

TRAFFICKING IN HUMAN BLOOD: TITMUSS (1970) AND PRODUCTS LIABILITY

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I

INTRODUCTION

The publication in 1970 of Richard M. Titmuss's *The Gift Relationship: From Human Blood to Social Policy*¹ occasioned some spirited debates about the relative roles of altruism and commercial markets not only in the collection and distribution of human blood, but in the general economy as well.² In his book, Titmuss, a British social theorist, provided evidence that blood collected in the United States, where blood banks obtained much of their supply by paying donors, was more dangerous (in communicating serum hepatitis) than blood collected in the United Kingdom, where voluntary donation was the norm. From this finding, Titmuss drew conclusions unsympathetic to all commercial enterprise. Market skeptics apparently still believe that the subject is one on which they can draw metaphorical blood, for the book was republished in 1997 with new commentary by Titmuss admirers.³ This symposium is a good occasion to recall the splash made by Titmuss's book and to revisit some of the issues it raised.

Although Titmuss received some criticism for lack of analytical rigor and for drawing conclusions broader than his evidence could support,⁴ his book was

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1. RICHARD M. TITMUSS, *THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY* (1970) [hereinafter *THE GIFT RELATIONSHIP* (1970)]. Publication in the United Kingdom was followed by publication in the United States in 1971.

2. No fewer than five reviews and columns focusing on the book appeared in the *New York Times* and the *Washington Post* alone. E. Wayles Brown Jr. & George E. Clifford, *The Blood Business*, WASH. POST, Mar. 12, 1971, at B1; Robert Claiborne, *Blood Will Tell*, WASH. POST, May 9, 1971, at 244; Alvin Gouldner, *The Gift Relationship*, N.Y. TIMES, Mar. 21, 1971, at BR2; Anthony Lewis, *Blood Relationship*, N.Y. TIMES, Jan. 25, 1971, at 43; Richard Locke, *Books of the Times*, N.Y. TIMES, Mar. 13, 1971, at 27; see also Alfred Friendly, *The Gift of Blood—U.S. Found Wanting*, L.A. TIMES, Jan. 31, 1971, at E3.

3. RICHARD M. TITMUSS, *THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY* (Ann Oakley and John Ashton eds., 1997) [hereinafter *THE GIFT RELATIONSHIP* (1997)].

4. E.g., Robert M. Solow, *Blood and Thunder*, 80 YALE L.J. 1696 (1971).

widely received as a welcome challenge to economic orthodoxy.⁵ A commentator writing in the 1997 edition, after recalling how the first edition impressed him and his fellow Ph.D. students in economics, conceded that many of Titmuss's claims and predictions did not stand up over time.⁶ He maintained, however, that the problem of blood quality still undercuts the case for commercialism in the blood industry.⁷ In so concluding, he revealed no awareness of some law-and-economics literature that the Titmuss book helped to inspire. This article, in revisiting the pros and cons of trafficking in human blood from a legal perspective, suggests a role for legal tools that Titmuss and others largely rejected, partly because they did not appreciate their theoretical basis or practical possibilities and partly because they thought them too blunt in view of the seemingly good intentions of many engaged in blood donation, nonprofit blood banking, and transfusions.⁸

Without purporting to provide a definitive treatment of the complex and now highly commercialized blood industry,⁹ this article recalls the explanation that some market-oriented scholars plausibly offered in the 1970s for the United States' poor experience with transfusion-linked hepatitis. Their hypothesis was that the blood-quality problem in the United States could easily be accounted for by the anomalous prevalence in U.S. law of the rule of caveat emptor ("let the buyer beware") in the case of blood and its byproducts,¹⁰ this legal rule contrasted with the law's usual imposition of some form of strict liability (that is, liability without proof of anyone's actionable fault) for injuries

5. *E.g.*, Lewis, *supra* note 2, at 43. Titmuss's raising the question of altruism in the economy and public policy prompted much thoughtful commentary. *See, e.g.*, Kenneth J. Arrow, *Gifts and Exchanges*, 1 PHIL. & PUB. AFF. 343 (1972) (reflecting on "the descriptive and prescriptive issues raised by Titmuss'[s] evidence and assertions"); A.J. Culyer, *Blood and Altruism: An Economic Review*, in BLOOD POLICY: ISSUES AND ALTERNATIVES 39 (David B. Johnson ed., 1977) (discussing both "overt issues regarding the best ways of collecting and distributing blood" and "the indirect issues relating to social policy and the role of altruism in society"). For a recent revisitation of Titmuss's ideas and influence, see Pete Alcock, *Richard Titmuss in the 21st Century—Commentary*, 20 EUR. J. POL. ECON. 803 (2004); Philippe Fontaine, *Richard Titmuss on Social Cohesion: A Comment*, 20 EUR. J. POL. ECON. 795 (2004); David Reisman, *Richard Titmuss: Welfare as Good Conduct*, 20 EUR. J. POL. ECON. 771 (2004); Jim Tomlinson, *Richard Titmuss, Welfare as Good Conduct: A Comment*, 20 EUR. J. POL. ECON. 799 (2004).

6. Julian Le Grand, *Afterword* to THE GIFT RELATIONSHIP (1997), *supra* note 3, at 333–35.

7. *Id.* at 335–37.

8. Titmuss wrote a chapter reciting many of the usual arguments advanced by the medical profession against relying on tort and antitrust law to ensure good performance in the health-care sector. THE GIFT RELATIONSHIP (1970), *supra* note 1, at 158–72.

9. For a full, relatively recent description of the worldwide blood industry, see DOUGLAS STARR, BLOOD: AN EPIC HISTORY OF MEDICINE AND COMMERCE (1998).

10. Clark C. Havighurst, *Legal Responses to the Problem of Poor-Quality Blood*, in BLOOD POLICY, *supra* note 5, at 21 (arguing that "legal rules designed with incentives and what Professor Coase calls 'transaction costs' in mind would have greatly alleviated the problems which Professor Titmuss regarded as conclusive proof of the dangers of commercialism"); Reuben A. Kessel, *Transfused Blood, Serum Hepatitis, and the Coase Theorem*, 17 J.L. & ECON. 265 (1974) (arguing from economic principles for strict liability for transferring defective blood).

caused by defective products.¹¹ This article first observes the theoretical benefits of applying the usual strict-liability rule in the case of blood products. It then presents some new information about the blood industry's response to the HIV/AIDS epidemic in the early 1980s—evidence strongly suggesting that things would have turned out better for some, perhaps many, recipients of blood products had the strict-liability rule been in effect. The more general message is that failings of private markets such as those identified by Titmuss justify antimarket conclusions only if one can reasonably assume the absence and political or other infeasibility of the law's normal remedies for recognized market failures, such as asymmetric information and the propensity of producers to collude.

II

THE LIABILITY RULE AND THE INCIDENCE OF BLOOD-RELATED INJURIES

In 1954, the New York Court of Appeals ruled that a blood transfusion constitutes a “service,” not a “sale” of the transfused blood, thus precluding a plaintiff contracting hepatitis from the blood in question from invoking the usual implied warranty of fitness that the law ordinarily attaches to purchased products.¹² Liability, if any, would therefore require proof of the defendant's negligence, generally defined as a departure from industry standards. Because caveat emptor similarly prevailed for blood products in most U.S. jurisdictions in the 1960s,¹³ Titmuss's finding of disproportionately poorer-quality blood in the U.S. market probably said more about the dangers of adopting the wrong liability rule for this product than about the capitalist system in general.

The legal consequences of transfusion-related hepatitis attracted the attention of law-and-economics scholars in the 1970s.¹⁴ In 1974, economist Reuben Kessel invoked the Coase Theorem to establish the logic of putting the

11. See *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1058–61 (D.D.C. 1987) (rejecting in a blood case strict liability both for “breach of the implied warranties of merchantability and fitness for a particular purpose under the Uniform Commercial Code” and “under the theory of strict liability in tort for an unreasonably dangerous product, under the *Restatement (Second) of Torts* § 402A”), *aff'd in part, vacated in part on other grounds*, 851 F.2d 437 (D.C. Cir. 1988).

12. *Perlmuter v. Beth David Hosp.*, 123 N.E.2d 792 (N.Y. 1954).

13. Marc A. Franklin, *Tort Liability for Hepatitis: An Analysis and a Proposal*, 24 STAN. L. REV. 439 (1972) (reviewing extensively and critically the state of the law governing liability for transfusion hepatitis).

14. See, e.g., Guido Calabresi & Kenneth C. Bass, *Right Approach, Wrong Implications: A Critique of McKean on Products Liability*, 38 U. CHI. L. REV. 74, 83–86 (1970) (seeking to identify optimal bearers of risk of transfusion hepatitis and endorsing strict liability); see also Clark C. Havighurst & Lawrence R. Tancredi, “Medical Adversity Insurance”—A No-Fault Approach to Medical Malpractice and Quality Assurance, 51 MILBANK MEM. FUND Q. 125 (1973) (using transfusion-related hepatitis to illustrate the potential benefits of a system imposing strict liability for predefined injuries deemed preventable in many, though not necessarily all, cases).

risk of receiving bad blood on the purveyor, not on its recipient.¹⁵ In 1975, I surveyed the legal environment of blood transfusions, also arguing against caveat emptor.¹⁶ That article identified a surprising number of specific ways in which blood banks and hospitals, if properly motivated by exposure to legal liability, might not only reduce the risk of collecting infected blood but might also use blood and blood products more safely.¹⁷ Even if the hepatitis risk could not be eliminated entirely, the variety of preventive measures that might be taken in particular cases was great enough to make it seem unwise to rely only on professionalism, industry standard setters, or regulators to achieve optimal safety.

None of the law-and-economics literature focusing on the optimal liability rule in blood cases ever entered mainstream discussions of Titmuss's book, nor was it referenced in the 1997 volume reprinting and updating that work.¹⁸ This scholarly neglect of the legal dimensions of the blood-quality problem is one justification for this article. Another is the continuing relevance of the earlier debates to today's concern about the general quality of U.S. health care.¹⁹

Although several state courts found doctrinal ways to reverse the rule of caveat emptor and to expose blood transfusers and their suppliers to strict legal liability, state legislatures in every case, facing heavy lobbying by blood banks and hospitals, quickly restored the old rule by enacting so-called "blood-shield" laws.²⁰ In Illinois, for example, the state supreme court in a 1970 case bypassed the law of implied warranties and applied the novel theory of strict liability in tort to blood transfusions.²¹ Predictably, the Illinois legislature soon restored the

15. Kessel, *supra* note 10. The so-called "Coase Theorem" emphasizes that, because of transaction costs, efficiency requires that risks fall on parties in the best position to minimize them or to induce others to do so. See Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960).

16. See generally Havighurst, *supra* note 10.

17. *Id.* at 21–37.

18. Likewise, there is also no discussion of strict liability as a potential restraint on abuses in commercial blood banking in Douglas Starr's generally fascinating journalistic account of the worldwide market for human blood. See STARR, *supra* note 9.

19. See *infra* notes 25–28 and accompanying text. For an early proposal to use strict liability for selected, often preventable, medical injuries as a way both to ensure fair compensation at low administrative cost and to strengthen incentives to prevent such compensable events, see Havighurst & Tancredi, *supra* note 14; see also Clark C. Havighurst, "Medical Adversity Insurance"—*Has Its Time Come?*, 1975 DUKE L.J. 1233 (1975). Over the intervening years, others have developed and elaborated versions of this proposal. See, e.g., Randall Bovbjerg & Lawrence R. Tancredi, *Liability Reform Should Make Patients Safer: "Avoidable Classes of Events" Are a Key Improvement*, 33 J.L. MED. & ETHICS 478 (2005); Lawrence R. Tancredi, *Designing a No-Fault Alternative*, 49 LAW & CONTEMP. PROBS. 277 (Spring 1986).

20. During the 1950s and 1960s, blood shield laws were adopted by 47 states. These laws exempt blood and blood products from strict liability or implied warranty claims on the grounds that they are a service rather than a product. The laws were developed on the premise that given the inherently risky nature of blood and blood products, those providing them required protection if the blood system was to be a reliable resource.

INST. OF MED., *HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING 2* (1995).

21. *Cunningham v. MacNeal Mem'l Hosp.*, 266 N.E.2d 897 (Ill. 1970) (relying on RESTATEMENT (SECOND) OF TORTS § 402A).

immunity of blood suppliers to any lawsuit not grounded in provable negligence.²² Before that happened, however, one Illinois physician operating a hospital blood bank reported observations in his hospital confirming the (then) “general feeling among those engaged in blood banking [in Illinois] that the trend of blood usage . . . changed significantly after the court decision” and that “[t]he impact of the case has been far greater than that by various educational activities hitherto taken in our hospital.”²³ Despite arguments that strict liability would both ensure compensation for patients suffering real injuries and induce practices reducing the number of such injuries, state legislatures generally accepted the blood industry’s invitation to “trust us.”²⁴

In a political world, it appears, health-care quality issues can be addressed only in ways acceptable to industry interests, which, like Titmuss, are generally unwilling to view the liability system as even a potentially useful component of the quality-assurance effort. This is somewhat ironic because medical tradition itself, as reflected in medical training and in the profession’s own peer-review activities, has long held that quality is best ensured by identifying errors and taking appropriate action with respect to those who make them.²⁵ Indeed, the malpractice system itself was at one time largely an extension of professional self-regulation: expert witnesses testified in court essentially as representatives of the profession and only on prevailing professional practice and opinion.²⁶ Over time, to be sure, the profession lost control of the system as various legal and practice changes increasingly permitted juries to hear experts (so-called “hired guns”) whose testimony on the question of fault did not necessarily reflect the profession’s own views. Providers may naturally feel victimized when a system they do not trust purports to blame them for injuries for which they may not feel professionally responsible.

Strict liability, however, bypasses the issue of fault altogether, so that the duty to pay for a patient’s injuries would no longer carry any necessary imputation of negligence or incompetence. Further, most payments could be made automatically through (experience-rated) insurance, thus obviating costly public trials and minimizing legal and experts’ fees.²⁷ Although the reimbursable costs of injuries might be substantial, providers with average or better experience could mostly pass them on to the public in higher fees and charges.

22. Blood and Organ Transaction Liability Act, 745 ILL. COMP. STAT. 40/2 (West 2000).

23. Takashi Okuno, Letter to the Editor, *The Cunningham Case and Blood Usage*, 220 J. AM. MED. ASS’N 1015, 1015 (1972).

24. See INST. OF MED., *supra* note 20, at 2.

25. See Lucian Leape, *Error in Medicine*, 272 J. AM. MED. ASS’N 1851, 1855–57 (1994) (describing shortcomings in the medical profession’s traditional, error-focused approach to quality problems).

26. See Allan H. McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549 (1959) (a classic article supporting the medical profession’s model of the tort system as one guided by experts representative of the profession).

27. For the suggestion that strict liability for transfusion-related hepatitis could be implemented through a form of provider-financed casualty insurance, which would automatically (that is, without litigation) compensate victims, see Havighurst & Tancredi, *supra* note 14.

Moreover, what might then be decried as a significant increase in “the cost of health care” would not be a new cost at all, since injured patients and those responsible for their care bear those costs already. Most important, better incentives to improve patient safety could reasonably be expected to lower the overall social cost of injuries.

In any event, current policy thinking about the quality of care rejects the notion—however deeply entrenched it may be in both the culture of medicine and the legal system—that the quality of care can be maintained and improved by finding fault in individual cases, either in medical peer-review settings or in court. The new goal is to get health-care practitioners and organizations to appreciate that human errors and other breakdowns are inevitable and to design systems that take that inevitability into account.²⁸ To be sure, because proposed reforms must pass muster with professional and industry interests, such thinking has so far led only to efforts to persuade institutions to adopt so-called “best practices” and to proposals to protect professionals against legal and other consequences of reporting any errors that occur, in order that systems can be redesigned to prevent future ones. To the extent financial incentives enter the reform picture at all, they appear only in proposals to pay providers *more* for meeting prescribed targets (so-called “pay-for-performance”), not in proposals to make them responsible for compensating those who suffer bad results at their hands. Nevertheless, strict liability, by tying financial incentives to the magnitude of potential harm, still seems the best way to focus organizations’ attention on optimally improving actual patient outcomes rather than on simply following customary practice or professional and regulatory prescriptions.

A huge hypothetical question looming over this discussion of issues arising in the 1970s is, of course, the effect that strict liability might have had when, almost out of nowhere, the HIV/AIDS epidemic emerged in the late 1970s and finally came to be recognized in the early 1980s as a disease transmissible by blood and blood products. It is impossible to know with certainty, of course, whether the crisis would have been any less severe for hemophiliacs and recipients of blood transfusions if suppliers had been held strictly liable for purveying lethal products. Certainly mass-tort cases and some bankruptcies in the blood industry would have occurred. But the crucial consideration in following up Titmuss’s and the blood industry’s hostility to legal remedies for

28. Leape, *supra* note 25, at 1857 (embracing “total quality management” for health-care organizations and stating “[e]rrors must be accepted as evidence of system flaws, not character flaws”). For proposals to assign liability to corporate actors that are in a better position than individual physicians to recognize and remedy quality problems, see Kenneth S. Abraham & Paul C. Weiler, *Enterprise Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381 (1994) (proposing hospital liability for physician torts); Clark C. Havighurst, *Vicarious Liability: Relocating Responsibility for the Quality of Medical Care*, 26 AM. J.L. & MED. 7 (2000) (arguing that making organized health plans vicariously liable for the torts of their participating providers would both inspire integrated efforts to improve quality and restore needed legitimacy to managed health care by making plans responsible for the quality, as well as the cost, of care).

patient injuries is not the financial health of individual firms but rather the physical health of patients. As it happened, thousands of individuals, both in the United States and around the world, died as a result of HIV/AIDS before reliable methods protecting patients against receiving HIV-tainted blood were finally implemented (around 1985).²⁹ The next section of this article describes in some detail the response by the blood-products industry to the HIV/AIDS threat during that period. This evidence suggests that the law-and-economics scholars were right and that policymakers, in thrall to both Titmuss-like thinking and industry interests, were wrong in rejecting a liability system that would impose the costs of injuries on those in the best position to minimize them. That choice appears to have had fatal consequences for many innocent persons.

III

THE BLOOD INDUSTRY'S RESPONSE TO THE AIDS CRISIS

In the 1990s and early 2000s, I was consulted by plaintiffs' lawyers in several cases brought against for-profit blood fractionators on behalf of hemophiliacs who had contracted HIV/AIDS from blood products (so-called clotting factors) in the period from late 1982 through early 1985, when the AIDS crisis was first emerging.³⁰ Specifically, I was asked for my expert legal opinion, based on documents from that period and supplied by the parties, concerning the legality under federal antitrust laws of the actions taken by the defendants during that period. Although these were not antitrust cases as such,³¹ a crucial issue was

29. See INST. OF MED., *supra* note 20, at 1 ("In the early 1980s blood became a vector for HIV infection and transmitted a fatal illness to more than half of the 16,000 hemophiliacs in the United States and over 12,000 blood transfusion recipients.").

30. A history of public and private responses to the HIV crisis in the United States, including some contemporaneous documents, has been provided by a committee of the Institute of Medicine. *Id.* That definitive history focused mostly on deficiencies in the FDA's response to the epidemic and not on the industry's own actions, but concluded that, although the likelihood that AIDS was transmitted by blood was fairly clear by early 1983 at the latest,

blood safety policies changed very little during 1983. Many officials of the blood banks, the plasma fractionation industry, and the FDA accepted with little question estimates that the risk of AIDS was low ("one in a million transfusions"), and they accepted advice that control strategies (such as automatic withdrawal of AHF [antihemophilic factor] concentrate lots containing blood from donors suspected of having AIDS, or a switch from AHF concentrate to cryoprecipitate in mild or moderate hemophiliacs) would be ineffective, too costly, or too risky.

Id. at 3-4. For a journalistic account of the blood industry's history, including poignant stories of many victims of HIV-contaminated blood and their efforts to obtain legal relief, see STARR, *supra* note 9. Starr describes scandals in government-managed programs, particularly in Japan and France, in a way suggesting that Titmuss was not necessarily right in thinking that government control would provide a reliable shield against bad blood.

31. In order to induce affected businesses to act as private attorneys general policing injuries to competition on behalf of the general public, the antitrust laws allow treble-damage recoveries only for harms to an individual's or firm's "business or property." 15 U.S.C. § 15(a) (2006). Conceivably, individuals suffering personal injuries as a result of an antitrust violation might have an implied right of action for ordinary damages.

whether the four firms constituting the blood-fractionation industry could be held jointly and severally responsible for injuries to an individual patient when the patient was unable to establish which firm's product had been used in his case.³² The plaintiffs' lawyers believed that, under state law, establishing collusive conduct, especially collusion offensive under federal antitrust law, would help their cases. None of the courts in which my testimony was offered believed that my expertise in antitrust law and the detection of unlawful conspiracies would be useful to a jury in deciding whether the requisite collusion had occurred.³³ Nonetheless, the conduct I discovered in my document review has a bearing on the possible effects of the caveat-emptor rule.³⁴

The first reports implicating blood products as causes of AIDS in hemophiliacs appeared in July 1982.³⁵ The items I reviewed related to the defendants' activities after that date and included excerpts from depositions and internal memos and records of meetings discovered in the course of litigation. These documents revealed exchanges of information, coordination of actions, and interactions by the fractionators with the Food and Drug Administration (FDA). The documents led me to opine that the four defendants "engaged in concerted action violative of the federal antitrust laws with respect to initiatives that they might have taken individually, under competitive and other pressures, to reduce the risk that their blood products would transmit the HIV virus to hemophiliacs."³⁶ To be sure, there was no intention to hurt hemophiliacs. Instead, the record revealed only businesspeople who, facing scientific uncertainty and serious legal and business risks, found it expedient to act in

32. See *Summers v. Tice*, 199 P.2d 1 (Cal. 1948) (holding any potential tortfeasor liable among a group of potential tortfeasors even though plaintiff could not prove which specific tortfeasor caused the harm); *Sindell v. Abbott Labs.*, 607 P.2d 924 (Cal. 1980) (adopting market-share liability whereby each defendant in a negligent industry must prove they didn't cause the specific harm or be held responsible for a percentage of the damage relative to their market share).

33. The district court in one AIDS case reviewed the plaintiffs' evidence of concerted action by the fractionators, including some of the documents mentioned herein, *Doe v. Baxter Healthcare Corp.*, 178 F. Supp. 2d 1003, 1010–12 (S.D. Iowa 2001), *aff'd*, 380 F.3d 399 (8th Cir. 2004), and concluded that, for purposes of the plaintiff's civil conspiracy claims, "plaintiffs have submitted sufficient evidence of concerted action to survive summary judgment on the merits." *Id.* at 1018.

34. All the documents I reviewed are, I believe, on the public record somewhere, but copies of the documents referenced here are also available in the files of *Law and Contemporary Problems*. Although I believe enough time has passed to make the observations in this article of only academic interest, I have avoided naming names and being any more specific than necessary to make my point. The editors of *Law and Contemporary Problems* have verified the descriptions of the documents and the accuracy of the quotations therefrom. I also concede that the factual circumstances were sufficiently complex that my antitrust conclusions could reasonably be disputed, especially since antitrust law has been used mostly to encourage independent *pricing* decisions rather than to ensure firms' competitive independence in areas affecting product quality. See *infra* notes 37, 46; *cf.* Clark C. Havighurst & Peter M. Brody, *Accrediting and the Sherman Act*, 54 LAW & CONTEMP. PROBS. 199 (Autumn 1994) (reviewing antitrust principles applicable to competitors' concerted action in setting quality standards and inducing compliance therewith).

35. INST. OF MED., *supra* note 20, at 58.

36. Expert Witness Report of Clark C. Havighurst, *Doe v. Baxter Healthcare Corp.*, 178 F. Supp. 2d 1003 (S.D. Iowa 2001).

concert in an effort to minimize those risks. Although the defendant firms did not succeed in suppressing all independent initiatives, it seems probable that they would have acted more independently and far more expeditiously if they had faced strict legal liability for marketing defective products.

To be clear, cooperation among industry members is not itself objectionable under the antitrust laws. Indeed, many kinds of cooperation are completely consistent with competition and highly desirable from the consumer's point of view; in antitrust jargon, they are procompetitive, not anticompetitive. If, for example, the fractionators were doing joint research, or were exchanging ideas about how to prevent AIDS, or even recommending what they collectively and honestly thought was an appropriate standard of care in producing blood products, there would probably be no antitrust problem.³⁷ But if they were simply agreeing on how they would actually conduct their individual businesses or coordinating their actions in such a way as to compromise their competitive independence, then their concerted action would be hard to defend. And that is what the documents revealed: too much conferring for no procompetitive purpose and too many agreements on how they would act on particular issues raised by the AIDS threat. Those actions had fatal consequences for competition—that is, the process of independent decisionmaking that the antitrust laws seek to protect.³⁸ The crucial issue here, however, is not whether a court would have found antitrust violations but whether a different liability rule would have driven firms to act independently, not collectively, in addressing the AIDS problem, probably yielding better results for patients.

A brief internal memo of one defendant, dated March 1983, on the subject of “AIDS Preparedness Study” reported progress on the following mission: “Work out concept for cooperative actions, talk to competitors.” It then stated, “Numerous contacts have been made, at various levels, on several subjects[,] [specifically] donor screening, additional testing (Hepatitis B core antibody) and guidelines to release the industry from further recall actions.” This memo showed that a framework had been developed at an early date for cooperative actions and regular consultations with competitors. Indeed, the documents showed that, as early as August 1982 (the month after evidence associating AIDS with blood products first appeared), one company had already “canvassed several of our competitors to determine what action they have or plan to take.” Another company's report of an October 1982 meeting of the

37. See *Allied Tube & Conduit Corp. v. Indian Head*, 486 U.S. 492, 500 (1988) (approving and protecting, under the antitrust laws, private processes for setting industry-wide standards, but stating, debatably, that “agreement on a product standard is, after all, implicitly an agreement not to manufacture, distribute, or purchase certain types of products”). On the difficult distinction between collectively developing, publishing, and certifying compliance with standards (all lawful) and actually agreeing to do business only in accordance with such standards (unlawful), see Havighurst & Brody, *supra* note 34, at 230–41 (discussing issues raised by the debatable dictum in *Allied Tube*).

38. See *Copperweld Inc. v. Independence Tube Corp.*, 467 U.S. 752, 769 (1984) (noting how concerted action “deprives the marketplace of the independent centers of decision making that competition assumes and demands”).

Biological Section of the Pharmaceutical Manufacturers Association (PMA) stated that the fractionators “agreed to share our current practices on audits of plasma suppliers” and that “[t]he purpose of this exchange of information was to ensure that all of us are doing about the same thing.” A deposition of one company executive revealed regular meetings, both formal and informal, in 1983. The witness said that the goal was “to make sure, once again, we wouldn’t do anything contradictory one to the other.” Another company official conceded that the defendant firms “had meetings on [what was being done] and agreed to go ahead as a group, or not to go ahead as a group, as the case might be.”

In the early stages of the AIDS crisis, donor screening was a crucial subject because much of the blood was being collected from donors associated with AIDS risks. In December 1982, in an “informal” meeting with an FDA official, the industry resisted agency pressure to stop using plasma from “high-risk” populations, such as homosexuals, Haitians, and drug users. Instead, the industry proposed a donor-education program under which it was hoped high-risk would-be donors would exclude themselves. According to one company’s report of a meeting with competitors, “Not everyone was convinced that a voluntary program would be completely successful, but it would be a first step. It was recommended that any educational program be coordinated between the manufacturers.” An FDA document dated March 24, 1983, stated (note the bureaucratic understatement eight months after the first reports signifying a problem) that AIDS

has caused serious concern because of the implications for recipients of plasma derivatives if this disease is proven to be transmissible by blood or blood products. The major organizations involved in plasma collection have reached a consensus as to appropriate steps [including a donor-education program] which should be taken to decrease the potential of blood or plasma donation by [high-risk individuals].

The picture that emerges here is one of industry and government working together to provide political-cum-public-relations cover for each other.³⁹ The industry’s working with the FDA, collectively and off the record, to shape the governing public policy seems, in the context of the then-pending litigation, to provide a very good reason why the industry should bear collective tort

39. For example, in another December 1982 memo, a company official stated that the FDA official wanted “ammunition [to support the position] that voluntary efforts of the industry precluded the need for any further regulation.” This perception of the interaction of government and the private sector is confirmed by a report of the Institute of Medicine. *See generally* INST. OF MED., *supra* note 20. Legally, FDA action in brokering the so-called “consensus” among private entities—including several nonprofit organizations such as the American Red Cross—could not immunize collective action from the antitrust laws. *See, e.g.,* *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 225–27 (1940) (“Though employees of the government may have known of those [anticompetitive] programs and winked at them or tacitly approved them, no [antitrust] immunity would have thereby been obtained.”). The hesitancy of the FDA about taking aggressive regulatory action in the AIDS crisis, relying instead on industry initiatives, appears to have been a regrettable response to criticism the government had received in the 1970s for its apparent overreaction to an earlier public-health threat, that era’s version of so-called “swine flu.” *See* INST. OF MED., *supra* note 20, at 59–60.

responsibility for harms that its products caused. At the least, such collective action would seem to invalidate industry standards and practices as a basis for determining negligence in subsequent tort cases.⁴⁰

On January 14, 1983, “PMA members involved in plasma fractionation” caucused before a meeting of the National Hemophilia Foundation “to develop an industry position related to AIDS.” The industry took agreed positions on donor screening, donor testing (concluding there was “insufficient information to warrant the incorporation of any new surrogate lab test into routine donor testing”), the impracticality of using small pools for fractionation to diminish the risk of contamination (declaring the “economics of this procedure [to be] relatively discouraging”), and the use of cryoprecipitate (“the ultimate in batch size reduction”) as an alternative for some hemophiliacs. Roughly the same conclusions were subsequently published as “recommendations” by the American Blood Resources Association, which included nonprofit as well as for-profit purveyors. To the extent they expected such standards to become the standard of care for judging negligence in tort litigation, industry members would have less legal incentive to take further precautions.

One company’s memo reporting on the January 14th meeting described its purpose as “to determine a consensus strategy” on, among other things, whether to test plasma in a new and somewhat costly way. The group “agreed that we would support testing in concept, but defer until a more specific test was available.” As late as December 1983, at a meeting sponsored by the FDA and the National Heart, Blood, and Lung Institute, one of the fractionators proposed a task force to study various tests and to report in three months. An internal memo of another company stated,

This proposal was one that had been agreed upon by all the fractionators the previous evening. The general thrust of the task force is to provide a delaying tactic for the implementation of further testing. It was generally agreed that core testing [for hepatitis B antibodies, a possible “surrogate” for freedom from HIV] would eventually become a requirement.

The industry was obviously seeking to avoid or delay both government compulsion to test collected plasma and competitive pressure to embark on testing. The same fractionator’s memo just quoted, however, revealed that the

40. In several negligence cases, courts refused to limit blood banks’ liability for communicating AIDS to instances where they deviated from industry or professional standards, leaving open the question whether those standards were themselves negligent. *E.g.*, *United Blood Services v. Quintana*, 827 P.2d 509, 523–24 (Colo. 1992) (holding that, although blood banks should be held to a professional standard of care, the plaintiff could attempt on remand to show that the blood-banking community’s standard of care was deficient); *Snyder v. Mekhjian* 582 A.2d 307, 313 (N.J. Super. Ct. App. Div. 1990) (deciding that when HIV-infected blood was transfused in August 1984, summary judgment was precluded by questions of fact regarding the reasonableness of the defendant blood bank’s conduct in collecting and distributing blood without using surrogate testing, regardless of whether it followed trade association’s guidelines); *Hernandez v. Nueces County Med. Soc’y Community Blood Bank*, 779 S.W.2d 867, 871–72 (Tex. App. 1989) (holding that compliance with federal and published industry standards would not necessarily absolve defendant blood bank from liability for negligence, especially when evidence suggested it had lagged in adopting new screening procedures for hepatitis).

firm was itself beginning such testing and recommended “that the implementation of [its own] core testing be accelerated to the maximum degree possible to obtain a competitive advantage in the marketplace.” The company had also been preparing to market heat-treated plasma (effective against hepatitis and, as it later turned out, HIV), another sign of its competitive independence. Ironically, these independent moves do not prove the absence of an industry-wide agreement to curb competitive initiatives with respect to testing, since it seemed probable that the firm in question agreed with the others without intending to adhere rigorously to its agreement, hoping to get a jump on those that did.⁴¹

In March 1984, a confidential letter between Red Cross officials reported a meeting of the task force on hepatitis B antibody testing and noted there was “general support for . . . the concept that any decision for surrogate testing [should] be based upon scientific merit rather than public relations pressure”—that is, pursuit of competitive advantage. The same letter reported that “it was felt that it would be advantageous to all to maintain communication and cooperation among all the commercial fractionators and voluntary blood collectors especially in regard to avoiding any precipitous action by any group in implementation.” Despite the apparent agreement to proceed in lockstep, the fractionator that had earlier kept its fingers crossed announced one month later its adoption of the hepatitis B antibody test. The documents revealed how three weeks earlier this fractionator had not tipped its hand in a meeting at which competitors voted on whether to commence using the test. Another company’s representative’s internal memo warned that a minority favored testing, creating a danger of “a ‘cascade’ effect” if anyone should move in that direction; the memo also stated, “I have received promises from representatives of those [minority] organizations that they will advise me if any decision to implement testing is made.” The documents include several statements warning that those firms not in favor of testing would nevertheless commence it if anyone else did—an apparent effort to discourage competitive initiatives, which nevertheless did finally, if belatedly, occur.

Another subject discussed periodically by industry members was warnings about AIDS risks that might accompany their products. Labeling of clotting factors for hemophiliacs was discussed at a May 1983 meeting, with plans for later discussion of “time frames for implementing the change.” In one deposition, a witness acknowledged that the participants had agreed that warnings would be issued “approximately in unison and the wording would be such that none of us contradicted each other so we didn’t confuse the patients

41. In any cartel, there is the possibility that one or more members will violate the anticompetitive agreement, profiting while others abide by it. Nevertheless, neither the possibility of such cheating nor even a likelihood that the cartel will soon self-destruct alters the agreement’s illegality under the antitrust laws. Even if one or more of the defendants in the blood cases entered into the restraint of trade with its fingers crossed (as appears to have been the case), the harm to competition and the restraint on the other companies’ possible initiatives remained.

receiving the product.” The industry’s agreement to speak more or less with one voice about the seriousness of the problem was apparently meant to ensure that hemophiliacs would not become alarmed—even though their lives were at risk and they might wish to seek safer ways to obtain the protection they needed. To be sure, FDA rules required prior approval of labeling or advertising claiming quality superiority, thus reducing the firms’ opportunities to compete by springing an advertising surprise.⁴² Nevertheless, strong warnings of the products’ dangers—such as a firm might use to establish an assumption-of-risk defense to strict liability—were not precluded. In any event, the industry took steps both to delay an FDA warning requirement and to reduce the likelihood that a single competitor would choose to tell the whole truth about the AIDS risk.⁴³ Although the risk to hemophiliacs first appeared in mid-1982, there were no significant AIDS warnings on the defendants’ labels until late 1983.

Beginning around May 1983, interest began to focus on recall policy when a pool of donated blood was found to include a donation by someone who later developed AIDS-like symptoms. Recalls of such contaminated lots would be costly to the fractionators, yet such situations presented substantial liability risks. In a letter to the interested FDA official, one company officer said, “I have taken the liberty of relaying to representatives of [the other three competitors] the following summary of your comments” on recalls. The following policy was thus attributed to the FDA official: “Based upon the current lack of clear evidence linking the transmission of AIDS to blood, blood products, and blood derivatives, the Office of Biologics does not believe that the destruction of any in-process or finished clotting factor concentrates or plasma pools is warranted or justified.” This reveals the industry’s insistence on waiting for definitive scientific proof before taking safety precautions. It also reveals an effort to obtain FDA cover for its policy of resisting recalls and to use weak FDA guidance to orchestrate parallel rather than independent action.

Under a rule of strict liability, individual firms facing the AIDS crisis would have been under pressure to focus only on product safety without much concern for what their competitors were doing. On the other hand, a legal regime making proof of negligence (defined as a departure from industry standards) a prerequisite for liability actually invites concerted action.⁴⁴ One company memo reported that, at a June 1983 meeting with FDA personnel, legal liability came up several times, but “we were not prepared to address [it].” Interestingly, an FDA official “pointed out that nothing prevents the manufacturers from imposing their own standards on top of those recommended by the [Office of Biologics],” and one company claimed to “have done just that,” suggesting that the negligence standard itself induced some precautions and that not all practices were uniform. One fractionator, however, pleaded with the FDA on

42. 21 C.F.R. § 601.94 (2005).

43. In July 1983, the fractionators began discussing “a possible industry-wide PR [public relations] program to stimulate use of [clotting] Factor VIII despite possible AIDS risk.”

44. *But see supra* notes 33–34 and accompanying text.

behalf of the industry to publish a recall policy, citing the competitive and legal (“standard of care”) pressures to recall products in the absence of definitive guidance from the FDA. Here is direct evidence that fear of liability for negligence actually encouraged concerted action to manipulate industry standards. Under strict liability, any collaboration by the fractionators would probably have taken the form mostly of procompetitive efforts to discover the sources of HIV/AIDS risks and ways to eliminate or reduce them.

Although the evidence reported above shows how prevailing tort doctrine slowed the adoption of safety measures rather than triggering a frantic search for effective prevention, it is impossible, given the early uncertainty surrounding AIDS, its etiology, and the efficacy of possible precautions, to say that many lives would have been saved under a different legal regime. But the experience summarized here strongly suggests that independent action by individual firms motivated by fear of strict liability (or perhaps by greater exposure to antitrust penalties for coordinating their response to a public-health catastrophe)⁴⁵ would have improved the survival chances of patients receiving blood or blood products. Contrary to Titmuss’s impulse, the wiser policy would have been to treat blood as an ordinary commodity and its purveyors as ordinary competitors.⁴⁶

IV

CONCLUSION

Today, the risks of contracting hepatitis or HIV infection from blood products have been greatly reduced, and adherence to industry standards (fostered in part by the threat of legal liability for negligently departing from such standards) should be sufficient to prevent nearly all such infections.⁴⁷ Human blood continues to present other challenges, however,⁴⁸ and hospitals and blood banks are reportedly seeking conscientiously to improve their

45. In a deposition, one company executive admitted that the competitors (at a meeting of the PMA Biologic Section) coordinated their donor-screening activities and the content and timing of warnings they would issue, but claimed, “We didn’t discuss anything of an antitrust nature.” Their lawyers had apparently cautioned them only against discussing prices.

46. The point that basic legal principles should be applied evenhandedly to professionals, nonprofits, and for-profit enterprises alike holds for antitrust as well as tort law and might be usefully developed by critically revisiting Titmuss’s lengthy criticism of an antitrust action by the Federal Trade Commission against hospitals and pathologists in Kansas City, Missouri, in the early 1960s. *THE GIFT RELATIONSHIP* (1970), *supra* note 1, at 158–72 (discussing *In re Community Blood Bank of Kansas City, Inc.*, 70 F.T.C. 728 (1966) (finding unlawful boycott of for-profit blood banks, allegedly prompted by quality concerns), *rev’d for lack of jurisdiction*, 405 F.2d 1011 (8th Cir. 1969)); see CLARK C. HAVIGHURST, JAMES F. BLUMSTEIN & TROYEN A. BRENNAN, *HEALTH CARE LAW AND POLICY: READINGS, NOTES, AND QUESTIONS* 545–50, 552–55 (1998) (reproducing, with discussion, extensive excerpts from FTC and dissenting opinions in the *Community Blood Bank* case).

47. *But see* Laura Landro, *Protecting Organ Recipients—From Donors*, WALL ST. J., Dec. 10, 2008, at D16 (describing one recent case of transfusion-transmitted HIV).

48. *See id.* (noting survey results finding “72,000 transfusion-related adverse reactions in 2006”).

practices in collecting, processing, storing, and using blood and blood products.⁴⁹ As typically occurs in health care, reports of new problems and improved practices are constantly being disseminated through industry and professional organizations and channels, and patient care is gradually being improved. This article, however, seeks to keep alive the notion that liability based not on fault but on iatrogenic injury alone would not only automatically compensate persons with real injuries but significantly hasten both the discovery and the adoption of improvements in medical practice.⁵⁰ Realism, to be sure, tells us that Titmuss-like views of the business of health care still dominate U.S. health policy, leaving us dependent mostly on professionalism, rather than on liability risks, consumer choice, and market forces, to ensure the quality of care and consumer welfare.⁵¹ The U.S. experience with blood nevertheless demonstrates one important way in which the public might have been better served had health policy taken a more, not a less, commercial view of the health-care enterprise.

49. *See id.* (describing cooperation among the Centers for Disease Control and Prevention, “private blood banks, tissue banks and organ-donation groups to develop a national ‘biovigilance’ network”); Laura Landro, *Hospitals Seek to Limit Use of Transfusions*, WALL ST. J., Oct. 29, 2008, at D1 (describing how stricter disease screening decreased the blood-donor pool thereby prompting improved blood-conservation measures at hospitals).

50. *See supra* note 19.

51. For the view that the apparent inability of U.S. political and legal institutions to adhere rigorously and consistently to market principles may force government to adopt nonmarket policies even when they are not theoretically or otherwise clearly justified, see Clark C. Havighurst & Barak D. Richman, *Distributive Injustice(s) in American Health Care*, 69 LAW & CONTEMP. PROBS. 7, 80–81 (Autumn 2006); *see also* Clark C. Havighurst, *Why Preserve Private Health Care Financing?*, in AMERICAN HEALTH POLICY: CRITICAL ISSUES FOR REFORM 87 (1993) (arguing that private health plans are hard to defend unless the legal system allows them to offer, and they do in fact offer, consumers a full range of health-care options, including meaningful economizing opportunities). For other statements concerning the price the public pays for treating health care as a field appropriately governed according to professional values and not as an ordinary commercial activity governed principally by private contracts and consumer choice, see CLARK C. HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* (1995); Clark C. Havighurst, *American Health Care and the Law—We Need to Talk!*, HEALTH AFF., July/Aug. 2000, at 84, 97 (“It is simply ironic that the same legal system that with one arm launched an antitrust initiative successfully challenging overt efforts by the medical profession to exercise decision-making authority has with its other arms given medical interests a monopoly over the most important economic decisions affecting American health care.”); Clark C. Havighurst, *How the Health Care Revolution Fell Short*, 65 LAW & CONTEMP. PROBS. 55 (Autumn 2002); Clark C. Havighurst, *Starr on the Corporatization and Commodification of Health Care: The Sequel*, 29 J. HEALTH POL. POL’Y & L. 947 (2004). For my critique of another scholar who, like Titmuss, strongly resists treating health care as a commercial activity, see Clark C. Havighurst, *An Apology for Professionalist Regimes*, 28 J. HEALTH POL. POL’Y & L. 159 (2003) (reviewing ELIOT FREIDSON, *PROFESSIONALISM: THE THIRD LOGIC* (2001)).