The Rise of the Regulatory State

Institutional Entrepreneurship and the Decline of Markets for Blood

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Regulation is ubiquitous in wealthy nations around the world today. No aspect of life in a modern Western economy remains unregulated, and although regulation of product safety, for example, often goes unnoticed, it is not costless (Thomas 2012; Chambers and Collins 2016; Coffey, McLaughlin, and Peretto 2016; McLaughlin and Stanley 2016). Research on the economic cost of red tape abounds, and yet the flood of new rules that enter the federal code of regulation each year seems unstoppable.

Edward Glaeser and Andrei Shleifer (2003) argue that this rise of the regulatory state is an efficient response to the court system’s failure to resolve property-rights disputes effectively (see also Shleifer 2010). In their model, courts and regulation are alternative institutional structures designed to achieve the social control of business. When businesses seek to avoid legal damages, courts can be the most efficient institutional mechanism for the facilitation of exchange. However, as businesses grow larger, they influence the courts more frequently in their favor, property rights become less secure, and regulation becomes relatively more efficient as a means of social control of business.

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We argue here that Glaeser and Shleifer (2003) are too optimistic about the potential for regulation to alleviate court-system failure. Our discussion suggests instead that institutional entrepreneurs often use regulation to undermine the court system when it successfully constrains business to socially useful activities. We suggest that the economic theory of regulation paired with a theory of institutional entrepreneurship is the more plausible explanation for the rise of the regulatory state. Lobbyists actively seek out regulation and provide the impetus for intervention in order to undermine the legal institutions that constrain the industries they represent.

Blood markets in the United States are a case in point. Prior to state and federal regulation of markets for blood in the 1970s, blood supply in the United States was sourced from both volunteer and nonvolunteer or paid donors. Since 1978, non-volunteer or commercial blood has essentially been banned. This ban was initially justified as an effort to combat hepatitis transmission. As we show, however, regulation of blood markets, despite its otherwise noble aim, effectively undermined a more efficient legal regime governing blood markets at the time and was ultimately merely the result of successful lobbying by a coalition of blood donor agencies and hospitals that benefited from the intervention.

The first section of this paper discusses Glaeser and Shleifer’s (2003) explanation for the rise of the regulatory state in the context of the existing literature on regulation versus litigation. Then in the second section we summarize the history of the legal institutions governing markets for blood before intervention. In the third section, we recount the rise of regulatory institutions governing markets for blood. We close by describing problems in the market for blood today and drawing conclusions from our inquiry.

**Theories of Regulation versus Litigation**

The earliest justification for regulatory intervention (Pigou 1920) famously suggests that government intervention is needed to address negative-spillover effects of market activities. This public-interest theory of regulation was first questioned by Ronald Coase in his article “The Problem of Social Cost” (1960). Coase famously argued that litigation will solve problems of negative externalities as long as property rights are well defined and transactions costs low. Following Coase, much of the literature in law and economics has discussed the trade-off between regulation and litigation in terms of transaction costs and more specifically in terms of potential information and incentive problems with either method of social control of business. Richard Posner argues, for example, that the choice between the two methods of public control, regulation or litigation, should “depend upon a weighing of their strengths and weaknesses in particular contexts” (1977, 271). He goes on to discuss several specific examples. In the case of consumer fraud (272), consumers will have a lack of incentive to complain to the respective agency tasked with the enforcement of regulation because the agency, in this
case the Federal Trade Commission, cannot award any damages or penalty to the defrauded consumers. In the case of mandated disclosure laws, consumers will already know about product defects or side effects by the time the respective agency has sufficient evidence to justify a disclosure mandate. And a tort action is not sufficient to remedy health and safety concerns associated with a particular product if the hazard cannot be linked clearly to the product. The case for health and safety regulation is strong wherever the costs of accident or illness are difficult to measure. The case for regulation is weakened when the cost of safety regulation is also safety itself, as may be the case when the drug-approval process for pharmaceuticals mandated by the Food and Drug Administration (FDA) delays the arrival of a drug on the market. Dale Gieringer (1985) estimates the cost of this sort of drug delay at between twenty-one thousand and fifty-one thousand lives lost per decade. Finally, in the example of regulation to mitigate environmental pollution, Posner (1977) argues that, on the one hand, the cost of the injury to the individual may be too small to warrant legal action but that, on the other, there is the significant potential problem of getting locked into an inferior technological equilibrium once regulation has mandated certain methods of pollution control.

Steven Shavell (1984) similarly discusses the efficiency implications of regulation versus litigation. He proposes four determinants that may make either regulation or litigation more advantageous in different situations (359). The first determinant is the difference in knowledge about risky activities on the part of the private parties involved as compared to the regulator. Shavell argues that when private parties have the information advantage, as they often do, litigation is the more appropriate means of social control of business activities. The second determinant is that private parties may be unable to pay for the full magnitude of the harm done, in which case regulation is usually the more appropriate response unless private parties can be incentivized to purchase liability insurance. The third determinant is that private parties might not face the threat of a suit for harm done, in which case regulation would again be the more appropriate response when externalities are present. The fourth and final determinant is the magnitude of the administrative costs incurred from regulation as compared to litigation. Shavell suggests that the advantage here will usually be with the tort system because administrative costs will be incurred only in the case of actual harm, and the administrative costs of regulation are independent of actual harm. Shavell’s analysis suggests that, depending on the case, either regulation or litigation will be the more appropriate response to negative-spillover effects.

Like Shavell (1984) and Posner (1977), Glaeser and Shleifer (2003) develop a theory of law enforcement that distinguishes between private litigation and government regulation as alternative institutional arrangements that secure property rights. Unlike Shavell’s and Posner’s views, however, Glaeser and Shleifer’s model of the relative efficiency of either method of social control of business is not based on informational and incentive considerations. They propose instead that firm size may be the relevant margin of analysis. Using evidence from the Progressive Era, they show
that with increasing firm size, private litigation becomes less effective at securing property rights because larger firms have an increasing ability to pay to avoid legal damages.

Glaeser and Shleifer (2003) suggest that regulation arose during this period because of a question surrounding the courts’ ability to adjudicate fairly between large powerful corporations and private individuals. They argue that during the Progressive Era the court system became widely used to privilege corporations who faced a constant cost structure of influencing justice (see also Shleifer 2010). In light of this critique, corporations came under scrutiny, and regulation became more prevalent. This story emphasizes an efficient institutional response when the court system breaks down: more regulation. Shleifer and Glaeser suggest that ultimately as corporations grow in size and the relative cost of undermining the court system decreases, regulatory oversight grows, which is efficient.

We argue here that although this explanation may account for intervention during the Progressive Era, it cannot explain the more recent expansion of the regulatory state, which has come at a great cost: lower economic growth in the most heavily regulated economies. A growing literature describes the costs of regulatory accumulation: Simeon Djankov and his colleagues (2002) show that countries with better formal institutions tend to have fewer barriers to entry and, as a result, greater economic growth. James Bailey and Diana Thomas (2017) show that more-regulated industries experienced fewer new firm births and slower employment growth between 1998 and 2011. Bentley Coffey, Patrick McLaughlin, and Pietro Peretto (2016) estimate the cumulative cost of federal regulation over a thirty-five-year period in the United States. They find that economic growth has been dampened by approximately 0.8 percent per year since 1980, which equates to a total cost of $4 trillion or about $13,000 per capita (8).1

This evidence suggests at least that the recent rise of the regulatory state has come with more-negative implications for economic efficiency than what Glaeser and Shleifer’s (2003) and Shleifer’s (2010) theory can account for. More specifically, Shleifer and Glaeser’s model underestimates the negative effects of rent seeking and political entrepreneurship by deliberately excluding the sort of rent-seeking entrepreneurship that initiates new, producer-benefiting regulatory intervention (Stigler 1971). Although Shleifer and Glaeser argue that their model is not in conflict with the interest-group theory of regulation, they specifically stipulate that efficiency-improving regulation can be consistent with their model only as long as producers do not initiate intervention but only lobby to shape changes in regulation (2003, 418 n. 10). This caveat suggests that in their model lobbying is merely a response on the part of producer interest to changing institutional constraints. Regulation is still public spirited and altered only at the margin to benefit producer

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1. A host of other studies show similar detrimental effects of regulation: see Maloney and McCormick 1982; Klapper, Laeven, and Rajan 2006; Sobel, Clark, and Lee 2007; and Nyström 2008.
interests. This assumption fundamentally limits the extent to which regulation can be subverted by producers and used as a means of limiting the social control of business. In line with a substantial literature on the economic theory of regulation, we argue here that lobbying, rather than being an ex post response to public-spirited regulatory intervention, is the primary cause of regulation and is usually employed by producers either to capture rents or to undermine more stringent institutional constraints on business. Regulation, rather than being an alternative institutional constraint on business, has become the primary means for some producers to subvert judicial institutions that constrain them. Our analysis reasserts the findings of the economic theory of regulation, which predicts that regulation is instituted primarily to benefit some producers at the expense of others.

Beyond merely reasserting the relevance of the economic theory of regulation, however, we also suggest that when regulation is used as a means of subverting legal precedent, it destroys institutional constraints on business rather than offering a means of controlling them. Lobbyists as political entrepreneurs use regulation as a means of subverting existing institutional constraints on business activity. This additional insight is based on work by Adam Martin and Diana Thomas, which suggests that political entrepreneurs will “devise institutional mechanisms to strengthen their political property rights” (2013, 24) when opportunities for rent seeking at the lower level of day-to-day politics and rent-seeking are thwarted.

In the example we present in the next section, hospitals and medical professionals first sought to undermine the existing precedent in the market for blood by capturing the legal system and changing liability rules in their favor. When the legal precedent later returned to an economically more-efficient but (for the medical industry) less-beneficial institutional structure, hospitals and blood banks took their fight to the state level and ultimately the national level. Regulation of markets for blood clearly benefited some producer interests and ultimately subverted the previously existing, economically more-efficient legal regime. Our example suggests that the rise of the regulatory state, rather than representing a move toward more-efficient social control of business, as suggested by Glaeser and Shleifer (2003), has come at the expense of institutional quality, economic efficiency, and economic growth at large.

**Legal Developments in Blood Markets before Regulation**

Before 1900, most recipients of blood transfusions did not survive the procedure. Three important scientific discoveries during the nineteenth and twentieth centuries

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2. This caveat to their model places Glaeser and Shleifer’s (2003) and Shleifer’s (2010) contribution firmly within what Peter Boettke and Peter Leeson (2015) have termed the “market-failure” presumption. Although Glaeser and Shleifer have nominally admitted the possibility of government failure, they have excluded from their model systematic considerations regarding one of the primary sources of government failure: interest-group-initiated regulatory intervention.

3. See also March, Martin, and Redford 2016 for a description of the different types of entrepreneurship.
significantly improved survival rates. First, sterilization gained widespread acceptance in the 1800s, greatly reducing the risk of infection. Second, blood types were discovered in 1900. Finally, mechanical devices were developed that controlled blood flow and pressure entering recipient bodies (Slonim, Wang, and Garbarino 2014). Following World War II, blood-transfusion technology became available in domestic hospitals. Battlefield doctors returning home had used the technique on the front lines and were now applying their new knowledge in civilian hospitals. At first, doctors used transfusions only in cases of extensive blood loss, but the new technology was quickly applied to other innovative procedures, such as open-heart surgery and trauma. With the expanding possibilities for application, the demand for whole blood increased steadily, but the supply of blood donations shrank when donations inspired by patriotism declined. Significant blood shortages were the immediate result of these two trends. In the face of such shortages, the emergence of blood banks that offered to pay donors for donations of commercial blood presented a promising solution to meeting the now higher demand for blood.4

Transfusion Hepatitis and Legal Liability

Although the new technology saved lives that would have been lost otherwise, it quickly became obvious that the technology came with some negative unintended consequences: patients could contract life-threatening diseases after they received transfusions. Battlefield conditions during the war had warranted high-risk experimentation because saving a soldier’s life, even if it meant transmitting disease to him, was the obvious choice. Some of the known communicable diseases, such as malaria and syphilis, were quickly contained by testing samples of donated blood. However, during the 1960s another pathogen was discovered: serum hepatitis.

Early torts brought by transfusion hepatitis victims against the hospitals that had transfused the blood tended to be decided in favor of the hospitals. Precedent was set in this direction by a case brought in 1954, *Perlmutter v. Beth David Hospital* (308 N.Y. 100 (1954)). The plaintiff in this case argued that the hospital had sold her the blood, which implied a “warranty that the good shall be of merchantable quality.”5 The court decided against Perlmutter and argued that the blood transfusion did not constitute a sale because the whole of the transaction could be classified as a service, which implied no warranty on the part of the hospital. This decision became precedent in several court cases of post-transfusion hepatitis victims against hospitals and blood banks during the

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5. Law of Sept. 1, 1911, ch. 571, §96, (1911) N.Y. Laws 1298, 1305 (repealed 1964): “(1) Where the buyer, expressly or by implication, makes known to the seller the particular purpose for which the goods are required and it appears that the buyer relies on the seller’s skill or judgment (whether he be the grower or manufacturer or not), there is an implied warranty that the goods shall be reasonably fit for such purpose. (2) Where the goods are bought by description from a seller who deals in goods of that description (whether he be the grower or manufacturer or not), there is an implied warranty that the goods shall be of merchantable quality.”
1960s. It protected defending hospitals and blood banks against liability and left post-transfusion hepatitis victims solely responsible for the monetary damage of their infection with the hepatitis virus.

The decision in *Perlmutter v. Beth David Hospital* was surprising for two reasons. First, it went contrary to the general legal development for product liability at the time. Although most legal decisions were moving away from a negligence standard, also called the “rule of caveat emptor” (let the buyer beware), toward strict product liability for producers, the legal development for cases of hepatitis transmission was moving in the opposite direction (Havighurst 2009, 2). In fact, the *Perlmutter* decision not only prescribed a negligence standard but basically exempted hospitals from any product-related liability, including transfusion-related illnesses, by classifying the relationship between the hospital and its patient as a service and arguing that the products used in treating a patient are “entirely subordinate to its paramount function of furnishing trained personnel and specialized facilities in an endeavor to restore plaintiff’s health” (at 106). By classifying the interaction in this way, the court established that there was no sale of a product and therefore no warranty.6

The second, related reason why this legal development was surprising was that it allowed hospitals and blood banks to turn a blind eye to the problem of post-transfusion hepatitis. Without a monetary incentive to reduce the number of post-transfusion hepatitis cases, they engaged in questionable recruiting and transfusion practices. An extreme example of the mismanagement of blood that resulted from this inefficient legal regime was the practice of transfusing blood from questionable sources just for a postoperative cosmetic effect: to make the patient look healthier. This use of a risky procedure for mere cosmetic benefit shows an institutional failure on the part of the medical industry in providing care. Similarly, blood banks accepted blood from donors independent of the donor’s medical records—for instance, blood purchased from prisons or areas of town known as “skid row” when volunteer donations didn’t cover demand.7 Even if one blood bank rejected a commercial donor because it had found evidence of a previous hepatitis infection in his blood, the donor could easily find another blood bank that would take his donation because no system existed to communicate this information to other blood banks in the area.8

As early as 1970 (Calabresi and Bass 1970), legal research on the topic of post-transfusion hepatitis had concluded that a strict-liability rule would better incentivize blood recruiters and hospitals to account for the differential incidence of hepatitis

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6. Marc Franklin (1972) notes that this interpretation was in line with the general practice of keeping charitable hospitals free from any liability even in cases of negligence, which was general precedent until 1957.

7. See Starr 1998 for a more detailed discussion of the blood-recruitment tactics of the Midwest Blood and Plasma Center run by Franklin and Margaret Bass (186–92) as well as a discussion of J. Garrott Allen’s reliance on blood purchased from prisons for his blood bank serving the University of Chicago clinics (219).

infections in different donor populations. Under strict liability, blood banks and hospitals would be liable if the product were defective (i.e., infected with a transmittable disease), even if they were not negligent in making that product. A strict-liability rule for blood transfusions would have left blood banks and hospitals financially responsible for any damage caused by hepatitis transmissions even though a screening test for the virus was not yet available.9

The theoretical rationale for the greater imposition of strict-liability rules for other products was that producers were the Coasean least-cost avoiders—that is, they faced a lower cost of decision making because of asymmetric information and high levels of technical knowledge required in the production of modern consumer products. This argument suggests that producers were better able than consumers to estimate the risk involved in the consumption of a good and therefore better able to take precautions against such risks. In addition, imposing strict liability on producers also spread the cost of the liability over the greatest number of people by raising the price of the product by the cost of liability insurance.

Marc Franklin (1972) distinguishes between three different rationales for strict tort liability in cases of post-transfusion hepatitis. First, the safety-incentives rationale “asserts that the person marketing the product should be forced to take into account the accident costs associated with that product . . . because of the defendant’s knowledge of, and access to, the intricacies of alternate product designs and production techniques” (462). In the case of markets for blood, blood banks in particular had knowledge about their donor population and could have improved the quality of the donor pool by adopting better screening techniques, by moving to an alternative location that attracted a different donor profile or both. Similarly, hospitals and physicians had more information about the quality of blood coming from different blood banks than did the recipient of a transfusion and were better able to judge safety.10

Second, the resource-allocation justification holds that prices should reflect the true cost of a product. “If social costs are not reflected in prices, then there will be excessive demand for underpriced products and the overall allocation of resources throughout society will be distorted” (Franklin 1972, 463). Franklin calls the third justification for a strict-liability regime “loss spreading.” According to this rationale, it is desirable to spread the cost of post-transfusion hepatitis incidents across a large number of people “in order to minimize its impact on each individual” (463). Such spreading of losses would best be achieved by producers of blood—that is, blood banks and

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9. The argument for the imposition of a strict-liability rule even in the absence of a screening test for the hepatitis virus was that the monetary incentive of being responsible for any damages caused by post-transfusion hepatitis would have resulted in the quicker development of a screening test or other methods of reducing the incidence of hepatitis in donor blood.

10. Hospitals often functioned as blood banks, which meant not only that they had a great deal of knowledge about the donor population but also that strict liability would have presented an incentive for them to expend additional resources on research to develop a hepatitis vaccine or a more reliable hepatitis test.
hospitals—through liability insurance that could be transferred to customers in the form of higher prices.11

Despite the fact that legal researchers on the topic concurred that strict liability would have been the more-efficient solution, and despite the fact that the Perlmutter decision went contrary to legal developments regarding product liability at the time, the decision became precedent in cases of post-transfusion hepatitis after 1954. As a result, producers, whether they were hospitals or blood banks, were now protected from any legal responsibility for damages in case of post-transfusion hepatitis.

The story of markets for blood throughout the 1950s very much mirrors the example of subverted courts that Shleifer and Glaeser (2003) give in their article. Court decisions favored producer interests at the expense of overall social efficiency. In the absence of efforts by the medical industry to influence justices to decide in their favor, the legal regime may have evolved in the direction of strict producer liability, as it did with all other products. Such a development would have provided the greatest incentive for the elimination of hepatitis transmission. Because of their relative power position vis-à-vis patients, however, hospitals were able to influence legal institutions in their favor and to help set an economically inefficient precedent, leaving themselves and blood banks free from any legal liability in cases of post-transfusion hepatitis.

In this case, regulatory intervention to ensure the exclusion of certain groups of the population from becoming blood donors through ex ante donor screening may have indeed been a bright line rule, like those envisioned by Glaeser and Shleifer (2003), that would have lowered hepatitis-transmission rates, given this inefficient common-law regime. Similarly, guidelines for transfusion use by hospitals would have staved off some of the most egregious misuses of the technology and thus would have surely reduced the incidence of post-transfusion hepatitis cases.

Changing Legal Institutions

In 1965, legal institutions surrounding blood markets took a turn toward greater efficiency, despite the continued lack of regulatory intervention through the federal government. Doctrinal changes finally led to a reversal of the existing precedent of due care in cases of post-transfusion hepatitis, which had effectively shielded hospitals and blood banks from any legal liability.12 Following these changes, the Illinois Supreme Court accepted strict liability as the appropriate rule in the case Cunningham v. MacNeal

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11. Reuben Kessel (1974) similarly concludes that strict liability was the appropriate rule because hospitals and physicians were the Coasean least-cost avoiders and better equipped than individual patients to overcome informational asymmetries between blood donors and recipients.

12. The restatement of section 402A of torts by the American Law Institute (ALI) provided for a more widespread application of strict liability for products. The ALI, which was founded by a group of judges, lawyers, and teachers in 1923, publishes “scholarly work to clarify, modernize, and otherwise improve the law.” The ALI’s restatement of torts recommended that “[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property” (1977, 402A).
Memorial Hospital (47 Ill. 2d 443 (1970)). After this decision, blood banks and hospitals were much more likely to be held legally liable in cases of post-transfusion hepatitis and therefore monetarily responsible for the damages of hepatitis infections following transfusions. Table 1 gives a list of court cases based on hepatitis transmission after 1965 by type of liability standard applied.

As a result of the wider application of strict liability, incentives facing the medical community changed dramatically for the better. In an article published in the Journal of the American Medical Association, Dr. Takashi Okuno reported that despite previous educational efforts, the trends of blood usage in his hospital did not change until after the Cunningham court decision in 1969. “The Cunningham case and the repercussions that followed the case have had, directly or indirectly, a greater impact on the minds of physicians, and have played a decisive role in the changes of trends of blood usage. The impact by the case has been far greater than that by various educational activities hitherto taken in our hospital” (1972, 1015).

This development of jurisprudence regarding exchange of blood for payment is a counterexample to the thesis advanced in Glaeser and Shleifer 2003 as well as in Shleifer 2010, which suggests that once courts have been subverted, the most efficient institutional response is to regulate in order to achieve efficient social control of businesses. At least in the long run, legal institutions in the market for blood seem to have been resilient to subversion by the medical community. Legislators, who became the new target of the medical lobby, were not so resilient, however. Despite the courts’ move in the direction of a strict-liability rule after the restatement of torts, and despite the greater economic efficiency of such a regime, widely acknowledged among legal

<table>
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<tr>
<th>Case</th>
<th>Deciding Court</th>
<th>Year</th>
<th>Liability Standard</th>
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<tr>
<td>Russel v. Community Blood Bank, Inc.</td>
<td>Florida Appeals</td>
<td>1967</td>
<td>Strict</td>
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<td>Hoder v. Sayet</td>
<td>Florida Appeals</td>
<td>1967</td>
<td>Strict</td>
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<td>Lovett v. Emory University, Inc.</td>
<td>Court of Appeals of Georgia</td>
<td>1967</td>
<td>Negligence</td>
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<tr>
<td>White v. Sarasota Co. Public Hospital</td>
<td>District Court of Appeal of Florida, 2d</td>
<td>1968</td>
<td>Negligence</td>
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<tr>
<td>Carter v. Inter-Faith Hospital</td>
<td>New York Supreme Court</td>
<td>1969</td>
<td>Strict</td>
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<td>Jackson v. Muhlenberg Hospital</td>
<td>New Jersey Appeals 2d</td>
<td>1969</td>
<td>Strict</td>
</tr>
<tr>
<td>Cunningham v. MacNeal Memorial Hospital</td>
<td>Illinois Supreme Court</td>
<td>1970</td>
<td>Strict</td>
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<tr>
<td>Hoffman v. Misericordia Hospital</td>
<td>Pennsylvania Appeals</td>
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Source: Cases compiled from Franklin 1972, p. 212.
scholars, legislatures at the state level quickly started intervening in markets for blood to change the strict-liability regime. In what follows, we explain how regulation reversed a favorable development in the courts and show that this regulation, rather than improving social control of business, provided significant benefits for one particular blood-recruitment agency at the expense of overall efficiency in the market for blood.

**The Rise of Regulation in Markets for Blood**

When hospitals that used blood transfusions as an input in the production of their services realized that legal precedent regarding post-transfusion hepatitis had turned against them, they united to take their battle to state governments to seek intervention through regulation to avoid what they perceived as an unfairly imposed cost.13 The regulations they sought, however, were not rules that might have improved the pool of blood donors and reduced hepatitis-transmission rates. Hospitals instead advocated for a return to protection from legal liability in cases of post-transfusion hepatitis. In their campaign for regulation of liability, they found a powerful ally in the American Red Cross. The Red Cross was motivated in its pursuit of regulation by a desire to obtain a monopoly position in the blood-recruitment industry and more specifically to become the “total blood supplier to the nation” (Starr 1998, 252), a goal the organization had been pursuing since the 1950s at the expense of both its customers as well as overall efficiency in the market for blood.

**The Red Cross Sees an Opportunity**

During World War II, the Red Cross’s blood-collection program had made the organization a national entity, but with declining patriotism after the war the number of blood donations shriveled, and continued operation of blood-collection centers across the country became financially difficult for the organization, which had primarily served war demand. In order to sustain its operation, the Red Cross turned its attention to recruitment of blood to meet domestic rather than just war demand for blood. While the Red Cross had been focused on blood recruitment for the war, physicians across the country had organized their own blood banks to meet domestic blood demand. Representatives of these independent blood banks gathered in Dallas in 1947 to form a national organization of independent blood banks, the American Association of Blood Banks (AABB). These two groups, the American Red Cross and the AABB, used different recruitment and distribution systems, but their differences were not just in how they operated. Douglass Starr reports that the “Red Cross believed in centralized control over the local blood banks; the AABB promoted local autonomy, with advice

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13. Franklin suggests that physicians, hospital associations, and blood bank groups began their lobbying efforts soon after the *Perlmutter* decision in 1954 because “the vote was close, the result was severely criticized, and it was by no means obvious that it [the decision] would be followed” (1972, 475).
and assistance from a national professional organization” (1998, 174–75). In addition, AABB-affiliated blood banks often used monetary incentives to recruit donors, especially during shortages (Starr 1998, 257), and the AABB charged patients who did not arrange to replace the blood that they used a nonreplacement fee (Starr 1998, 273).

The decision in Cunningham v. MacNeal Memorial Hospital confronted all blood recruiters and hospitals with the consequences of their negligent activities, but rather than adopting more-stringent blood-recruitment standards, a coalition of hospitals and the Red Cross lobbied state legislatures for a statutory limitation of liability for providers who used volunteer blood. A number of legislatures quickly instituted so-called blood-shield laws, which usually stipulated a negligence rule for post-transfusion hepatitis cases, as well as blood-labeling laws that required blood recruiters to label their blood as either volunteer or commercial. State health departments were tasked with the enforcement of the labeling regulation as well as with the development of definitions for what constituted payment and the enforcement of such standards. Together, these statutory requirements limited liability in cases of post-transfusion hepatitis to no liability as long as medical providers had used exclusively volunteer blood. Transfusions using commercial blood, in contrast, were presumed to be negligent, and providers transfusing commercial blood were therefore held liable. This new regime benefited the Red Cross, which drew its supply solely from volunteer donors. It also benefited hospitals, which were again able to operate without consideration of blood quality or the potential legal repercussions of their actions. It harmed the AABB network and clearinghouse system, however, which relied on commercial donations in times of shortages and used replacement fees in order to incentivize donations. Efforts by hospital associations and the Red Cross at the state level to lobby for blood-labeling laws were justified as serving the purpose of reducing hepatitis-transmission rates by eliminating commercial blood, but they were little more than thinly veiled attempts to return to a legal regime that favored hospitals while at the same time benefiting the Red Cross by strengthening its position relative to that of AABB-affiliated blood banks.

Regulation in the States

The State of Illinois was the primary battleground in the Cunningham case and therefore also became a center for the Red Cross’s efforts to create regulatory institutions that benefited its interests. It therefore serves as a case in point. Following their defeat in Cunningham v. MacNeal Memorial Hospital, the Illinois Medical Society, the Illinois Hospital Association, and the Mid-America Chapter of the American National Red Cross lobbied the Illinois state government to overturn the court ruling

14. Coye Mason (1973) discusses the difficulty of drawing a clear distinction between commercial blood and volunteer blood. Among the concerns he raises are whether time off work, inconvenience fees, free blood tests, and finders’ fees constitute payment and should result in a “commercial” label.

15. Clark Havighurst reports that forty-seven states adopted such blood-shield laws (2009, n. 20).
and advocated for a negligence rule that would hold producers of blood liable only if they had used commercial blood. Dr. James Hartney, an Illinois Medical Society trustee, a former hospital laboratory director, and a victim of post-transfusion hepatitis, led the effort and presented a draft bill establishing a negligence rule in a press conference on January 3, 1971. Supported by editorial endorsements of the draft bill on January 5 and March 12 in the *Chicago Tribune*, the bill was picked up and sponsored by state senator Robert Juckett (R), approved by the House of Representatives Judiciary Committee in early March, and passed by a 157–2 vote by the Illinois House on March 18, 1971, just five months after the court decision that had found a regional hospital strictly liable in a case of post-transfusion hepatitis.

Similar events unfolded in other states around the country. Before 1965, only three states had reached a determination of legal status on the subject. By 1972, forty-one states regulated liability for post-transfusion hepatitis, so that it was limited to negligence. In effect, there was no liability in cases of post-transfusion hepatitis as long as volunteer blood was used. Most of the statutes were implemented after the *Cunningham* decision in 1970, which had found the defending hospital strictly liable. In 1972, liability for hepatitis transmission was regulated under the common law in only nine states (Franklin 1972, 474).

The statutory regimes adopted in different states varied slightly, but at the core of most blood-shield laws was an exemption from legal liability for volunteer blood, whether contaminated or not, even when volunteer blood banks used questionable recruiting practices or when doctors used excessive amounts of blood in order to achieve post-operative cosmetic effects. The use of commercial blood, however, was always considered negligent, even if the commercial blood bank in question had implemented strict donor-selection criteria and had reduced the incidence of contaminated blood in their pool, as was the case with at least some commercial blood banks. This newly adopted liability regime set up a dichotomy between volunteer and commercial blood rather than between contaminated and uncontaminated blood. In doing so, it effectively removed the incentive for any blood bank (whether commercial or volunteer) to search for more effective means of screening blood donors or their blood. Volunteer banks were free from liability whether they employed reasonable recruiting practices or screened their donors; commercial blood banks and doctors that used their blood were strictly liable for all transfusion-related accidents and side effects. As a result, victims of post-transfusion hepatitis now had no hope of receiving any kind of compensation for their losses, volunteer blood banks had no

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16. Dr. Hartney’s case is interesting, and further exploration of his motivation might provide insight into the prevalent understanding of the hepatitis–transfusion problem at the time. Unfortunately, we are left to speculation as the only means of further investigation given that we are relying on a very small sample of newspaper articles and editorial comments by or about Dr. Hartney. It seems as though his primary concern was the incentives facing surgeons and hospitals under a strict-liability regime, which he characterized as leading to an excessive and potentially life-costing reduction in the number of surgeries performed.

17. Starr explains that the Mayo Clinic blood bank was able to develop a pool of healthy commercial blood donors by using significant amounts of information regarding the medical history of each commercial donor and by incentivizing staff to maintain relationships with existing commercial donors (1998, 257).
incentive to screen donors based on easily observable characteristics, and doctors had no incentive to be discerning in their use of blood transfusions.\textsuperscript{18} Some states didn’t stop at blood-labeling laws but went so far as to outlaw commercial blood completely.\textsuperscript{19} In Illinois, the lobbying for regulation of the liability regime governing blood transfusions had led to the creation of the Metropolitan Chicago Blood Council (MCBC), which was established by the Chicago Medical Society, the Chicago Hospital Council, and the Mid-America Chapter of the American Red Cross. Their common enemies were paid donor blood banks either because these paid donor blood banks were direct competition in the market for whole blood (in the case of the Red Cross) or because their product exposed them to liability concerns (in the case of hospitals and the medical society).

Beyond the elimination of commercial blood banks, the MCBC’s self-proclaimed aim was to coordinate the collection and distribution of all blood recruited by the city’s blood banks and thereby to secure for itself a monopoly position. Furthermore, its intention was to increase the supply of volunteer blood and to “reduce the cost of transfusion by eliminating the need for so-called professional donors.”\textsuperscript{20} In September 1971, the council received $10,000 from Illinois governor Richard B. Ogilvie, which were drawn from public-health funds, to start a recruiting program for voluntary blood donations, and it was greatly aided in its efforts by a \textit{Chicago Tribune} series titled “Task Force Report” on the high incidence of hepatitis transmission through commercial blood. A public-awareness campaign, the Blood Brothers’ Initiative, begun by the MCBC and intended to increase volunteer donations of whole blood, was launched just five days after the last article in the Task Force series was published on September 16. The \textit{Chicago Tribune} supported the MCBC’s effort further by publishing a pledge card on September 22, which readers of the newspaper were encouraged to mail to the council. Stirred on by the MCBC’s efforts to collect more volunteer blood, on August 18, 1972, Governor Ogilvie signed into law a bill that outlawed commercial blood completely for the State of Illinois.

\textbf{Flawed Arguments Based on Flawed Evidence}

In the absence of an effective test for the presence of the hepatitis virus in a pint of donated blood, regulation based on a distinction between commercial and volunteer blood seemed to make some sense, especially given existing academic arguments on the topic at the time. The two most well-known sources on the differential quality of commercial and volunteer

18. Mason reports an additional side effect of the law: “A considerable pool of biologically-tested donors who previously were compensated for their services are no longer available to us” (1973, 18). Mason here refers to repeat commercial donors who had a track record of donating blood that was uncontaminated.

19. This fact also explains why commercial blood banks were not part of the coalition of medical producers lobbying for intervention, and it became a crucial element in the eventual destruction of commercial markets for whole blood, which we discuss in more detail in the next section.

20. Dr. James B. Hartney, chairman of the Chicago Medical Society’s committee on blood banks, quoted in Kotulak 1971.
blood in the late 1960s were a short academic article by J. Garrott Allen and a book-length treatment of the problem by Richard Titmuss. In 1966, J. Garrott Allen of Stanford University Hospital published his article linking the commercial blood market with hepatitis-transmission rates that were ten times higher than comparable rates from voluntary recruitment. In the article, Allen advocated the elimination of markets in blood for the betterment of patient health. He had collected his evidence using ex post reports of transfusion-related hepatitis cases that occurred in the University of Chicago clinics, which were served by their own blood bank run by Allen himself. He had noted that the number of hepatitis cases increased dramatically when the donors in his donor pool were “of the prison–Skid Row variety” (Allen 1966, 297). Allen’s study had one major shortcoming, however. Rather than indicting blood purchased from prisons, it conflated prison blood with all commercial blood (Starr 1998, 220). This conflation is particularly problematic because to this day the prevalence of chronic viral infections among inmates far exceeds the prevalence in the general population. Shaili Gupta and Frederick Altice (2009) report, for example, that the incidence of Hepatitis C infections among inmates is ten times that of the rate of incidence in the general population. This more recent evidence suggests that the results reported in Allen’s study were highly questionable.

Richard Titmuss, the British advocate of socialized medicine, similarly made the case that paying donors for their blood compromised the safety of the blood supply because monetary incentives would attract higher-risk donors. Titmuss provided evidence in his book The Gift Relationship: From Human Blood to Social Policy ([1971] 1997) that the rate of hepatitis infections in the United States was higher than the rate in the United Kingdom, and he argued that this higher rate of hepatitis transmission was due to the fact that U.S. hospitals obtained a large share of their supply of blood from paid donor banks rather than from a voluntary donation system like the one that existed in the United Kingdom. In addition, Titmuss argued that the existence of commercial blood markets reduced the amount of blood donated by volunteers, who would be less willing to donate if paid. Robert Slonim, Carmen Wang, and Ellen Garbarino (2014) suggest that to this day none of Titmuss’s empirical assertions have been confirmed with empirically robust strategies.

Newspaper reports at the time, however, supported Titmuss and Allen’s arguments that one out of every twenty patients who received commercial blood would contract serum hepatitis, whereas only one in two hundred recipients of volunteer blood were infected (“Transfusion Blood” 1971).21 Because volunteer donations were scarce,

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21. The public debate on the issue of hepatitis transmission that occurred as a result of the evidence provided by Titmuss and Allen may provide an alternative explanation for the increase in regulation of blood markets. Robert Higgs (1987) famously argues that increases in the scope of government can be explained as a “ratchet effect” in which the perception of a crisis yields a dramatic increase in government activity. The hepatitis epidemic was certainly treated as a crisis, and the commercial market for blood was considered by both academic authors as well as the media as the primary culprit in perpetuating the crisis. In fact, the treatment of post-transfusion hepatitis as a crisis and the fact that it was discussed as an epidemic may have provided necessary public-interest cover (Yandle 1983) for the campaign for regulation, which was otherwise a special-interest campaign.
however, the majority of all whole blood used in transfusions came from commercial sources. In cities such as Chicago, for example, 69 percent of all blood needed was drawn from commercial sources, mostly prisons. Titmuss argued that the increased rate of hepatitis transmission through commercial blood was a market failure caused by the intrinsic perversity of market solutions to health care. For the British market critic, this failure was evidence of a larger set of market failures in health care.

Despite the questionable quality of the empirical and theoretical evidence on the relative incidence of the hepatitis virus in commercial blood as compared to in volunteer blood, these academic arguments provided perfect ammunition for the Red Cross in its efforts to become the “total blood supplier to the nation.” Paralleling the developments in the states, the FDA finally intervened at the federal level in 1978, ruling that blood products had to be labeled as “paid,” “volunteer,” or “autologous”—that is, donated by the individual who would also become the recipient of the blood donation. Federal regulation was a mirror image of the regulation that already existed in many states and combined labeling laws with a negligence standard, where the use of “paid” blood was the sole measure of whether a provider had been negligent or not in its use of blood transfusions. As a result, paid whole blood disappeared almost immediately, yet paid plasma continued to coexist with volunteer donations (Starr 1998, chap. 14).

This part of the history of the legal regime governing markets for blood is impossible to reconcile with Glaeser and Shleifer’s (2003) theory of the rise of the regulatory state. Torts had moved in the direction of a strict-liability standard, which increased economic efficiency in markets for blood and provided clear incentives for producers to develop a screening test for the hepatitis virus or better screening techniques for donors. Regulation reversed this favorable legal development and severely lowered the incentives for careful selection and use of blood. Rather than improving the fate of recipients of blood transfusions and increasing social efficiency by providing rules for donor selection, the only existing screening technique that would have improved the donor pool, regulation instead returned the blood industry to an inefficient legal standard. In addition, the adopted statutes also benefited one blood-recruiting agency, the American Red Cross, at the expense of its major competitor, the AABB.

This example supports the insights of the economic theory of regulation, which suggest that regulation is rarely an effective means of social control of business and rather a means of subverting otherwise effective legal institutions. In an entrepreneurial effort to secure its position as primary blood supplier to the nation, the American Red

22. Starr reports that Garrott Allen, in his capacity as director of the blood bank serving the University of Chicago clinics, was buying 69 percent of his product from area prisons (1998, 226).

23. A strict-liability regime would have ensured that blood banks and hospitals were liable for any cost associated with post-transfusion hepatitis. The reduction of such cost through innovation and development of an effective hepatitis screening test would have improved the profitability of these medical providers. Israel Kirzner suggests that “profit thus works . . . to attract notice to the most desirable (but possibly not yet perceived) of the existing opportunities” (1985, 100).
Cross, together with hospitals and volunteer blood banks, lobbied state governments to adopt an institutional environment that benefited its organizational goals rather than creating an efficient and safe market for blood.

**Blood Recruitment Today**

A market for blood does not exist in the United States today. Medical providers instead rely solely on blood from volunteer donors to meet their patients’ needs for blood. This has been the case since the FDA intervened at the national level in 1978 and imposed an unfavorable legal standing for anyone using blood recruited from paid donors. In addition to the original *Federal Register* notice dated January 13, 1978 (43 FR 2142), which stipulated a donor-classification system, the regulatory structure included stipulations regarding what did and did not constitute monetary compensation for donations, similar to the regulations that existed at the state level. Today, the Center for Biologics Evaluation and Research, which is a branch of the FDA, regulates the collection of blood and blood components for all medical and pharmaceutical uses and establishes standards for the various products.

With the exception of plasma products, all blood products have been sourced solely from volunteer blood donations since the FDA intervened, which has created a situation of perpetual misallocation problems for blood that persists to this day. Three specific types of misallocation problems occur with respect to blood in the absence of market prices. First, as Slonim, Wang, and Garbarino point out, although volunteer supply is usually able to meet demand, shortages are nevertheless frequent and recur seasonally in winter and around the holidays (2014, 177). No direct statistical information on such shortages is available, but Marian Sullivan and her colleagues provide survey data for 2001 describing the production and consumption of blood in the United States. They report that 138 of 1,086 hospitals surveyed (12.7 percent) reported cancellation of elective surgeries due to blood shortages on one or more days during 2001, with a median two days of cancellations. The total number of patients affected by such cancellations was 952 (2007, 388). Richard Toner and his colleagues (2011), also using survey evidence, report that 58 percent of respondents said they would postpone transfusions and 46 percent said they would postpone surgeries in the event of shortages. Only 14 percent of hospitals reported having canceled transfusions and 13 percent reported having canceled surgeries. In addition, Slonim, Wang, and

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24. In February 2014, blood shortages again became national news (Yorke 2014). The shortage that year was attributed to the winter cold, but shortages are an issue even in the summer months, as a push to accept donations by homosexual males in the summer of 2013 indicates (Stern 2013).

25. Slonim, Wang, and Garbarino (2014) also report empirical evidence on supply quantity and quality across different countries to compare volunteer and commercial systems. They find that even after controlling for income, countries with volunteer donations supply slightly more blood. They do not find a relationship between the percentage of blood collected from volunteer donations and transfusion-transmissible infections; that is, they do not find that volunteer blood is safer than commercial blood.
Garbarino suggest that there is ample evidence, at least when it comes to blood plasma, that volunteer systems underperform compared to commercial systems. Citing Philip Flood and his colleagues (2006), they report that in 2006 the U.S. health-care system, which compensates plasma donors monetarily, used more than twice the amount of immunoglobulin (the dominant plasma product) per person used in Italy, the United Kingdom, Germany, the Netherlands, and Japan, who do not compensate plasma donors (2014, 185), which suggests that systems that do not compensate donors may be limiting potential usage of blood products.

Second, surplus problems and, more specifically, a mismatch of blood type supplied versus blood type demanded are a constant problem in the absence of price signals. Sullivan and her colleagues report that 7.8 percent of the available blood supply in 2001 was not transfused largely because it could not be allocated before the blood was outdated (2007, 388). These authors also report by blood type the percentage of released units of blood (i.e., blood that passes requisite screenings) that were actually transfused in 2001 (again based on survey evidence). Figure 1 uses the information from Sullivan et al. 2007 to show the percentage of released units of whole blood that were not used. The highest transfusion usage was type O+, at 91.4 percent, and the lowest transfusion usage was type AB−, at 64.4 percent. This evidence suggests persistent and systematic misallocation of blood. Surpluses also frequently occur in times of national disaster, when donations spike despite a lack of demand. Starr offers a particularly devastating perspective on this problem of donation spikes: he documents that between one hundred thousand to three hundred thousand units of whole blood were discarded after increased blood donations in the wake of the terrorist attacks on September 11, 2001, at an estimated minimum cost of $18–54 million (Starr 2002).

Third, Slonim, Wang, and Garbarino argue that there are unseen dynamic problems due to the lower profitability of productive entrepreneurship for blood and blood-related products. More specifically, these authors argue that although the supply of blood usually meets current demand, the health industry is not pursuing research and development in blood technology and medical applications that might lead to greater demand for blood because entrepreneurs know the current volunteer system would not be able to supply greater amounts of whole blood (2014, 185). Because markets for blood were regulated out of existence, further investment into productive innovation in blood technology is extremely risky and therefore less likely to occur.

Conclusion

The example of the market for blood suggests that Glaeser and Shleifer’s (2003) theory of the rise of the regulatory state is at best an incomplete story of how regulatory institutions have come to dominate the institutional landscape. Regulation in the case of blood markets did

26. Whole blood and blood components other than plasma can be stored for only forty-two days.
not take the form of the efficient rules Glaeser and Shleifer imagine, and none of the advocates of regulatory intervention seem to have had improved outcomes for patients in mind. Rather, the regulatory structure advanced by the Red Cross and the medical community was a reversal of the legal precedent that held blood producers liable for damages they negligently inflicted on their patients on a frequent basis. This push for intervention was only thinly veiled behind an argument against monetary incentives in medicine, which has since been shown to be empirically ambiguous but remains one of the main defenses of current blood policy practices by the likes of the World Health Organization and the Red Cross.

We have argued here that the example of markets for blood suggests that rather than offering improved institutional constraints for businesses, regulation is usually used as a means of undermining the existing means of social control of business, in line with the kind of institutional political entrepreneurship described in Martin and Thomas 2013. Regulation, from the perspective we have advanced in this article, is the primary tool of the lobbyists representing business interests and is employed to subvert more favorable (from the perspective of economic efficiency and consumer interest) legal regimes when those regimes are opposed to producer interests.

References


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