beanal v. Freeport-McMoran, Inc.*, 969 F. Supp. 362, 383 (E.D. La. 1997). In *Flores*

v. Southern Peru Copper Corp., 343 F.3d 140 (2d Cir. 2003), the plaintiffs sought recovery for respiratory illnesses allegedly linked to the defendant’s mining, refining, and smelting operations in Peru, asserting that they had been deprived of the rights to life, health, and sustainable development in violation of customary international law. In analyzing whether the plaintiffs’ claims were actionable under the ATCA, the Second Circuit considered, among other things, whether a claim could be based on a “customary international law rule against *intranational* pollution.” *Id.* at 161. The court concluded that an ATCA claim was not actionable, after analyzing various sources and evidence of purported international law, including: “(i) treaties, conventions, and covenants; (ii) non-binding declarations of the United Nations General Assembly; (iii) other non-binding multinational declarations of principle; (iv) decisions of multinational tribunals; and (v) affidavits of international law scholars.” *Id.*

Federal district courts that have considered whether claims are actionable under the ATCA have reached similar conclusions. See, e.g., *Beanal*, 969 F. Supp. at 382–384 (rejecting the plaintiff’s allegations that “environmental destruction” resulting from “mining operations and drainage practices” violated three international environmental law principles: (1) the polluter pays principle, (2) the precautionary principle, and (3) the proximity principle and concluding that no “universal consensus in the international community as to their binding status and their content” existed); *Amlon Metals, Inc. v. FMC Corp.*, 775 F. Supp. 668, 671 (S.D.N.Y. 1991) (dismissing ATCA claims based on shipment of contaminated copper residues as not containing requisite “clear allegation of a violation of the law of nations,” as the international convention relied upon did “not set forth any specific proscriptions, but rather refer[red] only in a general sense to the responsibility of nations to insure that activities within their jurisdiction do not cause damage to the environment beyond their borders”). Additionally, at least one court has held that a plaintiff must exhaust its local remedies before seeking to obtain ATCA jurisdiction in federal court. See *Sarei v. Rio Tinto*, 550 F.3d 822 (9th Cir. 2008) (alleging that a defendant mining

company “intensely polluted the land, rivers, and air” in Papua New Guinea).

On the other hand, the plaintiffs survived a summary judgment motion in *Arias v. Dynacorp*, 517 F. Supp. 2d 221 (D.D.C. 2007), in which the Ecuadorian plaintiffs asserted ATCA claims based on allegations of physical harm and property damage arising from the over-drift of fumigants that the U.S. State Department contractors had sprayed over Colombia to eradicate cocaine and heroin farm crops and farming.

It remains to be seen whether the pleading of such causes of action becomes more prevalent.

***Iqbal/Twombly* Pleading Standards for Toxic Torts**

One final observation concerning the future of mass toxic torts is to consider how courts will apply the pleading standards articulated by the United States Supreme Court in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). Attorneys will want to think about how to use the *Iqbal/Twombly* standard as a defense tool. Under the *Iqbal/Twombly* standard, pleadings require more than “an unadorned, the defendant-unlawfully-harmed-me accusation.” *Iqbal*, 129 S. Ct. at 1949. Rather, these cases have established a “facial plausibility” standard requiring the plaintiff “to plead factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* The standard requires that a plaintiff plead facts that demonstrate more than a mere possibility that a defendant has acted unlawfully. *See id.* (“Where a complaint pleads facts that are ‘merely consistent with a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” (quoting *Twombly*, 550 U.S. at 557)).

Under the *Iqbal/Twombly* plausibility standard, must toxic tort plaintiffs now plead detailed facts that quantify exposure and dose, thoroughly explain causation mechanics, and identify the epidemiological associations on which that plaintiff bases a claim? Additionally, if plaintiffs fail, will courts grant Rule 12(b)(6) dismissals?

Few precedents on this point have yet appeared. In one recent case, the court did rely on the *Iqbal/Twombly* principles to dismiss a pharmaceutical product liability action in which the plaintiff alleged that the drug that she ingested—Trileptal—had caused her to suffer multi-organ hypersensitivity and multiple related complications. *Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp. 2d 787 (S.D. Ohio 2009). The plaintiffs’ first cause of action for strict product liability stated:

P 27. The product which was consumed by Plaintiff was defective in design and construction at the time it left the Defendants’ control.

P 28. Defendants failed to design, manufacture, test, and control the quality of Trileptal such that when it left the control of the Defendant, it deviated in a material way from the design specifications, formula or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula or performance standards.

P 28. As a direct and proximate result of the defect in manufacture or construction by Defendants, Plaintiff suffered the injuries and damages set forth herein.

Id. at 790.

The court granted the defendant pharmaceutical company’s motion to dismiss as to the strict product liability cause of action, based on the plaintiffs’ “failure to state a plausible claim for relief.” *Id.* at 795. The court observed that:

Plaintiffs have done nothing more than provide a formulaic recitation of the elements of a claim under the statute. They have failed to allege any facts that would permit the Court to conclude that a manufacturing defect occurred and that the defect was the proximate cause of Amanda Frey’s alleged injuries. Plaintiffs’ allegations in this regard fall far short of the sufficiency standard set forth in *Twombly*.

Id.

Given the variety of injuries and diseases that the plaintiffs in the Agent Orange cases alleged had been caused by exposure to herbicides, requiring pleadings to quantify exposure and dose, describe the mechanism of injury and the epidemiological associations relied on by the plaintiffs, among other detailed facts, would have resulted in fairly substantial pleadings. Regardless, consistent with *Iqbal/Twombly*, in the future courts should require toxic tort plaintiffs to present scientifically plausible bases for their claims at the outset in initial complaints. Had courts imposed that rule in the Agent Orange cases, the defendants would have avoided at least some of this three-decades-long litigation and the significant attendant costs.

Conclusion

The Agent Orange cases commenced some 30 years ago were among the first mass toxic torts. Some of the issues first posed in the Agent Orange context, such as the efficacy of the class action and causation proof, remain in debate. Other principles, such as the government contractor defense, and standards, such as those for ATCA environmental claims, have emerged in other litigation. We can learn and even develop new strategies by looking back at these Agent Orange cases. 