The Journal of Contemporary Legal Issues

Volume 23 | Issue 1 Article 5

12-16-2021

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Birth Rights and Birth Wrongs Through A Common Law Lens: Why the No Liability Regime is Likely to Endure

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Introduction: A saga in four parts: Dov Fox's recent book, the aptly named *Birth Rights and Wrongs*, is, as its title suggests, a study of the stark conflicts that arise in the highly contested area of reproductive rights. Fox makes the powerful case that the legal protection of reproductive rights, in all their protean forms, is systematically under-protected relative to two key benchmarks: the standards of ordinary decency, and social expectations. In my view, he has an acute awareness of these failures. But his greatest strength is also his greatest weakness, as he systematically ignores the great successes wrought through the current system, as disjointed as it might seem on first appearance. Since these triumphs are not sufficiently accounted for, Fox fails to develop a general theory which explains how these technological advances are two-sided developments.

In my view, there are always powerful incentives to do better, no matter which way the liability or regulatory rules are set, which tends to account for the higher performance and lower risk rates observed over time in this area notwithstanding the void in tort and regulatory protections.

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Still, as the liability situation need not be first-best, it is important to note that all of these birth wrongs occur not as harms to strangers, but as harms that arise out of consensual arrangements, where contractual solutions are all too often pushed aside in favor of adopting tort solutions that don't quite jibe with the situation.

Accordingly, this article is divided into four parts. Part I deals with the paradigmatic failures; Part II deals with the underappreciated successes. Part III offers a typology for change. Finally, Part IV deals with the serious difficulty in finding a contractual liability scheme that is better than the status quo.

Three paradigmatic failures: Fox begins his exposition by noting in detail the many instances in which the miracle of birth brings forth new life to the pleasure and celebration of all. On the other side, he develops in exquisite detail an endless catalogue of all the mishaps that can happen in this highly charged area. Under Fox's useful terminology, this grim cascade of events divides up into three categories, which he neatly summarizes as "Procreation Deprived," Procreation Imposed," and "Procreation Confounded."

These three headings convey the basic message that the attitudes and expectations that surround both sex and procreation are wide and diverse, and that it is not possible to think that anyone has ever proposed one uniform solution ideal for all women or couples. Many men and women are desperate to have children, either now or in the future, but who find that serious biological difficulties—sterility and disease—could easily stand in their path. People (including single persons who hope to marry at some future time) take steps to mitigate the dangers that have befallen them, only to have their desires thwarted by the negligence—occasionally worse—of other various professionals and organizations, both business and charitable, in whom they put their trust.

There are three common patterns. One of the most common scenarios, painfully retold by Fox, is that their precious eggs or sperm are put into the hands of a fertility clinic only to be destroyed because of an equipment malfunction before they can be used—procreation deprived. Next, there are individuals who do not want to have further children even as they want to continue to enjoy an active sex life. They discover that their supposed birth control pills were in fact vitamins, or that a vasectomy did not take hold, leaving them saddled with the prospect of an abortion or unwanted children, either of which could break their psyches, personal relationships, or finances—procreation imposed. Last, there are instances where laboratories mishandled various specimens, resulting in offspring with serious birth defects and genetic diseases, such as Fabry disease or Down syndrome, which can be a burden to the family, society, or both—procreation confounded.

Each of these mishaps have destructive consequences, yet none of them result from natural events, for all of them stem from the negligence of various professional actors in the health care system. Fox belabors the obvious point that these injuries are severe and substantial. But more critically, he then documents with painstaking care how, all too often, these failures are left without redress through any tort regime or regulatory scheme.

One the one side, individual tragedies are often regarded as noncompensable events under the tort law. The standard rationales, which I shall not belabor here, are both numerous and unpersuasive. It is said that these losses are too abstract, too remote, that they are only the disappointment of not getting some indefinite future benefit and not the subject of an immediate or tangible individual loss. Fox expresses his deep frustration with these claims, and I think he is successful by any standard in showing that the effort to make these serious losses disappear from view, often by mere linguistic sleights of hand, are not worthy of the judges who defend these supposed principles and distinctions. There is a jarring inconsistency between the specific situations detailed above and the current tort system generally, which has already found liability in many cases that present similar difficulties in dealing with probabilistic valuation.

To give but one pointed example, is it so much more difficult to calculate the loss of grieving parents in a wrongful death case if a physician's negligence harms the child the moment before birth rather than the moment after? In both cases the imponderables are large. What kind of abilities would the child have developed? What kind of personality traits would the child have had, leading to questions of future success in work, play and marriage? Forget about getting any reliable estimate of future income levels—questions of valuation are devilishly difficult to solve in the abstract, for it is next to impossible to estimate what the life fortunes will be for an individual who dies before their personality or skills are developed. But these estimation problems with respect to value are only infinitesimally smaller when the death occurs a week after birth as compared to a week before, if there are any differences at all. So why draw a hard legal line in the sand between two types of cases that show far more similarities than differences?

We struggle through with various guidelines and damage levels, even if we are confident that the numbers chosen are more or less pulled out of (not quite) thin air. We unhappily do these calculations because the deterrent and compensation objections cannot be served with a zero damage award,

so that some positive, even if imprecise, award tends to work better than nothing. This enterprise is of course not risk free, because of the possibility that excessive damages represent a second form of error against which few, if any, precautions are taken. The level of uncertainty in damages is an issue that runs through not only these extreme cases, but throughout the entire tort law, especially in wrongful death cases. A conventional test of value (which works tolerably well for the destruction or condemnation of real property) asks what a willing buyer would pay a willing seller in a voluntary exchange, which can often produce (especially in thick markets, such as those that involve real estate valuation) estimates that routinely tend to differ by ten percent, more or less. But these measures are utterly useless here—there is no willing buyer for the life of another individual, nor is there is a willing buyer to purchase birth defects and behavioral abnormalities from individuals who have suffered these sorts of injuries or deficits.

Come to think of it, there are no willing sellers of their own lives—and only in odd cases will individuals subject themselves to pain and suffering in order to claim some supposed financial advantage which would be summarily stripped if it were discovered that the loss was willfully self-inflicted. Hence valuations of human life start from a shaky assumption that seeks to estimate the amount that it would take to have a person take a one percent increase in the risk of death, which is then multiplied, perhaps by 100, to determine the requisite amount needed to compensate for certain death. Of course, the connection between partial and total loss of life is not linear, and so the inferences are necessarily uncertain whether we use these figures to compensate individuals through the tort system, or to determine the value of some "statistical life" to deal with environmental risks from various kinds of mishaps ranging from hurricanes to disease. But here, the best is not allowed to become the enemy of the good. Thus, the collective "we" perseveres, and continues to do so within the confines of traditional tort doctrine for issues that are encountered in every area of life. We know that the one figure that is wrong for all of these cases is zero, and yet it is just that number that is picked when liability is denied on any of these grounds.

As hinted above, the situation on the regulatory side is every bit as problematic. We know that losses of biological specimens, or the conduct of improper tests, have potentially deadly consequences. Thus, in an ordinary malpractice case, liability is a slam dunk if a physician uses the wrong reagents, or stores various plasmas and fluids intended for human use in a way that compromises their chemical integrity. Why then should losses associated with procreation be treated in a different fashion? Again, I can see no principled reason why the three classes of cases should fall outside of government regulation under some per se rule when so

many other transactions or activities in the health care space are already covered. Indeed, the common pattern today is to have dual systems—the FDA can regulate the permits and warnings for new drugs, while a medical malpractice suit serves as a backstop for individual cases of harms that still nonetheless occur. Admittedly, I think this system can go seriously awry insofar as it allows for tort actions to be brought for allegedly inadequate warnings, say, even when these warnings have been approved by the FDA.[1] The correct response in cases of this sort is not to allow juries to second-guess the FDA, whose major weakness is to overemphasize the downside of treatments. Rather, the appropriate course of action is to gather this new information in an orderly fashion, after which it can be used to revise the standard warnings and instructions associated with the drug reaching the market. The greater predictability of outcomes thus obtained is a far preferable outcome to having juries find large verdicts against physicians and companies that have played by the rules.

However, Fox does not use the topic of birth rights and birth wrongs to deal with questions of regulatory excess. Instead, he deals only with those cases for which there is evidently far too little regulation against well-defined harms that could be sensibly prevented. A rule that protected parties from a tort action if they complied with public regulations would not constitute the kind of legal vacuum that Fox decries in this book. Yet indeed, quite the opposite, this is a legal regime that he should encourage, because it would allow companies to realize that they have the benefit of a safe harbor if they comply with standards that are well-known and established in advance, without having to expose themselves to the vagaries of a tort system whose complex risk/utility balancing tests offer no safe harbor to insulate a defendant from liability.[2] The effect of that uncertainty is to reduce the flow of capital and expertise into this area, which could in fact slow down the rate of medical and technical innovation, with adverse consequences to individuals for whom reproductive rights are an issue.

Again and again, it should be stressed that the ideal system of tort and regulation does *not* try to minimize the number of accidents that occur without compensation. That number could easily be driven to zero by the

1. *See, e.g.,* Wyeth Inc. v. Levine, 555 U.S. 555 (2009), critiqued in Richard A. Epstein, *What Tort Theory Tells Us About Federal Preemption: The Tragic Saga of* Wyeth v. Levine, 65 N.Y.U. ANN. SURV. AM. LAW. 485 (2010).

2. *See, e.g.,* John Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825 (1973), critiqued in Richard A. Epstein, *The Risks of Risk/Utility*, 48 OHIO STATE L.J. 469 (1987).

imposition of some combination of heavy fines on the one hand and tort damage actions on the other—but what is essential to consider in this state of the world is the accompanying reduction in the number of cases for which needed reproductive treatment would be supplied. If the market were to dry up under the weight of harsh liability standards, it could in the extreme lead to a world with no mishaps *and* no activities.

So do this simple calculation. In one state of the world, there are one thousand value-adding procedures performed, out of which twenty go bad, with all twenty the victims receiving full compensation. In a second state of the world, there are ten thousand such procedures, out of which one hundred cases go bad, but with *no* adverse event receiving any compensation. Which world do we prefer? I would take the second, even if you put aside the evident fact that the transactions costs of running a legal system without compensation are zero, while those costs in a system with compensation are very expensive and drawn out. Simply put, in the first case we only have a thousand successful events, if we accept the questionable assumption that the twenty cases in which compensation is supplied are left as well off as they would have been if the injuries had never happened. But this is a rosy assumption, as it is quite likely that the errors in application are such that some of the people who get compensation do not deserve it, while others who deserve compensation will not get it—notwithstanding that in many cases, such as the birth wrongs described above, no amount of compensation can make an aggrieved individual whole. Not only do these errors result in individual injustices, but they also undermine the deterrence function of the tort system. Why bother to take a high level of precautions if you could be wrongfully sued no matter how well you perform? Likewise, why bother to take the same high level of precautions if you are likely to get off either way? These cases do not have the kind of clarity that is possible to achieve in traffic accidents, where the rules of the road in most cases make determinations of liability far more accurate than they are in the shadowy area of reproductive rights.

Now look at the dynamics of the second scenario. Here, we have 9,900 clear value-added successes against one hundred clear poor outcomes, which suggests that the increase in the number of happy outcomes wholly dwarfs the predicament of the hundred randomly chosen losers. Of course, these assumptions could be contestable, but not, I think, on the ground that higher success rates count for nothing. And if we look at the rate of medical progress, historically, it is very difficult to find a close connection between the rate of tort actions on the one side and regulatory innovations on the other.

There are no meaningful studies that address this issue in connection with reproductive rights, where the volume of litigation is relatively small. However, a recent book that seeks to examine the effects of various kinds

of tort reform on the frequency and reliability of the tort system, *Medical Malpractice Litigation: How It Works, Why Tort Reform Hasn't Helped*, paints a mixed picture (at best) of the benefits that the invocation of tort remedies can supply.[3] As the authors note, the object of the system is a combination of justice in the individual case combined with overall deterrence. The book then documents the litany of difficulties that come in designing the overall system, in terms of both error and expenses. It notes how difficult it is to assign the blame for rising liability costs, as there are likely imperfections in both the tort system and in the insurance markets. It also notes how difficult it is to draw any operational distinction between the administration of "careful" medicine as opposed to flatly "defensive" medicine. Contrary to what one might expect, the book finds that subtle refinements in liability influence the outcome in only a few cases, and even then only to an uncertain extent. They are unlikely to make any change in either the overall frequency or severity of litigation. Indeed, the only kind of reform that appears to meaningfully impact primary behavior is a cap on damages, which are typically restricted to pain and suffering. But again, it is hard to decide whether or not the changes that are observed improve the overall social calculus. It is commonly the case that the huge verdicts announced in a few cases are trimmed on appeal, so that the total payouts are less than these numbers would isolate.[4] I would describe the tone of *Medical Malpractice Litigation* as fatalistic. As a general rule, the more careful the analysis required to prove the point, the less confident we should be about the particular reforms in question. In my view, that uneasiness should carry over into the area of reproductive rights and wrongs. Liability reforms have not made much of a difference when they have sought to limit liability. They are not likely to make much of a difference if they were to increase liability. So the question then becomes, where does the needed action actually take place?

Many underappreciated successes: At this point, it is important to pick up the pieces that Fox may be missing in his dramatic account. Quite

3. BERNARD S. BLACK ET AL., MEDICAL MALPRACTICE LITIGATION: HOW IT WORKS, WHY TORT REFORM HASN'T HELPED (2021).

4. *See, e.g.*, Katie Thomas, *$8 Billion Verdict in Drug Lawsuit Is Reduced to $6.8 Million*, N.Y. TIMES (Jan. 17, 2020), https://www.nytimes.com/2020/01/17/health/jnj-risperdal-verdict-reduced.html [https://perma.cc/MC39-NTL2]; Jonathan Stempel, *U.S. Judge Slashes Roundup Jury Award to $25.3 Million; Bayer Still Plans to Appeal*, REUTERS (July 15, 2019), https://www.reuters.com/article/us-bayer-glyphosate-lawsuit/u-s-judge-slashes-roundup-jury-award-to-25-3-million-bayer-still-plans-to-appeal-idUSKCN1UA2CH [https://perma.cc/T74V-KKCQ].

simply, his exclusive focus on the failures of the current system ignores the success within that system—an observation that, as we shall see, tends to play out not only here, but in medical malpractice litigation as well.

To revert to the Fox analysis, his discussions of individual cases of failure are done without attention to the overall systematic effects. I am not an expert on this topic, but it is not difficult to assemble a host of data that talks about the rate of progress within the health care system as measured by a set of variables, such as the number of cases in the system, the rate of success, and of course, their associated costs. With a little bit of research, it was possible to collect some numbers about the state of play in connection with in vitro fertilization (IVF), a program that began with the birth of Louise Brown a little over 40 years ago. On this point, I summarize an obvious puff piece produced by Shady Grove Fertility entitled *Evolution of IVF Treatment*.[5] The highlights include improved pregnancy and delivery rates with an accompanying decrease in twin and multiple pregnancies. Of course, what drives these changes are not any particular reforms in the legal system as such, which has remained relatively constant over time. Rather, it has been the relentless improvement of the techniques that are used to conduct IVF, leading to the observed consistent trend in improvement.

More concretely, when Shady Grove Fertility began in 1993, they achieved a 32 percent delivery rate for women under the age of forty. Twenty years later, that number has moved sharply upward, as the clinic now achieves a 43 percent delivery rate for women under the age of forty.[6] Part of the explanation for this trend is improved culture media that allow for eggs after retrieval to receive better nutrition until they reach the so-called blastocyst stage, just prior to implantation. Better nutrition reduces uncertainty, and with it the need for multiple transplants. These embryos, moreover, can now be transferred directly into the uterus, instead of into the fallopian tubes. The eggs, moreover, are of much better quality due to advances in genetic testing which can remove from the reproductive cycle defective embryos, resulting in the occurrence of fewer miscarriages and fewer birth defects. In addition, the rise of improved freezing techniques, most notably vitrification, has allowed for the storage of eggs and embryos that can be used at some later time, where results indicate that the success rates are today comparable for those observed in what is termed "fresh" IVF cycles. This delayed practice is of obvious importance for women who should need to wait until they are cured of diseases before it is safe for them to become pregnant. Similarly, it allows for married couples

5. *Evolution of IVF Treatment*, SHADY GROVE FERTILITY (July 17, 2018), https://www.shadygrovefertility.com/blog/treatments-and-success/evolution-of-ivf-treatment/ [https://perma.cc/D2EH-D9WT].

6. Additionally, for women under the age of 35, the delivery rate is 57 percent. *Id.*

to store fertilized eggs if the husband has to undergo chemotherapy or other treatments that could result in the destruction of their capacity to have offspring. Applied across the vast multitude of IVFs happening across the world, these are huge advances, and they dwarf the number of losses that take place through the (inexcusable) mishandling of fertilized eggs.

These results are even more impressive when appreciating that the noted higher success rates have occurred even as technological advances have allowed for IVF clinics to tackle cases that were deemed untreatable a generation before. Thus, the Shady Grove Report states that today, the class of treatable conditions includes such dysfunctions as endometriosis, male factor infertility, advanced reproductive age issues, ovulatory dysfunctions, and even some cases of unexplained infertility. To expand on one previously untreatable condition, it has long been known that the difficulties in IVF cases do not solely reside on the female side, as weak sperm counts have historically been a major source of infertility, which in many cases forced married couples to rely on sperm donors for fertilization. But starting in the 1990s, a process known as intracytoplasmic sperm injection (ICSI) has been used to allow previously infertile husbands to become fathers as well.

The upshot is that, as of 2018, some eight million IVF babies have been born worldwide. Therefore, the relevant numbers to identify are the rates of IVF failures that have occurred over the past four decades and their corresponding rates of decline. To briefly describe the situation, as stated above, perhaps the most notable IVF failure is that of twin or other multiple pregnancies. However, rapid gains have been made on this front—in 2006, for women under the age of 35, 32.4% of IVF deliveries involved twins.[7] Just ten years later, the 2016 IVF twin rate had plummeted to 7.0%.[8] Additionally, a well-chronicled disorder associated with IVF is that of ovarian hyperstimulation syndrome (OHSS), an adverse event resulting from drug treatment given before an IVF.[9] Over the past ten years, great progress has been made with respect to identifying high-risk patients, as

7. CENTERS FOR DISEASE CONTROL AND PREVENTION, 2006 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES, NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 89 (2006), https://www.cdc.gov/art/pdf/archived/2006-ART_508tagged.pdf [https://perma.cc/4W8P-3QN9].

8. CENTERS FOR DISEASE CONTROL AND PREVENTION, ASSISTED REPRODUCTIVE TECHNOLOGY, NATIONAL SUMMARY REPORT 5 (2016), https://www.cdc.gov/art/pdf/2016-report/ART-2016-National-Summary-Report.pdf [https://perma.cc/B7FZ-U9D3].

9. *See, e.g.,* Pratap Kumar et al., *Ovarian hyperstimulation syndrome*, 4 J. HUM. REPROD. SCI. 70 (2011).

well as modifications to traditional dosage regimes and the introduction of new drugs that have collectively significantly reduced instances of moderate and severe OHSS.[10] None of this is unexpected—a combination of knowledge that comes from the development of sound protocols, coupled with a steady stream of technological advances, all seem to point in one direction. Unfortunately, there is a regrettable tendency to talk only of the failures, which are all heartbreaking in their own way. But it is equally, indeed more important, to talk about the success stories as well, and these numbers look very much like the simple hypothetical calculations that I introduced above.

The pattern that has been observed in connection with reproductive rights is I think capable of generalization. Across all industries and situations, the general tendency is for accident rates to fall over time. That situation is certainly true with respect to automobile accidents and traffic fatalities. To emphasize the point, while the raw numbers certainly ignore many confounding variables, fatal automobile crashes per 100 million annual vehicle-miles of travel decreased from 36.00 in 1900 to 1.36 in 2007, a more than 26-fold decrease.[11] And the same trend holds true with respect to pipeline accidents. While the frequency of accidents and fatalities in this domain are somewhat sporadic as compared to motor vehicle incidents, given the relatively small absolute number of pipeline accident cases, a study analyzing over four decades of pipeline incidents reports that from 1968–2009, "fatalities and injuries from pipeline accidents are generally decreasing over time."[12] And again, the same trend is present with respect to railroad accidents. Excluding highway-railroad crossing accidents, the United States had an average of 7.5 train-related fatalities per year across 2009–2019.[13] This rate stands in stark contrast to the average 1990–1999 train-related fatality rate of 18.4 deaths per year.[14]

Beyond the accident rates described above, there have been substantial positive increases in outcomes with respect to essentially any disease or condition that has been documented in the medical literature. Consider infant mortality rates—in 1980, there were 12.6 deaths per 1,000 live births

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10. Omar El Tokhy et al., *An update on the prevention of ovarian hyperstimulation syndrome*, 12 WOMEN'S HEALTH 496 (2016).

11. FEDERAL HIGHWAY ADMINISTRATION, MOTOR VEHICLE TRAFFIC FATALITIES, 1900 – 2007 (Jan. 2009), https://www.fhwa.dot.gov/policyinformation/statistics/2007/pdf/fi200.pdf [https://perma.cc/L2UB-LP6L].

12. Kyle Siler-Evans et al., *Analysis of pipeline accidents in the United States from 1968 to 2009*, 7 INT. J. CRIT. INFRASTRUCTURE PROT. 257 (2014).

13. BUREAU OF TRANSPORTATION STATISTICS, TRAIN FATALITIES, INJURIES, AND ACCIDENTS BY TYPE OF ACCIDENT, https://www.bts.gov/content/train-fatalities-injuries-and-accidents-type-accidenta [https://perma.cc/97QZ-99FB].

14. *Id.*

in children under twelve months old, compared to only 5.96 deaths per 1,000 live births in children under twelve months old in 2013.[15] Across 1944–1954, a patient with breast cancer had only a 25.1% chance of surviving ten-years after their initial diagnosis; for 1995–2004, the ten-year survival rate had increased to 76.5%.[16] Even disorders affecting remarkably small populations of individuals have seen tremendous advances in treatment options over the past several years.[17] As a recent notable example, on May 24, 2019, Novartis's Zolgensma® was approved by the FDA, the first gene therapy for pediatric patients with spinal muscular atrophy (SMA), potentially representing the only long-term cure for the rare disorder, which occurs in only 1 in 10,000 live births.[18] Invariably, these increases can be attributed to collective improvements in molecular biology and biochemistry, enabling enhanced pharmaceutical drug design and discovery, personalized treatment regimes through basic disease genotyping, and so much more.

At this time, it is also appropriate to add a reference to the enormous progress in the design of vaccines, driven by new technology in the response to Operation Warp Speed, which managed to bring to market multiple vaccines that to date have proved far more effective and safe than anyone had imagined when this process was first started by the Trump administration in March 2020. The overall process involved new technologies for the design and fabrication of the disease.[19] It also involved improvements

15. Carrie K. Shapiro-Mendoza et al., *CDC Grand Rounds: Public Health Strategies to Prevent Preterm Birth*, 65 MORBIDITY & MORTALITY WKLY. REP. 826 (2016).

16. Aman Buzdar, *Breast Cancer Survival on the Rise*, CONQUEST, MD ANDERSON CANCER CENTER (2011), https://www.mdanderson.org/publications/conquest/breast-cancer-survival.h37-1586679.html [https://perma.cc/832T-QQ4D].

17. Raymond A. Huml et al., *Accelerating Rare Disease Drug Development: Lessons Learned from Muscular Dystrophy Patient Advocacy Groups*, 55 THERAPEUTIC INNOVATION & REGUL. SCI. 370 (2021), https://doi.org/10.1007/s43441-020-00221-4.

18. Novartis Press Release, *AveXis receives FDA approval for Zolgensma®, the first and only gene therapy for pediatric patients with spinal muscular atrophy (SMA)*, (May 24, 2019), https://www.novartis.com/news/media-releases/avexis-receives-fda-approval-zolgensma-first-and-only-gene-therapy-pediatric-patients-spinal-muscular-atrophy-sma [https://perma.cc/Y4FZ-3L77].

19. Peter Loftus, *Covid-19 Vaccines Yield Breakthroughs in Long-Term Fight Against Infectious Diseases*, WALL ST. J. (Feb. 28, 2021), https://www.wsj.com/articles/covid-19-vaccines-yield-breakthroughs-in-long-term-fight-against-infections-disease-11614537238 [https://perma.cc/M8LT-34Z4].

in the overall distribution of the vaccine.[20] The processes developed in this effort will clearly spill over to find new applications in other areas.

Overall, these beneficial results cannot be attributed to any major change in the system of liability rules. Indeed, with respect to vaccines, the burdens of liability have been so great that Congress intervened in order to prevent the wholesale destruction of the vaccine market with duty-to-warn product liability suits.[21] In other areas, it is unlikely that the product liability rules have contributed much to safety either.[22] Indeed, the height of liability in torts was probably achieved in the early 1980s, which is one of the reasons explaining that period's large spurt in cases often attributable to asbestos-related[23] or silicon-related conditions,[24] or medical conditions resulting from the administration of DES to pregnant women,[25] even if the manifestation of those losses was delayed for a generation or more. So if it has not been through any notable reform in liability rules, what has been driving the change behind all of the positive increases noted above? Improvements in every single factor of production, from cars, to roads, to communications, and so on down the line. The same situation of course applies with respect to all forms of infrastructure, such that the newer the product, the safer the overall situation, which means that quick replacement of obsolete stock with the most current, cutting-edge technology is far more important than any liability rule for any damage that may occur. Delay in innovation is the ultimate danger in an field with innovation technology.

A typology for change: It is important to see why all this is so. For example, the famous 1932 case of The T.J. Hooper is said to stand for the legal proposition that because an entire calling can "lag" in its adoption

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20. Peter Loftus, *Covid-19 Vaccine Manufacturing in U.S. Races Ahead*, WALL ST. J. (Mar. 21, 2021), https://www.wsj.com/articles/covid-19-vaccine-manufacturing-in-u-s-races-ahead-11616328001 [https://perma.cc/5T9Q-AC9C].

21. *See* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1), (capping damages at $250,000 given proof of vaccine caused injury, which is not that easy to establish); *See also* Paffold v. Sec'y Health & Human Services, 451 F.3d 1352, 1352 (Fed. Cir. 2006). For an early critique of the liability rules in vaccine cases, see Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985).

22. A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Product Liability,* 123 HARV. L. REV. 1436 (2010).

23. Deborah R. Hensler, *Asbestos Litigation in the United States: A Brief Overview*, THE INSTITUTE FOR CIVIL JUSTICE, RAND (1991) (noting that from "1980 through 1984, approximately 10,000 [asbestos] cases were filed – about a ten-fold increase over the preceding five-year period.").

24. *See, e.g.,* In re Corning, Inc., Sec. Litig., 349 F. Supp. 2d 698 (S.D.N.Y. 2004) (detailing the first judgement finding liability for defective silicone breast implants in 1984).

25. *See, e.g.*, Sindell v. Abbott Laboratories, 26 Cal. 3d 588 (1980).

of safety precautions, industry custom can never set standard of care.[26] Yet, this statement is based on an erroneous interpretation of the facts, which resulted in the court focusing on the wrong question. In that case, the court asked whether ships at sea should have radios that would allow them to receive storm warnings. However, the problem didn't arise out of a crash between two ships. Instead, a barge owner brought the suit against the tug that was towing his boat up past the Delaware breakwater. The two parties were in privity with each other and were both anxious to cut the best deal they could. When parties are in privity we do not face problems of low level of precautions, which can lead to strangers being harmed, and for which a strict liability rule is often appropriate. But in these cases, it is often ruinous to apply strict liability standards. In fact, in medical malpractice strict liability is uniformly rejected because the patient (unlike the stranger in many cases) does not want the activity to stop and thus has to moderate the demands. As a result, negligence, usually in connection with the accepted standard of care in the particular line of medicine, is the proper standard.

Once we are in these consensual arrangements between repeat sophisticated players the simple but insistent question is who would resist that innovation? In *The TJ Hooper,* the only ambiguity in the record was whether the captain or the boatowner should supply the radio. But Judge Learned Hand confused the entire situation,[27] writing as if the failure of this one boat to be equipped with a radio was evidence of some backward industry-wide custom, when, in reality, it was just a blunder that rendered the boat unseaworthy, as the district court below had found without further ado.[28] The analysis slightly differs in cases where one boat crashes into another, but even in that situation there is a high correlation between outcomes and the choice of liability rule—for example, negligence versus strict liability. In any event, the risk of loss of one's own life and limb also creates strong pressures on both parties to take these precautions to protect both themselves and others. So just as with the consensual case, there are strong incentives to adopt new technologies regardless of the legal rule. Unfortunately, Hand's analysis, which missed these dynamics, has taken on a life of its own. As a result, there are huge deadweight losses

26. The T.J. Hooper, 60 F.2d 737 (2d Cir. 1932).
27. *See* Richard A. Epstein, *The Path to* The T.J. Hooper*: The Theory and History of Custom in the Law of Tort*, 21 J. LEGAL STUD. 1 (1992).
28. The T.J. Hooper, 53 F.2d 107 (S.D.N.Y. 1931).

in product liability cases today, as juries and judges second guess various design decisions in developing many factor tests to decide whether some design was or was not unreasonably dangerous.[29]

It is important in dealing with reproductive technologies to reflect on the relationship between the liability rule and the level of technical progress. These are consensual cases so that the transmission of information and the control of risk should take place more rapidly than in cases involving strangers. *The TJ Hooper* offers a reference point. In *The Costs of Accidents: A Legal and Economic Analysis*, Guido Calabresi explains that a liability rule can only shift the loss from one party to another in the hopes that putting it on some efficient party will reduce the sum of accident costs and the costs of their prevention.[30] In the ideal contractual world, the parties will shift that liability to the cheaper cost avoider, assuming that this party could be identified. But Calabresi's simple formulation cannot account for the fact that the ideal solution involves a joint care situation in which the contribution of one party only makes sense if the other party makes good on its part of the deal. Nor is there any guarantee in these cases that the correct solution will remain constant across different parties, different technologies, or different places. But amidst all of that variation, one point remains constant: both parties would much prefer to find a way to eliminate the risk rather than shifting it back and forth. So if there were no liability for tugs that carried no radios, non-radio-carrying tugs could not attract the level of business that a firm that announced it had the latest radio communications could (even without warranties). If there were liability, the non-radio-carrying tug owners would take precautions to minimize the risk. Indeed, no matter what the liability rule, a sensible firm would advertise that it has radios that allow it to track the weather. Thus, we see the innovation market will not be particularly responsive to changes in liability rules, because no matter what they are, both sides are better off if the risk is eliminated. As a result, drive for improvement continues apace, which is exactly what we observe here.

The same evolution takes place in medicine. The number of lawsuits is not a good measure of the overall state of affairs. Instead, we should look to whether improvements in technology allow for the use of more ambitious techniques that could not be done a generation earlier regardless of the liability rule. The reality is we observe exactly this kind of innovation in various areas. To give but one illustration, there was a time when it was not possible to administer anesthetics on a continuous basis, and so patients

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29. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L. J. 825 (1973); Richard A. Epstein, *The Risks of Risk/Utility*, 48 OHIO ST. L.J. 469 (1987).

30. GUIDO CALABRESI, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS (1970).

had to be heavily dosed to make sure they did not wake up toward the end of a difficult operation. Just who should be opposed? Once it became possible to give incremental dosages, the all-or-nothing cases became far less common. As a result, the number of cases in which heavily sedated patients were injured trying to get out of bed was sharply reduced.[31] Innovative changes like these exist in drug treatments, surgery, and just about every other area of endeavor. They take place at about the same rate as with the reproductive technologies and for the same reasons. So, if one looks again at the pessimistic conclusion about the state of tort reform in medicine, it is a side issue relative to the transformation in techniques, sometime frequent and incremental, and other times uncommon but discontinuous. There is a huge market for these innovations in a no-liability world just as there is a huge market in a liability world. So the message remains the same, looking too hard at the downside overlooks the major gains on the upside.

IV. Contractual refinement. The gravamen of the above argument is that liability rules do not matter as much as technical innovation in a consensual arrangement where, as a first approximation, both sides can be made better off with any improvement, regardless of the liability rule. Over a very broad range of cases this is true. But there are situations when an extrinsic liability risk—one imposed as a matter of law, and not by the parties—can become so great that it can, at least in the short run, lead to a breakdown of the market. If the liability rule imposes a net cost that exceeds the gain from voluntary exchange, the market breaks down. This has happened periodically in medical malpractice cases when, for example, the price for medical services cannot be raised sufficiently to cover the anticipated risk of liability. Indeed, in this area the decisive precedent was handed down in 1963, for at that time, it was clear that the basic doctrines of medical malpractice—the use of a customary standard of care, and the cautious use of res ipsa loquitur—were breaking down. Hence health care providers sought to fill the gap by contractual limitations on liability, for which they were roundly rebuffed.[32] In so doing, judicial regulation was left unimpeded, which eventually led to the medical malpractice crises that arose in the mid-1970s for one simple reason: the diversion between the legal

31. For one such case, dealing with informed consent, see Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

32. Tunkl v. Regents of University of California, 60 Cal.2d 92 (1963). For the parallel anti-contractual bias in product liability law, see Greenman v. Yuba Power, 59 Cal.2d 57 (1963).

rules on the one side, and the optimal contract regime on the other, became sufficiently great that adjustments in either the price term or other conditions were not sufficient to keep the market fully active, so in the locales where the impact was greatest, some contraction of the market occurred. Such a breakdown could last until the next round of innovation reduces the probability of occurrence to a low enough level that the market could then start to revive. Indeed, today with superior technology, the malpractice issue looms far smaller because the frequency of adverse events goes down, and with it the possibility of major litigation.

Given the ebb and flow in these markets, it becomes clear why, in principle, there is a place for limitation on damages to prevent matters from going out of control. The first approximation in these cases is that the proper (expectation) measure of damage is equal to the gains that the innocent party would have received if the party in breach had performed in full. That formulation does work well in certain financial cases, as when an owner of goods sells them out from his buyer to some third party. In these cases, there is a learned debate as to whether the party who wrongfully sold the goods is entitled to the gains that the seller had received or whether, as in *Acme Mills & Elevator Co. v. Johnson*, the buyer is only entitled to lost profits.[33] The dispute between expectation and restitution in case of nondelivery because of resale at a profit raises an esoteric issue because no matter which measure of damage is used, the party in breach always has the resources to pay for the losses in question. Thus, in *Acme Mills*, the contract price for wheat for future delivery was $1.03 per bushel. The wheat was wrongfully sold to a third party $1.16 per bushel, as the price of wheat had risen sharply between the signing of the contract and the delivery date, before it fell back down again to $0.97. If we use the expectation measure, the buyer would owe the seller money given the decline in prices, a result that never happens typically because the seller will always deliver fungible goods. But if the price goes up, requiring the seller in the wrong to disgorge the profits will not be the mark of financial ruin because he always has a fund at his disposal—namely, the higher payment received from the third party buyer—that is sufficient to cover the loss in question. Neither measure of damage therefore threatens to impose intolerable burdens on the operation of the system.

The same is not true, however, when the expectation measure of damages no longer deals with lost profits, but instead is intended to cover consequential losses sustained by the buyer of goods or the purchaser of services from the defendant's breach. Those losses in question could be, and indeed often are, far in excess of the purchase price of the goods—as would be the case

33. Acme Mills & Elevator Co. v. Johnson, 141 Ky. 718 (1911).

if, for example, a defendant sells a plaintiff a camera for $1,000 which is then taken to the top of Mount Everest for pictures for an expensive spread for National Geographic for $100,000, only to fail because of some defect in the equipment. In general, no seller of goods (even—or especially—if apprised of the purpose of the purchase) would agree to pay for losses of that magnitude because he could not procure insurance to cover that loss and still remain in business. The usual solution therefore is to impose a limitation on consequential damages, often in the form of a liquidated damage clause that limits, say, the loss in the event that the camera malfunctions to the purchase price of the good, even some fraction thereof, or indeed any fixed number that is acceptable to both parties.

The result here doesn't overreach as it's efficient from the ex-ante perspective. At this point, the buyer knows that she will be without protection in the event of failure, which incentivizes her to take steps in advance of the loss to mitigate potential damage. The simplest way to do this is to buy two cameras from independent vendors so that the backup from the second reduces the probability of loss to an acceptable level. It is also the case, however, that the buyer still would want some assurance that her seller would take precautions at his end to reduce the likelihood of product failure. A positive sum for consequential losses equal to $100 supplies a powerful signal that the reliability of the camera is sufficiently high that the seller can insure (or self-insure) over that risk and still turn on profit on the transaction. Thus, if there were a 10 percent chance of failure, the seller would be bankrupt because the entire purchase price would have to fund the insurance, leaving none revenues to supply the goods sold. Limited consequential damages thus operate as an effective signal that the risk of loss is (probably) well under one-percent, so that the purchase of two cameras for the trip reduces the risk of loss to at most one part in ten thousand on the numbers posited.

This feature applies not only to contracts for sales of goods, but also to delivery contracts, as in the famous case of the delayed delivery of the crankshaft in *Hadley v. Baxendale*.[34] The standard formula that speaks of—to use Fuller's standard terminology—restitution, reliance, and expectation damages misses the entire market dynamic.[35] In some cases we may need a precise dollar figure, while in others we need a formula for damages.

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34. 156 Eng. Rep. 145 (1854).

35. Richard A. Epstein, *Beyond Foreseeability: Consequential Damages in the Law of Contract*, 18 J. LEGAL STUD. 105 (1989).

This principle carries to the workers' compensation system, where employer and employee incentives work together to ensure the level of overall injury is below that which occur in a tort law system that contains the standard contributory and assumption of risk defenses. Limited transfer payments let the seller signal to its employees that it has taken appropriate precautions (often backed up by insurance and inspections), while workers are similarly incentivized to take care to avoid injury because they know that the compensation payments do not fully offset their personal losses. The level of workers' compensation is deliberately set below the expected losses, pecuniary and otherwise, to the injured worker, but in turn eliminates defenses based on assumption of risk and contributory negligence. A broad coverage formula with limited damages produces a figure that can be insured against at low enough levels that it can be covered solely with firm revenues. At the same time, workers are incentivized to take precautions not to get injured on the job as any compensation for injury would be at below-market levels.

Workers' compensation systems should reduce the number of overall injuries compared to those covered by contributory negligence and assumption of risk defenses. How do we know?[36] These systems were adopted voluntarily, before required by law, when the risk of injury was high enough that administration of a compensation system was worthwhile. As a result, worker' compensation systems were often adopted in mines, mills, and railroads, where accidents were most frequent.

The question then arises as to how this analysis can be applied to reproductive losses. As in other contexts, full tort damages may prove too burdensome, while zero damages may expose the patient or patients to excessive risk of loss. In principle, we should be able to think of some system of liquidated damages that could operate much like it does in contractual cases of defective goods or their delayed delivery (as in *Hadley*) or workplace injuries. However, these systems have not been observed in practice. Why is that the case?

One possible reason is that parties anticipate these systems won't stand up in court such that judicial invalidation makes expenditures pointless. Another explanation is that it becomes difficult to figure out what counts as the compensation event that triggers the payment. This is difficult in the extreme when procedures fail, but less so in cases where the breakdown comes in the form of a mechanical failure like that of a cooling element at some storage facility. Even in the latter case, it's unclear how risk should be allocated if the electrical grid fails for reasons beyond the owner's

36. Richard A. Epstein, *The Historical Origins and Economic Structure of Workers' Compensation*, 16 GA. L. REV. 775 (1982).

control. In any event, it seems these devices are obsolete today. As a result, we can assume the error rates are sufficiently low that no one thinks that the introduction of some compensation system makes sense. It's costly to devise any system of this sort, and the possible gains are offset by the usual deadly combination of administration and error costs, both broadly conceived.

Therefore, it's possible to interpret Fox's data very differently. His stories of reproductive losses that matter are surely correct. But his failure to grapple with two other points undercuts the case for a fundamental revision of either direct regulation or liability rules. First, no one wants to jeopardize the massive gains from the system. Second, any system of either tort or schedule damages could jeopardize those gains. All social institutions are formulated in a second-best world. In this instance, leaving matters to run their course without legal intervention may be the most prudent course of action. Perhaps what's most telling is that neither the public nor the profession are clamoring for any type of legal reform, which certainly was not the case when the medical malpractice system fell out of whack. The higher the level of performance on the ground, the weaker the case for a stronger system of liability. The power of the status quo ante on matters of this sort should never be underestimated. So some birth wrongs will go unredressed, as the overall success rate improves—the right result.