

COLLECTIVE PRODUCTS LIABILITY ACTIONS IN THE
EUROPEAN UNION AND THE UNITED STATES: A
VIOXX CASE STUDY

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I. INTRODUCTION

When a defective medical product injures a consumer, she can retain counsel and file a claim against its manufacturer. What if it injures eighty million consumers across multiple continents? While the single consumer's ability to recover largely relies on the merits of her claim, the eighty million's collective ability to recover lives or dies with procedural rules. Those rules differ between the United States and European Union. This annotation compares the effect of these differences in the products liability context using the high-profile Vioxx litigation as an example. Part II overviews the general liability regime of each jurisdiction. Part III details the case of Vioxx. Part IV outlines the elements of an E.U. agreement to expand collective redress procedures. Part V asks whether the agreement is the best way for policymakers to address the inability of European consumers to recover in mass harm cases, ultimately concluding it is not.¹

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1. The regulatory approval processes for marketing drugs and medical devices is not the subject of this annotation, although some discussion of regulatory approval may be necessary to understand how the interconnected tools of regulation and legal liability facilitate consumer recovery and safety. *See generally* Susan Bartlett Foote,

II. CURRENT LAW

A liability regime as used in this annotation² is broadly a function of two factors: (1) substantive legal claims (and defenses to these claims) (e.g. strict liability, negligence, breach of warranty, etc.) which set a ceiling for recovery; and (2) procedural rules (e.g. class or mass action procedures, contingent fee, and loser pays rules), which determine how and when substantive claims are brought, if at all.³ This annotation focuses on procedural rules, particularly class actions.

The U.S. class action, “[t]hat most American of judicial procedures,”⁴ is a controversial tool; it provides access to the courts for class members who cannot themselves afford to sue, promising to address the problems of inconsistent judgments and duplicated litigation expenses.⁵ In contrast, E.U. consumers have nothing like the U.S. class action; the European Commission recently panned E.U. collective redress procedures as in need of expansion, particularly in the mass harm context which is typical of defective medical

Product Liability and Medical Device Regulation: Proposal for Reform, in NATIONAL ACADEMY OF SCIENCES, NEW MEDICAL DEVICES: INVENTION, DEVELOPMENT, AND USE 73 (Karen B. Ekelman ed., 1988) (appraising the strengths and weaknesses of conducting public policy via the simultaneous use of tort liability and regulation). For a comparison of European and U.S. approval processes for new drugs and devices, see generally Gail A. Van Norman, *Drugs and Devices: Comparison of European and U.S. Approval Processes*, 1 J. AM. COLL. CARDIOLOGY: BASIC TO TRANSLATIONAL SCI. 399 (2016). An additional issue left unexamined is how consumers pay for liability regimes in the form of higher market prices of medical products.

2. “Liability regime” here refers to the rules of a jurisdiction for civil recovery (including various substantive claims and procedural rules) as understood and applied by legal actors who have a voice in the daily making of these liability regimes, often distinct from the blackletter rules promulgated by lawmakers. For a similar approach in a discussion of comparative tort law see Marta Infantino & Eleni Zervogianni, *The European Ways to Causation*, in THE COMMON CORE OF EUROPEAN PRIVATE LAW, CAUSATION IN EUROPEAN TORT LAW 85, 85 (Marta Infantino & Eleni Zervogianni eds., 2017). Additionally, “manufacturer” here refers to any person or organization that places medical products on the market under its own name, except where expressly distinguished from other actors in a product’s manufacturing and marketing process. To clarify a common misconception, manufacturers’ liability is distinct from physicians’ liability.

3. See generally Han W. Choi & Jae Hong Lee, *Pharmaceutical Product Liability*, in PRINCIPLES AND PRACTICE OF PHARMACEUTICAL MEDICINE 688 (Lionel D. Edwards et al. eds., 2011) (discussing several landmark cases to illustrate principles of product liability law, specific claims, types of defects, defenses, international issues, and the operation of these issues).

4. Edward F. Sherman, *Consumer Class Actions: Who Are the Real Winners?*, 56 ME. L. REV. 223, 236 (2004).

5. *Id.* at 224 (2004).

products.⁶

III. CASE STUDY: VIOXX

Merck & Co., Inc. (“Merck”), a large, U.S. pharmaceutical company, manufactured and sold a nonsteroidal anti-inflammatory drug (NSAID), Vioxx, to treat arthritis and acute pain.⁷ Over five years beginning in mid-1999, approximately eighty million people worldwide used Vioxx,⁸ generating more than \$11 billion in sales.⁹ But on September 30, 2004, Merck suspended worldwide sales of Vioxx¹⁰ following a discovery that Vioxx quadrupled the risk that its users would experience a heart attack or stroke.¹¹

6. See *Commission Proposal for a Directive of the European Parliament and of the Council on Representative Actions for the Protection of the Collective Interests of Consumers, and Repealing Directive 2009/22/EC*, at 1 COM (2018) 184 final (Nov. 11, 2018) (“[T]he Collective Redress Report showed that a number of Member States still do not provide for collective compensatory redress mechanisms tailored for mass harm situations.”). But see *In re Vioxx Prods. Liab. Litig.*, 448 F. Supp. 2d 741, 746 n.1 (E.D. La. 2006) (collecting articles that support the court’s finding that Italy and France have collective action mechanisms allowing groups of similarly situated plaintiffs to file together).

7. *COX-2 Selective (Includes Bextra, Celebrex, and Vioxx) and Non-selective Non-steroidal Anti-inflammatory Drugs (NSAIDs)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/cox-2-selective-includes-bextra-celebrex-and-vioxx-and-non-selective-non-steroidal-anti-inflammatory> [<https://perma.cc/9QCV-2QZA>] (last updated Feb. 6, 2018).

8. Mark Greener, *First Do No Harm: Improving Drug Safety Through Legislation and Independent Research*, 9 *EMBO REPS.* 221, 221 (2008).

9. Peter Loftus & Brent Kendall, *Merck to Pay \$950 Million in Vioxx Settlement*, *WALL ST. J.* (Nov. 23, 2011), <https://www.wsj.com/articles/SB10001424052970204531404577054472253737682> [<https://perma.cc/42VF-TR2U>].

10. Terence Neilan, *Merck Pulls Vioxx Painkiller from Market, and Stock Plunges*, *N.Y. TIMES* (Sept. 30, 2004), <https://www.nytimes.com/2004/09/30/business/merck-pulls-vioxx-painkiller-from-market-and-stock-plunges.html> [<https://perma.cc/Q2TL-JRCH>].

11. The discovery arose from ongoing clinical trials that compared a Vioxx user’s risk to a baseline risk established from use of another available anti-inflammatory drug. Greener, *supra* note 10, at 221; see also Mike Ferrara, *Vioxx Killed Half a Million? The Facts Are Grim*, *LEGAL EXAMINER* (May 1, 2012), <https://www.legalexaminer.com/health/vioxx-killed-half-a-million-the-facts-are-grim/> [<https://perma.cc/7V2T-YZAQ?type=image>] (estimating Vioxx killed half a million users in the United States alone).

A. *Vioxx*: U.S. Results

The September 2004 sales suspension resulted in enough U.S. plaintiffs suing Merck that courts had to employ an irregular administrative procedure to keep the flood of litigation from overwhelming the courts, designating all federal *Vioxx* litigation as multidistrict litigation (MDL), and assigning it to a single district judge.¹² By the summer of 2006, nearly 6,000 cases were pending in the MDL alone, not to mention many thousands more filed in state courts.¹³

In 2007, Merck settled virtually all products liability claims from U.S. *Vioxx* users for \$4.85 billion.¹⁴ Individual awards under this agreement are estimated at between \$150,000 and \$200,000.¹⁵ Merck's products liability insurance covered \$630 million of the 2007 settlement.¹⁶

12. *In re Vioxx Prods. Liab. Litig.*, 448 F. Supp. 2d 741, 744 (E.D. La. 2006).

13. *Id.*

14. *See In re Vioxx Prods. Liab. Litig.*, 760 F. Supp. 2d 640, 644-45 (E.D. La. 2010) (“The private Settlement Agreement establishes a pre-funded program for resolving pending or tolled state and federal *Vioxx* claims against Merck as of [November 9, 2007] . . . for an overall amount of \$4.85 billion.”); Merck & Co., Inc., Annual Report (Form 10-K) 28 (Feb. 27, 2009).

15. Fred Charatan, *94% of Patients Suing Merck over Rofecoxib Agree to Company's Offer*, 336 BMJ 580, 580 (2008). Merck paid several other settlements and judgments related to *Vioxx* not pertinent here. For example, in 2008 Merck paid \$399 million to settle Medicaid rebate and kickback allegations under the False Claims Act, *see* Press Release, Department of Justice, Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks (Feb. 7, 2008), https://www.justice.gov/archive/opa/pr/2008/February/08_civ_094.html [<https://perma.cc/P5C4-ACD3>] and \$830 million to settle shareholders claims, discussed *infra* at Part V. Additionally, in 2011, Merck plead guilty to a criminal misdemeanor charge arising from its manufacture and sale of *Vioxx*, agreeing to pay federal and state government actors \$950 million for unlawful promotion of *Vioxx*. Anna Yukhananov, *Merck to Pay \$950 Million to Settle U.S. Vioxx Charge*, REUTERS (Nov. 22, 2011), <https://www.reuters.com/article/us-doj-merck/merck-to-pay-950-million-to-settle-u-s-vioxx-charge-idUSTRE7AL2C120111122> [<https://perma.cc/2CJC-89G6>]; Press Release, Department of Justice, Merck to Pay \$950 Million for Illegal Marketing (Nov. 22, 2011), <https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion> [<https://perma.cc/P3W5-DQ6S>].

16. Merck Sharp & Dohme Corp., Annual Report (Form 10-K) 31–32 (Mar. 30, 2010). Notably, the *Vioxx* MDL that facilitated the \$4.85 billion settlement was a mass tort action, although many claims transferred to the MDL were brought on behalf of a putative class of plaintiffs. Frank M. McClellan, *The Vioxx Litigation: A Critical Look at Trial Tactics, the Tort System, and the Role of Lawyers in Mass Tort Litigation*, 57 DEPAUL L. REV. 509, 516 (2008) (“By the time a settlement was proposed in

B. *Vioxx: E.U. & Canadian Results*

Since at least 2005, Merck has been involved in European Vioxx litigation.¹⁷ Merck noted in its 2016 annual report that litigation in Europe was “generally in procedural stages and Merck expect[ed] that the litigation may continue for a number of years.”¹⁸ However, references to this litigation suddenly disappeared from Merck’s investor reports in 2017.¹⁹

Somewhere in between the U.S. and E.U. results lies Canada, where Merck settled a number of Vioxx class action filings for \$36 million in 2011, a settlement corresponding to individual awards estimated at between \$15,000 and \$20,000.²⁰

IV. AGREEMENT TO EXPAND E.U. COLLECTIVE ACTION PROCEDURES

As part of a general program to expand consumer rights,²¹ the European Parliament and European Commission came to an agreement in June 2020 to pass legislation to expand access to

November 2007, Merck faced more than 27,000 product liability claims in federal and state courts. Until the agreed upon mass tort settlement, Merck had not settled a single claim . . .”).

17. Merck referenced European litigation in all annual reports from 2004 to 2016. Merck & Co., Inc., Annual Report (Form 10-K) 18 (Mar. 11, 2005); Merck & Co., Inc., Annual Report (Form 10-K) 27 (Mar. 13, 2006); Merck & Co., Inc., Annual Report (Form 10-K) 27 (Feb. 28, 2007); Merck & Co., Inc., Annual Report (Form 10-K) 31 (Feb. 28, 2008); Merck & Co., Inc., Annual Report (Form 10-K) 33 (Feb. 27, 2009); Merck Sharp & Dohme Corp., Annual Report (Form 10-K) 31 (Mar. 30, 2010); Merck & Co., Inc., Annual Report (Form 10-K) 126 (Feb. 28, 2011); Merck & Co., Inc., Annual Report (Form 10-K) 115 (Feb. 28, 2012); Merck & Co., Inc., Annual Report (Form 10-K) 108 (Feb. 28, 2013); Merck & Co., Inc., Annual Report (Form 10-K) 103 (Feb. 27, 2014); Merck & Co., Inc., Annual Report (Form 10-K) 108 (Feb. 27, 2015); Merck & Co., Inc., Annual Report (Form 10-K) 106 (Feb. 26, 2016); Merck & Co., Inc., Annual Report (Form 10-K) 100 (Feb. 28, 2017).

18. Merck & Co., Inc., Annual Report (Form 10-K) 100 (Feb. 28, 2017).

19. Merck & Co., Inc., Annual Report (Form 10-K) 101–04 (Feb. 27, 2018). Two further issues complicate the Vioxx case in Europe: (1) Merck’s primary E.U. subsidiary headquartered in Switzerland may have paid E.U. settlements out of its un-repatriated profits without requiring public disclosure; and (2) some E.U. Member States have extensive insurance schemes for their citizens that may have functioned to compensate consumers for Vioxx injuries. *See* Infantino & Zervogianni, *supra* note 2, at 87.

20. Merck & Co., Inc., Annual Report (Form 10-K) 115 (Feb. 28, 2012).

21. European Commission Press Release IP/18/3041, A New Deal for Consumers: Commission Strengthens EU Consumer Rights and Enforcement (Apr. 11, 2018).

collective action procedures.²² The 2020 agreement follows a more detailed 2018 proposal.²³ While the agreement clearly heralds an expansion of collective actions, it distinguishes itself from U.S. class action procedure by limiting plaintiffs to qualified entities, defined as non-profit independent organizations or public bodies with at least twelve months of demonstrated consumer interest protection activity.²⁴ Additionally, the agreement provides for dismissal of certain cases “at the earliest possible stage of proceedings in accordance with national law,” and a renewed commitment to the loser pays rule, thus balancing consumers’ interests in access to justice and business’ interest in avoiding abusive lawsuits.²⁵

V. ANALYSIS OF THE AGREEMENT

The agreement fails to further the ability of E.U. consumers to recover in mass harm cases because it is directed at the wrong problem. Additionally, even if it were directed at the right problem, the agreement is not written to significantly enable consumer recovery.

First, it is directed at the wrong problem. One way to see this is to observe how little work the class action procedures did in the Vioxx litigation. The per-user compensation from the U.S. settlement agreement of \$200,000 was nearly high enough to make it financially feasible for each plaintiff to hire her own counsel and experts. For the

22. The agreement will: (1) require at least one representative action procedure be available to consumers in every Member State; (2) allow representative action at national and E.U. level; (3) allow qualified entities to launch actions on behalf of groups of consumers; (4) establish the loser pays rule for collective redress actions, requiring that the defeated party pays the costs of the proceedings of the successful party; and (5) require that courts may dismiss manifestly unfounded cases at the earliest possible stage of the proceedings in accordance with national law. European Parliament Press Release (Ref. no. 20200619IPR81613), New Rules Allow EU Consumers to Defend Their Rights Collectively (June 22, 2020) (noting E.U. Parliament and Council negotiators reached a deal on collective redress rules that will go before Parliament as a whole and the Council for final approval); *see also* European Parliament Press Release (Ref. no. 20190321IPR32135), New Rules to Help Consumers Join Forces to Seek Compensation (Mar. 26, 2019) (providing additional background on earlier stages of negotiation between the European Parliament and Commission).

23. *Commission Proposal for a Directive of the European Parliament and of the Council on Representative Actions for the Protection of the Collective Interests of Consumers, and Repealing Directive 2009/22/EC*, COM (2018) 184 final (Nov. 11, 2018).

24. European Parliament Press Release (Ref. no. 20200619IPR81613), New Rules Allow EU Consumers to Defend Their Rights Collectively (June 22, 2020).

25. *Id.*

Canadians to achieve the same savings in reduced expert and attorney's fees, they would only need a collective redress system that would permit ten plaintiffs to file together. E.U. consumers, however, cannot say how many plaintiffs would need to file together to make litigation financially feasible because virtually none recovered against Merck. While the European Union may lack collective redress procedures to begin with, the complete absence of compensatory recovery in the case of Vioxx suggests that this procedural deficiency is not the primary obstacle to E.U. consumer recovery in mass harm cases.

The European Union's prevailing loser pays rule has a chilling effect on the filing of uncertain claims, as does the absence of contingent-fee arrangements. Where the recoverable amount from a successful claim is further reduced by social insurance that has already covered some of the cost of an injury, consumers are still less likely to sue. These factors together likely do much more work in accounting for the failure of E.U. consumers to recover against Merck than the weak or non-existent collective redress procedures available at the time.

This may not pose a problem, as policymakers may prefer low consumer recovery via liability. So long as social insurance can make consumers reasonably whole for their injuries, the worst of the harm of defective medical products may be abated. The fear for E.U. consumers might be that medical manufacturers will escape without ever compensating those that they injure, and so will be insufficiently deterred from engaging in risky behavior in the future. This fear is likely unfounded both because of the testing requirements imposed by regulatory agencies, and because of the global development and testing costs of an international medical product market.²⁶

The case of Vioxx, however, may support this fear. U.S. and E.U. regulatory agencies approved the drug for sale, and neither's liability regime deterred Merck from entering the market until it could better quantify the cardiovascular risk associated with Vioxx. Moreover, neither system incentivized Merck to disclose the results of its internally conducted trials before 2004, an omission sufficient to underlie an \$830 million settlement to its stockholders.²⁷

26. While this is ultimately an empirical question, because most medical product manufacturers operate in both the United States and the European Union, high U.S. liability driving extensive testing benefits E.U. consumers by providing them with better tested products without altering their liability regimes.

27. *Merck Agrees to Pay \$830 Million to Settle Vioxx Securities Lawsuit*, REUTERS (Jan. 15, 2016), <https://www.reuters.com/article/us-merck-vioxx-settlement/merck->

Nonetheless, the Vioxx case does not necessarily compel a conclusion that more punishing liability regimes with more powerful collective redress rules would have saved consumers from exposure to Vioxx via deterrence. Instead, it is likely the case that certain risks are extremely difficult or prohibitively costly to detect, and that Vioxx's risks were of this kind.²⁸ Because the benefits of medical products may outweigh the harms of these difficult-to-detect risks, even when viewed retrospectively, policymakers and consumers may prefer a system that does not make manufacturers attempt to ascertain every risk before selling a product. It is impossible to certainly identify every risk to each potential user, and any testing plan seeking that result would be financially ruinous and time consuming, preventing good and bad products alike from succeeding.

Second, even if the inability to seek collective redress were the right problem, the agreement is not written to significantly expand collective redress procedures. Requiring semi-public enforcement adds a layer of bureaucracy that may frustrate individual recovery. For example, an unrepresentative qualified entity with the sole power to file class actions may block a consumer with an individual claim from recovering. Compounding this problem, qualified entities would be restricted by an arbitrary twelve-month lookback period in judging their ability to advocate for consumers. Moreover, even where qualified entities meet the agreement's requirements, they would still be disincentivized from bringing uncertain claims on behalf of consumers by the loser pays rule.

VI. CONCLUSION

Consumers in the United States and European Union enjoy nominally similar substantive claims when seeking to recover against medical product manufacturers. However, the comparative ease of filing claims collectively via class actions in the United States facilitates consumer recovery and in the case of Vioxx, may have allowed U.S. consumers to recover billions of dollars from the drug's manufacturer where E.U. consumers recovered nothing. The 2020 agreement reached by E.U. negotiators likely fails to further the ability of consumers to recover in mass harm cases by reaffirming a

agrees-to-pay-830-million-to-settle-vioxx-securities-lawsuit-idUSKCN0UT1PX [https://perma.cc/MNC5-GJEM] (noting settlement of stockholder claims that Merck should have disclosed Vioxx risks earlier).

28. According to the eventual disclosure of the quadruple risk compared to another standard anti-inflammatory, the elevated risk was not observed until the eighteenth month of Vioxx usage. McClellan, *supra* note 19, at 516.

commitment to the larger obstacle of the loser pays rule and restricting filing rights to qualified entities. The agreement would be more successful in advancing consumer rights if it expanded filing rights to individuals and limited the loser pays rule.