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NOTE

Default Difficulties: The Case for Regulatory Intervention in Merchants' Reliance on Default Rules That Harm Consumers

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Abstract. This Note investigates how incomplete contracting between merchant parties may harm third-party consumers. After defining this phenomenon and noting several examples, this Note considers solutions to the social inefficiencies arising from these merchant-to-merchant contracts. To do so, this Note engages in a detailed case study of generic drug shortages and how incomplete failure-to-supply provisions affect patients' ability to access essential drugs. Such shortages typify the incomplete contracts at issue in this Note. Ultimately, this Note proposes a regulatory solution to firms' reliance on default rules that would reduce the incidence of extreme negative externalities on third parties.

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Introduction

"Our patients are in a war, and what we're doing is we're taking their weapons away," said one oncologist in 2023 about the effect of chemotherapy drug shortages on his patients.[1] Although drug shortages are a complicated phenomenon, new evidence suggests that merchant parties' incomplete contracting may be part of the problem. Specifically, merchants are content to rely on a default rule of impracticability that excuses drug manufacturers' failure to supply the market.[2] Meanwhile, patients bear the grave effects of resulting drug shortages, up to and including "increased morbidity and mortality."[3] More generally, this type of incomplete contracting between merchant parties can harm downstream third-party consumers in a variety of settings where public and private incentives may be misaligned.[4] Therefore, this Note studies the circumstances in which merchants' reliance on default rules can be socially suboptimal and weighs potential solutions to help mitigate consumer harm.

In doing so, this Note builds on the scholarly literature that investigates incompleteness and potential inefficiencies in merchant-to-merchant

1. *Quotation of the Day: Drug Shortages Spur Rationing to Critically Ill*, N.Y. TIMES (May 17, 2023), https://perma.cc/V27B-NY36.

2. *See* FRANK H. EASTERBROOK & DANIEL R. FISCHEL, THE ECONOMIC STRUCTURE OF CORPORATE LAW 27-28 (1991). This constitutes a "divergence between private and social optimality." *Id.* (explaining that there are strategies that do not "violate any rule of contracting" and are "beneficial to parties to the contract" that nonetheless may injure third parties, such as other firms, and that this type of externality generates the aforementioned divergence).

3. OFF. OF ASSISTANT SEC'Y FOR PLAN. & EVALUATION, IMPACT OF DRUG SHORTAGES ON PATIENTS IN THE UNITED STATES: A CASE STUDY OF THREE DRUGS 6 (2024), https://perma.cc/UV93-FAB9 (outlining how "[d]rug shortages are a persistent problem that can cause substantial disruption in patient treatment regimens and adversely impact a patient's health . . . . including high costs, delayed care, and potential medication errors or unintended side effects when using alternative or unfamiliar drugs," and that "[d]rug shortages within the injectable oncology space are particularly concerning as patients with cancer are vulnerable to increased morbidity and mortality when treatment is interrupted or delayed, and there are often few substitutes for these drugs"); *see also* Celeste R. Caulder, Brenna Mehta, P. Brandon Bookstaver, LaVetra D. Sims & Bill Stevenson, *Impact of Drug Shortages on Health System Pharmacies in the Southeastern United States*, 50 HOSP. PHARMACY 279, 280 (2015) (explaining that "[d]rug shortages often impact vulnerable populations including cancer patients or neonates, for whom few, if any, equivalent alternatives exist").

4. For example, some long-term waste disposal contracts between merchants fail to "adequately specify waste data reporting obligations." Heinrich Oosthuizen, Roger Willett, Trevor Wilmshurst & Belinda Williams, *The Constraining Effect of Incomplete Contracts on the Public Reporting of Waste Management Data*, 26 AUSTRALASIAN J. ENV'T MGMT. 370, 382 (2019). Such issues can make it difficult for governments to identify "illegal storage, dumping, transboundary shipment and trafficking of hazardous waste" that may harm, inter alia, property owners' asset valuations. *Id.* at 380.

contracts. Incompleteness and resulting inefficiencies may arise out of the economic rationality of firms. For example, "[c]ontracts may be incomplete because the transaction costs of explicitly contracting for a given contingency are greater than the benefits."[5] In reality, "all contracts are incomplete,"[6] and more recent scholarly work considers how incomplete contracts may arise for economically "irrational" reasons. Omri Ben-Shahar and John Pottow consider how and why "parties might choose not to opt out of a legal default even when a better provision can easily be identified and articulated at a negligible drafting cost."[7] Julian Nyarko also highlights the role of template contracts in "transactions between sophisticated commercial actors" that may fail to optimize the parties' joint surplus.[8] Taking these works as a jumping-off point, this Note argues that harm may come to third parties regardless of the specific explanation behind commercial parties' incomplete contracting.

This Note similarly draws on and extends the already expansive literature on default rules. Popular topics in this area range from the optimal design of default rules[9] to the scenarios in which parties should prefer to rely on them.[10] Debates have also raged, for example, around the optimality of tools like "penalty default rules," which "'force[] the revelation of information which the revealing party might generally wish not to reveal."[11] This Note builds on the

5. Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 92 (1989).

6. Robert Anderson IV, *Path Dependence, Information, and Contracting in Business Law and Economics*, 2020 WIS. L. REV. 553, 553 (2019).

7. Omri Ben-Shahar & John A.E. Pottow, *On the Stickiness of Default Rules*, 33 FLA. ST. U. L. REV. 651, 651-52 (2006) (arguing that such incompleteness arises not only due to "drafting costs" but also because, for example, "a transactor might fear that proposing an opt-out from the default will dissuade his potential counterparty from entering into the agreement" because it is possible that "the counterparty will suspect that the proposer's decision to deviate from the norm and use an unfamiliar provision . . . is a 'trick'").

8. Julian Nyarko, *Stickiness and Incomplete Contracts*, 88 U. CHI. L. REV. 1, 4, 6-7 (2021) (finding that "contractual gaps . . . are no exception in even the highest-value transactions between the most sophisticated actors" because "external counsel relies heavily on templates").

9. *See, e.g.*, Ayres & Gertner, *supra* note 5, at 91; EASTERBROOK & FISCHEL, *supra* note 2, at 34 (arguing that "the deals people actually strike when they bargain over the subject" provide "a ready source of guidance . . . to draw on in filling in blanks").

10. *E.g.*, Clayton P. Gillette, *Commercial Relationships and the Selection of Default Rules for Remote Risks*, 19 J. LEGAL STUD. 535, 540-41 (1990); Robert E. Scott, *A Relational Theory of Default Rules for Commercial Contracts*, 19 J. LEGAL STUD. 597, 600 (1990).

11. *Compare* Jason Scott Johnston, *Strategic Bargaining and the Economic Theory of Contract Default Rules*, 100 YALE L.J. 615, 616 (1990) (arguing that the theory behind penalty default rules "fails to account for strategic incentives in bargaining"), *with* Ayres & Gertner, *supra* note 5, at 127-28 (noting that "[w]hen parties fail to contract because

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existing literature to consider the optimality of default rules from the perspective of not only the parties but also nonparties who are affected by the parties' choice to rely on a given default. It then considers whether and, if so, how policymakers should respond to reliance on default rules that generates negative externalities on nonparties. Although traditional theories of fairness around default rules generally focus on the interests of the contracting parties,[12] a broader definition of fairness may warrant consideration of how such rules benefit or harm society overall.

This Note also contributes to a smaller body of work on protecting third parties in contracts. For example, Kishanthi Parella considers a corporation's duty to protect against supply chain human-rights abuses.[13] Similarly, David Hoffman and Cathy Hwang discuss the public cost of contracts during the COVID-19 pandemic and when contracting parties or the courts should "not enforce contracts as written in an effort to protect public health."[14] This Note differs from the existing work in this literature by (1) considering cases in which commercial actors' *failure to write complete contracts*[15] leads to consumer harm; and (2) proposing a solution to such harm that is regulatory rather than contractual.[16]

This Note proceeds in five parts. Part I outlines why one may not expect merchant-to-merchant contracting to be socially efficient—both under

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they want to shift the ex ante transaction cost to a subsidized ex post court determination, a penalty default of nonenforcement may be appropriate").

12. *E.g.*, EASTERBROOK & FISCHEL, *supra* note 2, at 15 (arguing that "corporate law should contain the terms people would have negotiated, were the costs of negotiating at arm's length for every contingency sufficiently low"); *see also* Steven J. Burton, *Default Principles, Legitimacy, and the Authority of a Contract*, 3 S. CAL. INTERDISC. L.J. 115, 118 (1993) (discussing, inter alia, the "fairness" of expansive or precise default rules and the extent to which "[v]oluntary participants in a cooperative scheme, from which they derive benefits, each are obligated in fairness to do their part to maintain the cooperative venture"); Clayton P. Gillette, *Cooperation and Convention in Contractual Defaults*, 3 S. CAL. INTERDISC. L.J. 167, 167 (1993) (describing Burton, above, as an "ambitious project involv[ing] a search for a normative grounding of default rules").

13. Kishanthi Parella, *Protecting Third Parties in Contracts*, 58 AM. BUS. L.J. 327, 329 (2021).

14. David A. Hoffman & Cathy Hwang, *The Social Cost of Contract*, 121 COLUM. L. REV. 979, 985 (2021).

15. The contracts of interest to this Note are "incomplete" in both the legal sense (i.e., "in which [their] obligations are not fully specified") and in the economic sense (i.e., in which they "fail to fully realize the potential gains from trade in all states of the world"). *See* Ian Ayres & Robert Gertner, *Strategic Contractual Inefficiency and the Optimal Choice of Legal Rules*, 101 YALE L.J. 729, 730 (1992).

16. Aditi Bagchi also comments on the potential benefits offered by "an interpretative rule that *expressly* considers third party interests" in the case of ambiguity in a contract. Aditi Bagchi, *Other People's Contracts*, 32 YALE J. REGUL. 211, 212 (2015). This Note focuses on the parties' *incomplete* contracting rather than the *ambiguity* of contract provisions.

standard assumptions of firm sophistication and under arguably more realistic assumptions about merchants' propensity to succumb to "behavioral" forces like path dependence. Part II describes how a contract between merchants may have adverse downstream effects on consumers who are not parties to the agreement. Part III makes the case that regulators could step in to protect customers from harmful incomplete merchant contracting. Part IV grounds this theory in the specific example of generic drug shortages and how incomplete failure-to-supply provisions may affect patients' ability to access the drugs necessary for treatments like chemotherapy. Finally, Part V discusses the potential risks of regulatory intervention and flags a few reasons to proceed with caution.

I. The Efficiency of Incomplete Merchant Contracting

In a strict sense, "[c]ontracts are *never* fully complete, because some contractual incompleteness is inevitable."[17] However, this Note is not focused on inevitable incompleteness but rather the ways in which "contracting parties . . . sometimes leave contracts incomplete on purpose," relying instead on "the court . . . to gap-fill any incomplete terms."[18] Some scholars, noting that "[l]egal certainty is a central principle for the rule of law,"[19] regard incomplete contracts as "antithetical to efficient business decisionmaking"[20] and to "the core principles of contract law."[21] Yet the "problem of contractual incompleteness" remains pervasive and well-documented in both case law and the scholarly literature.[22]

The traditional law-and-economics view of incomplete contracting rationalizes parties' choice not to contract around default rules as justified by the parties maximizing their joint surplus.[23] The costs in this analysis would

17. Scott Baker & Kimberly D. Krawiec, *Incomplete Contracts in a Complete Contract World*, 33 FLA. ST. U. L. REV. 725, 725 (2006) (emphasis added).

18. *Id.* at 725-26. The scholarly literature suggests that over time, courts increasingly accepted (and potentially even expanded) their gap-filling role. *See* Subha Narasimhan, *Of Expectations, Incomplete Contracting, and the Bargain Principle*, 74 CAL. L. REV. 1123, 1125-26 (1986) (noting that "[c]urrent trends seek to expand greatly the areas in which 'relief' is available for incomplete contracting").

19. Wendy Netter Epstein, *Facilitating Incomplete Contracts*, 65 CASE W. RSRV. L. REV. 297, 298 (2014).

20. *Id.* at 298 n.1 (quoting Albert Choi & George G. Triantis, *Strategic Vagueness in Contract Design: The Case of Corporate Acquisitions*, 119 YALE L.J. 848, 882 (2010)).

21. *Id.* at 299 (quoting Robert E. Scott, *A Theory of Self-Enforcing Indefinite Agreements*, 103 COLUM. L. REV. 1641, 1643 (2003)).

22. James W. Bowers, *Incomplete Law*, 62 LA. L. REV. 1229, 1234 (2002).

23. Epstein, *supra* note 19, at 301 (arguing that "[i]f the normative goal of contract doctrine is to incentivize commercial activity and efficient dealmaking, the doctrinal approach

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include, among other things, "legal fees, negotiation costs, drafting and printing costs, the costs of researching the effects and probability of a contingency, and the costs to the parties and the courts of verifying whether a contingency occurred."[24] Avoiding these costs for provisions where "either the magnitude or the probability of a contingency is sufficiently low" is therefore efficient.[25] The default rules—i.e., the "gap filling" provisions authorized by Uniform Commercial Code (U.C.C.) section 2-207—recognize and facilitate such efficiency by "ascertaining what the parties' intentions would have been at the time that they entered the contract."[26] The traditional rationale is that firms should not waste time on a provision when the cost to the parties of relying on a given default rule "would be no larger than the cost of contracting around the rule."[27] That is to say that, if the parties have chosen not to contract around a given rule, it is because doing so would have been costlier than the default.

However, there are cases where this theory of party rationality fails to explain observed outcomes. Namely, "many high-value contracts are not merely a reflection of the costs and benefits conferred upon the parties" but rather reflect a "contractual drafting process [that] is 'sticky.'"[28] For example, "the overwhelming majority of implied contract terms are simple and categorical" and not ridden with the types of complexities that scholars would expect to drive up the costs of contracting over such provisions.[29] And recent

deriding incompleteness is out of step with the goal"). Others argue, relatedly but with some distinctions, that "rational commercial actors are motivated by a dominant strategy of cooperative *risk* reduction." Scott, *supra* note 10, at 599 (emphasis added).

24. Ayres & Gertner, *supra* note 5, at 93; *see also* Baker & Krawiec, *supra* note 17, at 725 (attributing the inevitable incompleteness of contracts to "the costs of thinking about, bargaining over, and drafting for future contingencies"); Robert E. Scott & George G. Triantis, *Incomplete Contracts and the Theory of Contract Design*, 56 CASE W. RSRV. L. REV. 187, 190 (2005) (noting that "complete, contingent contracts are impeded by the transaction costs of contracting").

25. *See* Ayres & Gertner, *supra* note 5, at 93.

26. *Gap Filling*, LEGAL INFO. INST. https://perma.cc/6J62-4SE9 (archived Jan. 2, 2025); Ayres & Gertner, *supra* note 5, at 93 (explaining that "[t]he 'would have wanted' approach to gap filling is a natural outgrowth of the transaction cost explanation of contractual incompleteness"); *see also* Marc Newman, *Introduction to the Uniform Commercial Code or "UCC"*, MILLER L., https://perma.cc/XP4L-3YCB (last updated Sept. 21, 2022) (explaining that a "primary purpose of the UCC is to facilitate the predictability and efficiency of business activities"); Steven J. Burton, *Collapsing Illusions: Standards for Setting Efficient Contract and Other Defaults*, 91 IND. L.J. 1063, 1064 (2016) (noting that "[e]fficiency is a sensible goal for defaults").

27. Ian Ayres, *Default Rules for Incomplete Contracts*, *in* THE NEW PALGRAVE DICTIONARY FOR ECONOMICS AND THE LAW 585, 585 (Peter Newman ed., 1998).

28. Nyarko, *supra* note 8, at 24.

29. *See* Scott, *supra* note 10, at 599.

scholarly work demonstrates the extent to which sophisticated parties may fail to maximize their joint surplus in legal agreements. Robert Anderson and Jeffrey Manns, for example, suggest that boilerplate language in contracts evolves through the copying of past provisions with only ad hoc "editorial churning."[30] And Julian Nyarko identifies significant stickiness in contractual *gaps* and describes how firms' and outside counsels' "unwillingness to amend their templates [can] lead to a particularly profound path dependence that [can] lock parties into suboptimal agreements for extended periods of time."[31] Together, these literatures on path dependence and contractual stickiness suggest that even sophisticated commercial actors cannot be assumed to maximize their joint surplus, and that, in addition to suboptimal contractual provisions, the parties may inefficiently rely on default rules that they neglect to contract around.

On top of the potential losses experienced by the parties because of such inefficient contracts, these agreements may impose externalities on third parties through their reliance on default rules. It seems unclear, therefore, that commercial parties can be relied upon to produce efficient contracts for themselves, much less for society broadly, and this reality may justify the type of regulatory intervention discussed in Parts III and IV.F below.

II. Third-Party Impacts of Incomplete Contracts Between Merchants

Incomplete contracts between merchants can have downstream effects that impact the safety, health, privacy, and general well-being of everyday consumers who are not parties to the original agreement. These externalities arise in various settings, including critical industries like pharmaceutical manufacturing.[32] This Note does *not* argue that all externalities in merchant contracts are problematic and worthy of potential regulation.[33] Not all

30. Robert Anderson & Jeffrey Manns, *Boiling Down Boilerplate in M&A Agreements: A Response to Choi, Gulati, & Scott*, 67 DUKE L.J. ONLINE 219, 223 (2019).

31. Nyarko, *supra* note 8, at 24.

32. *See infra* Part IV (discussing the example of generic drug shortages and incomplete failure-to-supply provisions in greater detail).

33. Under similar logic, the Department of Justice and Federal Trade Commission do not sue to block a proposed merger or acquisition merely when there is potential for *any* price increase. Rather, they focus on those that constitute "a small but significant and nontransitory increase in price." Michael L. Katz & Carl Shapiro, *Critical Loss: Let's Tell the Whole Story*, ANTITRUST MAG., Spring 2003, at 49, 55 n.9 (quoting U.S. DEP'T OF JUST. & FTC, HORIZONTAL MERGER GUIDELINES § 1.11 (rev. 1997)).

contracts are Pareto-improving,[34] but they are generally enforceable as long as their externalities are not illegal.

Instead, this Note argues that attorneys, regulators, and scholars may want to specifically pay attention to cases where merchant parties leave a gap to be filled by the U.C.C. that ends up hurting consumers.

Moreover, not all default rules threaten consumer welfare—most do not. For example, if the parties fail to specify the place of delivery, U.C.C. section 2-308(a) helpfully provides that "the place for delivery of goods is the seller's place of business or if he has none his residence."[35] Other provisions like payment terms, delivery date, and even price also have default rules provided by the U.C.C.[36] These unproblematic default rules are not the focus of this Note.

This Note instead focuses on defaults with more troublesome potential. Consider, for example, incomplete provisions in contracts between manufacturers and wholesalers or between wholesalers and retailers prior to a sale to a consumer far downstream—i.e., a "remote purchaser."[37] Despite disagreement in the courts about whether a manufacturer's disclaimer of implied warranties at the point of original sale extends to subsequent purchasers,[38] "there is no reason that the [manufacturer] cannot disclaim its warranty liability by policing its dealers and making sure that its disclaimer reaches the ultimate user of its product during the negotiations for the product's sale."[39] The manufacturer could, for example, negotiate a provision in the purchase agreement with the intermediary that "require[s the intermediate buyer] to notify the retail purchaser of the disclaimer."[40] However, in the absence of such an explicit provision in the contract, an end user in a jurisdiction like Texas may find himself without recourse despite having had no notice of such a disclaimer at the time of purchase, because the

34. Pareto improvements describe "situation[s] where it is possible to make one party better off without negatively affecting another party." *Pareto Improvement*, CORP. FIN. INST., https://perma.cc/P6N8-2279 (archived Jan. 2, 2025).

35. U.C.C. § 2-308(a) (AM. L. INST. & UNIF. L. COMM'N 1977).

36. *Id.* §§ 2-310(a), 2-309(1), 2-305(1).

37. Michael E. McWilliams & Caroline B. Smith, *Will It Travel Downstream? Remote Purchasers and Manufacturers' Disclaimers of Implied Warranties*, BUTLER SNOW (Feb. 22, 2022), https://perma.cc/L6S5-2VD3.

38. *Compare* Telco Supply Co. v. Remee Prod. Corp., No. CIV-13-207, 2014 WL 4826648, at *2 (E.D. Okla. Sept. 29, 2014) (refusing to extend the disclaimer and relying on Tenth Circuit precedent rather than statute), *with* MAN Engines & Components, Inc. v. Shows, 434 S.W.3d 132, 140 (Tex. 2014) (extending disclaimers to downstream purchasers).

39. Peterson v. N. Am. Plant Breeders, 354 N.W.2d 625, 632 (Neb. 1984).

40. McWilliams & Smith, *supra* note 37.

default rule is that "a downstream purchaser cannot obtain a greater warranty than that given to the original purchaser, so if the manufacturer at the point of original sale makes a valid disclaimer of implied warranties, that disclaimer extends to subsequent purchasers."[41] The consumer in this case would therefore be harmed by the lack of an explicit provision in the upstream merchant-to-merchant contract.

Alternatively, consider conditions that would cause a supply agreement to be terminated between merchant parties, such as poor quality assurance on the part of the supplier that renders it unable to meet the contracted quality,[42] damage or delay by the shipment or storage intermediary that renders those goods unable to enter the market,[43] or mechanical problems that render the supplier unable to meet the contracted quantity.[44] Depending on the specific circumstances, the absence of a contractual provision specifying the penalty to be imposed on the breaching party in the case of a failure to supply requires a default rule to be applied by the courts.[45] Yet the default rule may excuse performance without *any* additional penalty when a contract is "obligationally incomplete, since it does not specify the damages for breach in the unanticipated state of the world."[46]

> This contract is [also] . . . contingently incomplete because it does not make the parties' contractual duties dependent upon the unanticipated state of the world. When faced with such contracts, courts use the excuse doctrines of impossibility and impracticability to fill the damages gap with zero damages.[47]

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41. *See MAN Engines*, 434 S.W.3d at 140 (interpreting Tex. Bus. & Com. Code Ann. §§ 2.316, 2.318 (West 2013)).

42. *See* W. Plains Co. v. Jelinek, No. A-10-1179, 2012 WL 299533, at *1-2 (Neb. Ct. App. Jan. 31, 2012) (considering a case where the defendant "delivered some loads of unblended good corn at [the plaintiff's] request, ran out of good corn to mix with bad corn, and stopped supplying corn after [the plaintiff] refused to take loads of bad corn only," leading the plaintiff to "file[] a complaint for breach of contract in the district court").

43. *See* Azzil Granite Materials, LLC v. Canadian Pac. Ry. Co., No. 20-CV-2381, 2023 WL 3346765, at *8 (E.D.N.Y. May 10, 2023) (where the plaintiff failed to deliver stone to a customer because the defendant failed "to deliver further shipments . . . to end users, resulting from [its] delay or failure to timely return railcars" for refilling with stone), *aff'd* No. 23-833, 2024 WL 1827289 (2d Cir. Apr. 26, 2024).

44. *See* Alcan Forest Prods., LP v. A-1 Timber Consultants, Inc., 982 F. Supp. 2d 1016, 1022-23 (D. Alaska 2013). For a discussion of this case, see note 50 below and accompanying text.

45. That is to say that, in these cases, "[i]t falls to public institutions . . . to create background, or 'default,' rules to govern private relationships when such unaddressed contingencies arise and private ordering, thus, has failed." Russell Korobkin, *Status Quo Bias and Contract Default Rules*, 83 CORNELL L. REV. 608, 609-10 (1998).

46. Ayres & Gertner, *supra* note 15, at 731.

47. *Id.*

This default rule intends to protect a supplier against situations that are "unforeseeable and beyond [its] control," such as "a hurricane [that] destroys its factory," "rending performance of the contract impracticable."[48] However, a hurricane is a uniquely exogenous cause of breach, and the excuse is sometimes applied more broadly to situations that are less clearly outside of the party's control.[49] For example, one court permitted a defendant to raise an impracticability defense after it breached its contract to "harvest second growth timber" due to "mechanical breakdowns" and "high employee turnover" attributed to "ground conditions" on which other loggers nonetheless "operated effectively."[50] This default rule may provide supply-side firms with insufficient incentives to invest in measures that would diminish the probability of breaches that may occur in the context of broader (and perhaps unanticipated) conditions or market events. Although the link between consumers and timber harvesting is somewhat attenuated, the potential harm to consumers becomes clear when thinking about essential goods and the people who can no longer obtain the products they need.[51]

Essential goods and services often receive additional attention from and regulation by policymakers. Consider, for example, financial markets and the potential harm that could befall consumers if merchants were left to their own devices and incentives. The 2007-2009 financial crisis arose in part out of "inadequately regulated securities," such as subprime mortgage loans and credit default swaps, and an overall "laxity of financial regulation that encouraged superfluous risk taking behavior."[52] In the absence of regulatory oversight, bankers took risks for which consumers ultimately bore the consequences, demonstrating why "financial stability can be thought of as a 'public good'" and "should be provided through regulation."[53] Thus, "[financial] regulation has

48. Patrick Taylor, Brandon Krajewski & Hannah Schwartz, *Supply Chain Survival Series: Impracticability, Impossibility and Frustration of Purpose (Article #10)*, QUARLES (June 21, 2023), https://perma.cc/EL3F-EGAL.

49. Even in *Taylor v. Caldwell* (1863) 122 Eng. Rep. 309, 309 (QB)—a standard example of impossibility from any law student's first-year contracts class where a fire destroyed a music hall, rendering its rental impossible—it seems plausible that the defendant could have taken steps to prevent such a destructive fire.

50. Alcan Forest Prods., LP v. A-1 Timber Consultants, Inc., 982 F. Supp. 2d 1016, 1021-23, 1037 (D. Alaska 2013).

51. This Note delves into one such example at length in Part IV below.

52. M. Imtiaz Mazumder & Nazneen Ahmad, *Greed, Financial Innovation or Laxity of Regulation? A Close Look into the 2007-2009 Financial Crisis and Stock Market Volatility*, 27 STUD. ECON. & FIN. 110, 113-14, 116 (2010).

53. *See* Frank Partnoy, *Financial Systems, Crises, and Regulation*, *in* THE OXFORD HANDBOOK OF FINANCIAL REGULATION 68, 70 (Niamh Moloney, Eilís Ferran & Jennifer Payne eds., 2015).

welfare benefits, and . . . it is rational for (particularly retail) consumers of financial services to demand regulation of financial services firms."[54]

Such examples are not unique to the United States. Market failures occur abroad as well when essential products are left to private firms' contracting decisions. For example, many cities in Eastern Europe, Latin America, Africa, and Asia privatized water during the 1990s, entrusting the stability of city-wide supplies to corporations whose incentives were not inherently aligned with consumers' needs.[55] And, indeed, these contracts fell out of favor over the next decade when "the companies were not making the expected investments in extending and improving the networks, nor making the expected improvements in efficiency, *and the contracts and regulatory systems did not create sufficient incentives to do so.*"[56] Ultimately, many of these water supplies were re-nationalized—and some countries went so far as to make water privatization illegal.[57]

Examples like these demonstrate that contracts alone can fail to provide sufficient incentives for merchant parties to avoid welfare-diminishing states of the world. And, when regulators do choose to intervene, it is generally in such situations where additional "constraints and inducements [a]re necessary to align private actions with the public interest."[58]

III. The Case for Regulatory Intervention

Regulatory intervention tends to be the exception rather than the rule in the United States, where "private good"[59] markets are generally left to the (sometimes "shaky"[60]) invisible hand.[61] Regulation is even harder when it

54. David Llewellyn, *The Economic Rationale for Financial Regulation*, FIN. SERVS. AUTH. OCCASIONAL PAPERS IN FIN. REGUL., Apr. 1999, at 1, 5.

55. DAVID HALL, EMANUELE LOBINA & VIOLETA CORRAL, REPLACING FAILED PRIVATE WATER CONTRACTS 3 (2010).

56. *Id.* (emphasis added).

57. *Id.*

58. *See* SCOTT HEMPLING, REGULATING PUBLIC UTILITY PERFORMANCE: THE LAW OF MARKET STRUCTURE, PRICING AND JURISDICTION 3 n.4 (2d ed. 2021).

59. Unlike public goods like financial stability, "[t]he majority of the goods and services consumed in a market economy are private goods, and their prices are determined to some degree by the market forces of supply and demand." Eleanor G. Henry & Rebecca Summary, *Private Good*, BRITANNICA, https://perma.cc/9ZWR-VQ92 (archived Jan. 2, 2025).

60. Marc Ribaudo, Fred Kuchler & Lisa Mancino, *Market Failures: When the Invisible Hand Gets Shaky*, U.S. DEP'T AGRIC. (Nov. 1, 2008), https://perma.cc/X9WL-GLSF.

61. Existing scholarly work documents how, "[i]n some doctrinal areas, such as products liability and insurance, courts have been interventionist." Alan Schwartz, *Relational Contracts in the Courts: An Analysis of Incomplete Agreements and Judicial Strategies*, 21 J.

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comes to intervening to address a harmfully *lacking* contract provision, as opposed to a provision that affirmatively harms consumers (such as a "contract[] among business rivals to raise prices" anticompetitively as a cartel).[62]

Proposals to imbed consumer protection in the default rules of U.C.C. Article 2 are not new.[63] Observers generally raise concerns about protecting consumers in agreements where they are a purchasing party.[64] In contrast, this Note investigates how default rules between merchants may have adverse effects on *nonparty* consumers later down the line—for instance, the impracticability excuse of U.C.C. section 2-615(a) as it pertains to failures to supply during drug shortages—and considers how legislators might protect consumers in such scenarios.

One's first impulse might be to amend the default rules directly to achieve this type of consumer protection. A rule revision that might ameliorate the third-party harms discussed above could resemble the "penalty defaults" proposed by Ian Ayres and Robert Gertner as a way to "give at least one party to the contract an incentive to contract around the default rule and therefore to choose affirmatively the contract provision they prefer," rather than rely on the default.[65] For example, failure-to-supply provisions in the case of market-

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LEGAL STUD. 271, 271 (1992). Courts in those areas "have interpreted contracts to realize social goals and have refused to enforce clear contract language that conflicted with their sense of justice. In other areas, such as franchising *and the contract-excuse doctrines*, the courts have been reticent." *Id.* (emphasis added).

62. *See* EASTERBROOK & FISCHEL, *supra* note 2, at 23 (explaining that "[s]ome contracts are not honored because they have adverse effects on third parties," such as "[c]ontracts that yield pollution" or "contracts among business rivals to raise price[s]"). Lawmakers have codified such concerns for third parties in, e.g., "laws to control pollution and monopolies." *Id.*

63. *See, e.g.*, Morris G. Shanker & Mark R. Abel, *Consumer Protection Under Article 2 of the Uniform Commercial Code*, 29 OHIO ST. L.J. 689, 689 (1968); Jennifer S. Martin, *An Emerging Worldwide Standard for Protections of Consumers in the Sale of Goods: Did We Miss an Opportunity with Revised UCC Article 2?*, 41 TEX. INT'L L.J. 223, 272 (2006); Edith Resnick Warkentine, *Article 2 Revisions: An Opportunity to Protect Consumers and "Merchant/Consumers" Through Default Provisions*, 30 J. MARSHALL L. REV. 39, 40 (1996); Fred H. Miller, *Consumer Issues and the Revision of U.C.C. Article 2*, 35 WM. & MARY L. REV. 1565, 1570 (1994); Jean Braucher, *Politics and Principle in the Drafting of the UCC Consumer Protection Provisions*, 29 UNIFORM COM. CODE L.J. 68, 68 (1996).

64. *See, e.g.*, Martin, *supra* note 63, at 272 (arguing that Article 2 can and should "include[] statutory provisions that recognize the need for protections of consumers and specifically address the imbalance in the bargaining position between big sellers and consumers"); Warkentine, *supra* note 63, at 39 (urging that, "[w]hile revising Article 2, the [National Conference of Commissioners on Uniform State Law] must decide how, and to what extent, Article 2 should include special rules to protect consumer buyers").

65. *See* Ayres & Gertner, *supra* note 5, at 91. Generally, scholars suggest that "the appropriate default rule should reflect the bargain that most parties would have reached on their own" if the contract were incomplete because of binding transaction

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wide shortages could trigger large monetary penalties rather than be excused. As a result, suppliers would want to negotiate a complete provision for this contingency rather than leaving it up to the U.C.C. However, if rules are too explicitly tailored to specific circumstances, they will cause harm to the parties (and social welfare more broadly) in situations that do not perfectly conform to the case that they were designed around. For example, as discussed above, not all externalities imposed on third parties by merchant contracts warrant an intervention of the type contemplated in this Note—such as cases where the parties have other contractual or judicial tools to obtain relief from negative effects.[66] A default rule that only applies as intended in a small subset of cases will force other parties to contract around it, and research suggests that "increasing the costs of contracting around a default a small amount can disproportionately decrease or increase the net gains from trade."[67] Flexibility and priority of "the reality of the relationship" are at the heart of the U.C.C.'s approach to contract law in a way that a hyper-specific default rule could confound.[68]

Moreover, the reality is that "[d]efault rules, by their nature, are not instruments well-suited to protecting third parties from deleterious effects of contracts" because the parties can choose to contract around such protections.[69] If, for example, the buyer fails to internalize the total cost to consumers of failures to supply,[70] the parties will continue to contract around the provision, such as by reinstating the current default rule of zero penalties under market-wide shortages due to impracticability.

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costs but that penalty defaults may be more appropriate when "a contract is left incomplete for strategic reasons." Scott Baker & Kimberly D. Krawiec, *The Penalty Default Canon*, 72 GEO. WASH. L. REV. 663, 663 (2004). For example, a commonly proposed penalty default is "contra proferentem doctrine that ambiguities in a contract should be construed against the drafter." Michelle Boardman, *Penalty Default Rules in Insurance Laws*, 40 FLA. ST. U. L. REV. 305, 306-07 (2013). Although there is skepticism that penalty default rules accomplish Ayres and Gertner's goal of resolving an "asymmetric information" problem, that is not to say that they would be ineffective in particular scenarios that require additional legislation or regulation for reasons other than the resolution of information asymmetries. *See* Eric A. Posner, *There Are No Penalty Default Rules in Contract Law*, 33 FLA. ST. U. L. REV. 563, 571 (2006).

66. After all, "[t]he Coase theorem teaches that if parties can efficiently contract to internalize externalities, the choice of legal rules will only affect distribution, not allocative efficiency." Ayres, *supra* note 27, at 585.

67. Ayres & Gertner, *supra* note 47, at 762.

68. Omri Ben-Shahar, *The Tentative Case Against Flexibility in Commercial Law*, 66 U. CHI. L. REV. 781, 781 (1999).

69. Korobkin, *supra* note 45, at 610.

70. This seems likely to occur when it comes to necessity goods like chemotherapy drugs, as discussed in Part IV below.

One might conclude, therefore, that legislators should lay out some immutable rule for situations where third-party harm occurs due to incomplete contracting on the part of merchant parties.[71] For example, the immutable rule might be that, if the parties to a supply agreement for a necessary product neglect to specify the penalty for failures to supply when the market price is impossible to determine due to market-wide shortages, as discussed in Part IV below, the penalty is something like three times the contracted price.[72] Such a solution would achieve proportionality to the contract and provide a disincentive to fall into a failure to supply.

However, immutability strips the rule of its flexibility. The U.C.C., which was itself "drawn to provide flexibility,"[73] generally prefers default rules to immutable rules,[74] except when it comes to "good faith, diligence, reasonableness, and care."[75] For example, not all failures to supply by a manufacturer are equally blameworthy, and legislators would not want to disincentivize entry into inherently risky manufacturing sectors. Legal scholars have often emphasized the importance of "specific contextual features" when thinking about the efficacy and justness of such rules.[76] Thus, a default rule seems too weak (in that it is easy to contract around), and an immutable rule seems too strong (in that it lacks the nuance of context) to tackle the specific and yet significant harms that consumers experience due to the merchants' incomplete contracting within the broader context of contemporary contract law.

Thus, this may be an area for regulators to step in to fill the gap and impose penalties for certain contingencies that cause significant consumer

71. *See* Korobkin, *supra* note 45, at 610 (arguing that it is better to enact "substantively identical *mandatory* . . . rules which private parties are not free to change" when wanting to "protect[] third parties from deleterious effects of contracts, or to protect[] the parties from each other").

72. The three-times multiplier here is an arbitrary example and meant to roughly align with, for example, the mandatory treble-damages approach taken in antitrust to deter anticompetitive behavior. *See* Christina Chu Ma & Matthew Alan Michaloski, *The Trouble with Treble? Examining the Effects of Mandatory Treble Damages*, AM. BAR ASS'N (Feb. 15, 2023), https://perma.cc/Z3QU-YSPR. However, one could easily imagine some other multiplier that legislators might consider sufficient to penalize suppliers for failures to supply in shortages when the market price is effectively infinite.

73. U.C.C. § 1-103, cmt. 1 (AM. L. INST. & UNIF. L. COMM'N 1977).

74. *See* Kerry Lynn Macintosh, *Liberty, Trade, and the Uniform Commercial Code: When Should Default Rules Be Based on Business Practices?*, 38 WM. & MARY L. REV. 1465, 1466 & n.4 (1997) (noting that the "revised articles reflect a strong trend toward choosing default rules" as opposed to immutable rules).

75. U.C.C. § 1-302 (AM. L. INST. & UNIF. L. COMM'N 1977).

76. Jules L. Coleman, Douglas D. Heckathorn & Steven M. Maser, *A Bargaining Theory Approach to Default Provisions and Disclosure Rules in Contract Law*, 12 HARV. J.L. & PUB. POL'Y 639, 708 (1989).

harm. Regulators can more easily tailor penalties and other interventions to individual circumstances. For example, they could design regulatory penalties to fit both an individual party's fault and its potential pecuniary gains from triggering the contingency. Such an approach would provide an appropriate disincentive without the downsides of the approaches outlined above. To do so, regulators may even "[e]nlist the [c]ooperation of the [r]egulated" to understand the "'best practical' performance" of firms in a given industry so that they do not penalize merchants who are not actually at fault—e.g., those who fail to supply due to circumstances entirely beyond their control such as natural disasters.[77]

In this way, as in other settings where "nonlegal sanctions" like reputation effects fail to constrain commercial actors from writing contracts in a way that harms consumers,[78] "[l]egal regulation . . . could serve a corrective function by altering the strategic environment in which buyers and sellers interact."[79] Regulation can "eliminate inefficient equilibria" like socially inefficient, incomplete contracts that the parties themselves have no incentive to change given palatable default rules.[80] The regulator can thus provide much of the same process efficiency of default rules—e.g., encouraging "the use of simpler, better written, and shorter contracts"—but also supply some otherwise absent incentives for more *socially* efficient contracting.[81] Regulatory intervention therefore stands out among the potential solutions as a promising step towards resolving the market failures discussed above.[82]

IV. An Application to Shortages of Generic Sterile Injectables

Considering a case study helps ground the broad discussion above in the specific context of how harm to nonparty consumers may arise out of reliance

77. *See* William F. Pedersen, *Contracting with the Regulated for Better Regulations*, 53 ADMIN. L. REV. 1067, 1080 (2001).

78. *See* David Charny, *Nonlegal Sanctions in Commercial Relationships*, 104 HARV. L. REV. 373, 376 (1990).

79. Yuval Procaccia & Alon Harel, *On the Optimal Regulation of Unread Contracts*, 8 REV. L. & ECON. 59, 61 (2012).

80. *See id.* (explaining that "[b]y changing the rules of the game, [legal regulation] could be used to eliminate inefficient equilibria" in "the strategic environment in which buyers and sellers interact").

81. Jon Stern, *The Relationship Between Regulation and Contracts in Infrastructure Industries: Regulation as Ordered Renegotiation*, 6 REGUL. & GOVERNANCE 474, 477 (2012) (emphasis omitted). The existing literature identifies some of the factors that correlate with the circumstances where "long-term contracts without regulation by external agencies . . . . are most likely to work well or poorly." *Id.*

82. That said, like every approach, it has its own potential drawbacks discussed in Part V below.

on default rules. This section proceeds in six subparts. Subpart A provides a primer on drug shortages in the United States, focusing on shortages of generic sterile injectables (GSIs). Subpart B discusses a nonexhaustive set of reasons why the market has historically failed to correct these shortages. Subpart C looks at a specific contractual factor that economists and legal scholars have proposed as relevant to these shortages: failure-to-supply penalties. Subpart D provides a few examples of failure-to-supply provisions in recent pharmaceutical contracts and notes the manner in which they are incomplete. Subpart E provides empirical evidence from quarterly earnings calls at publicly listed pharmaceutical firms that suppliers and their shareholders are concerned about failure-to-supply penalties when they do take effect. Finally, Subpart F discusses how regulators may provide disincentives through civil-money penalties to fill the gap in these provisions that could otherwise lead to consumer harm under the default rule.

A. A Brief Primer on Drug Shortages[83]

Although serious drug shortages "first emerged" in the United States in 1999, Americans have faced *persistent* shortages of generic drugs at an accelerated rate since the Great Recession.[84] Data on historical drug shortages from the University of Utah Health are summarized in Figure 1 below.[85] These shortages have been especially pronounced among GSIs, which are a "staple of hospital care" and include essential medicines like injectable oncology drugs.[86]

83. This primer is not meant to provide the reader with a comprehensive accounting of the pharmaceutical supply chain. Rather, it is intended to provide sufficient background that the reader can place the failure-to-supply provisions discussed below in context. Therefore, it skips over certain actors in the market who may be relevant to analyses focused on other parts of this problem. For a more robust discussion of the various players in the pharmaceutical product supply chain, see HEALTH MGMT. ASSOCS. & OFF. OF THE INS. COMM'R OF WASH. ST., STUDY OF THE PHARMACY CHAIN OF SUPPLY (2017); *Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective: Hearing Before the S. Comm. on Fin.*, 118th Cong. (2023) (statement of Inmaculada Hernandez, Professor, University of California, San Diego); ANDREW W. MULCAHY & VISHNUPRIYA KAREDDY, PRESCRIPTION DRUG SUPPLY CHAINS: AN OVERVIEW OF STAKEHOLDERS AND RELATIONSHIPS (2021).

84. Sharona Hoffman, *The Drugs Stop Here: A Public Health Framework to Address the Drug Shortage Crisis*, 67 FOOD & DRUG L.J. 1, 2 (2012).

85. The data in Figure 1 was provided by Dr. Erin R. Fox. *See* Data Package from Erin R. Fox, Professor, University of Utah Health (Dec. 8, 2023) (on file with author). A replication package is on file with the *Stanford Law Review*.

86. MARTA E. WOSIŃSKA & RICHARD G. FRANK, FEDERAL POLICIES TO ADDRESS PERSISTENT GENERIC DRUG SHORTAGES 4 (2023), https://perma.cc/2SRT-2S7T. For example, the chemotherapy drugs carboplatin, cisplatin, and oxaliplatin have all faced shortages in recent years according to the University of Utah Health data. *See* Data Package from Erin R. Fox, *supra* note 85. That being said, oncology drugs are not the only example of

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After more than a decade of persistent shortages, the United States is still "experiencing a shortage of 15 cancer drugs due to manufacturing and supply chain issues."[87] As a result, these shortages represent a critical policy issue not only from the perspective of patient welfare,[88] but also as a potential "threat to national security."[89]

These shortages are often triggered by issues at manufacturing plants, especially once unsafe conditions or practices are uncovered by U.S. Food and Drug Administration (FDA) inspections.[90] A manufacturer may have to cease production at its plant if the FDA discovers a quality issue.[91] For example, drug manufacturer Teva "halted operations" at its Irvine, California facility in 2022 after an FDA inspection revealed that "the company [had not] repaired water damage at the site and failed to maintain procedures to keep factory workers from spreading mold and bacteria."[92] This one shutdown put as many as twenty-four GSIs at risk of shortage, "including five essential medications of

GSIs in shortage; the availability of other essential drugs like the anesthetic lidocaine has also been significantly impacted. *See, e.g.*, Austin Pytlowany, Noah Leja & Stanley Kent, *Comparing Drug Shortages Experienced by Institutions with National Metrics*, ONCOLOGIST (forthcoming 2025) (manuscript at 1, 3) (on file with author) (discussing oncology "drug shortages, . . . how health systems mitigate their effects, and . . . the difference in reporting mechanisms at a national level").

87. OFF. OF SCI. & TECH. POL'Y, STRENGTHENING THE SUPPLY CHAIN FOR CANCER DRUGS (Sept. 12, 2023), https://perma.cc/X94B-BMZ6.

88. For example, a 2015 survey found that "drug shortages create unsafe conditions for patients and staff 60% of the time." Caulder et al., *supra* note 3, at 281-82.

89. AM. HOSP. ASS'N, AM. SOC'Y OF ANESTHESIOLOGISTS, AM. SOC'Y OF CLINICAL ONCOLOGY, AM. SOC'Y OF HEALTH-SYS. PHARMACISTS & INST. FOR SAFE MEDICATION PRACS., DRUG SHORTAGES AS A MATTER OF NATIONAL SECURITY: IMPROVING THE RESILIENCE OF THE NATION'S HEALTHCARE CRITICAL INFRASTRUCTURE 3 (2018), https://perma.cc/2DB4-YH3G.

90. *See* Mary Van Beusekom, *Shortcuts, Coverups in Drug Plants Often Precede Quality Problems, Shortages*, CTR. FOR INFECTIOUS DISEASE RSCH. & POL'Y (Aug. 28, 2023), https://perma.cc/EB3Q-JM4R. Shortages may also occur for other reasons, though, such as discontinuations or supply chain disruptions related to inputs of the manufacturing process (e.g., raw materials).

91. *See id.* (quoting a pharmaceutical research scientist at the Resilient Drug Supply Project as saying that "there is a strong positive correlation between maintaining quality standards and drug shortages," and that "[a]s products are pulled from the market, or citations force the shutdown for cleaning and retooling, . . . products . . . are absent from the market"); S.L. Kweder & S. Dill, *Drug Shortages: The Cycle of Quantity and Quality*, 93 CLINICAL PHARMACOLOGY & THERAPEUTICS 245, 248 (2013) (urging that "a complete shutdown of a plant to address manufacturing-quality problems is an alarm call that the health-care system must heed").

92. Joseph Keenan, *Teva's Halt at Troubled Plant Threatens to Create Shortages in Wide Range of Injectable Meds: Report*, FIERCE PHARMA (May 24, 2022, 9:50 AM), https://perma.cc/2P8A-2ECJ; Fraiser Kansteiner, *Updated: Teva Won't Reopen Troubled California Site, Where 300-Plus Are Losing Their Jobs*, FIERCE PHARMA (Aug. 23, 2022, 8:00 AM), https://perma.cc/TL8Q-GNG4.

which the company supplied more than 15% of the market."[93] In fact, the FDA cites manufacturing quality issues as "*the* major reason for drug shortages."[94] After the FDA identifies a quality issue, it discloses the issue to the manufacturer and to the public in a Center for Drug Evaluation and Research (CDER) warning letter.[95] Inspections are a critical means of identifying such issues: In a sample of 236 warning letters relating to violations of Current Good Manufacturing Practice (CGMP) issued by the CDER between January 2019 and December 2023, 122 letters focus on violations uncovered during inspections.[96] A variety of CGMP violations might trigger a warning letter, such as a firm's failure to "establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile."[97] These shortage-triggering quality issues appear most frequently in GSIs,[98] due to the elevated level of cleanliness and caution required to manufacture "terminally sterilized drugs."[99]

93. Keenan, *supra* note 92.

94. *Frequently Asked Questions About Drug Shortages*, U.S. FDA, https://perma.cc/P6TD-VT6B (last updated Dec. 18, 2024) (emphasis added).

95. *See* U.S. FDA, MAN-000007, REGULATORY PROCEDURES MANUAL ch. 4, at 5, 8-9 (12th rev. 2024), https://perma.cc/M9CC-RSLE.

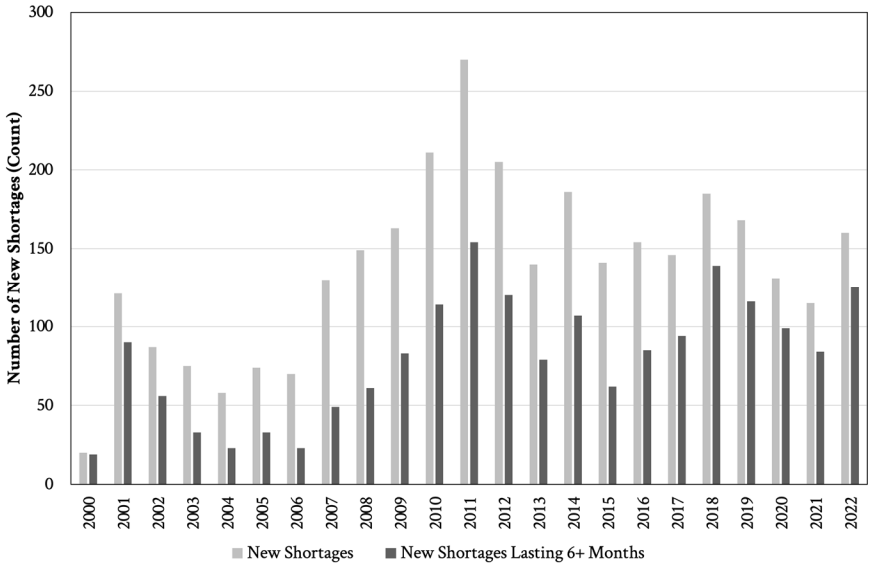
96. *See Warning Letters*, U.S. FDA, https://perma.cc/WE9H-87BA (last updated Dec. 31, 2024). Although the share of letters pertaining to inspections was large during this period, it was actually unusually *low* because the FDA was frequently testing hand sanitizer and rubbing alcohol products to ensure the stated alcohol levels were accurate as part of its response to the ongoing COVID-19 pandemic. *See id.* This implies that the share of inspection-related letters would be even larger during other periods.

97. Letter from Ctr. for Drug Evaluation & Rsch. to Nimish Chudgar, CEO & Managing Dir., Intas Pharmas. Ltd. (Nov. 21, 2023), https://perma.cc/F7RU-6MQ7.

98. *See* Marta Wosińska & Richard G. Frank, *Federal Policies to Address Persistent Generic Drug Shortages*, BROOKINGS (June 21, 2023), https://perma.cc/K3NU-DXYF (explaining that GSIs are "particularly prone to shortages"); *Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective: Hearing Before the S. Comm. on Fin.*, 118th Cong. 2 (2023) (statement of Marta E. Wosińska, Senior Fellow, Brookings Institution) (describing why "GSI drugs are the most likely drugs to experience shortages").

99. *See* Letter from Ctr. for Drug Evaluation & Rsch. to José E. Almeida, Chairman & CEO, Baxter Healthcare Corp. (July 25, 2023), https://perma.cc/2KQU-HCT9; *see also* WOSIŃSKA & FRANK, *supra* note 98 (explaining that "[t]here is little room for error in the production of GSIs because the resulting product must be free of microorganisms and particulate matter").

Figure 1
Number of New Shortages by Year: 2000 to 2022



B. Market Solutions to Drug Shortages

The market struggles to resolve GSI shortages on its own. On the one hand, demand for medically necessary drugs is highly inelastic. That is to say that the quantity demanded by consumers is relatively constant and insensitive to price. Therefore, one might expect prices to rise during shortages and induce additional supply to meet market demand. However, the supply-side market for GSIs is highly concentrated. According to a recent empirical analysis, "20 percent of GSI molecules have only one generic manufacturer," meaning that there is no supplier for the market if this manufacturer is required to cease production for any reason.[100] Most GSIs have three or fewer manufacturers.[101] The "relatively low profit margins for generic drugs,"[102] as well as the additional costs of manufacturing GSIs[103] due to the need for "dedicated

100. WOSIŃSKA & FRANK, *supra* note 86, at 3.

101. *See* Stacey B. Lee, *The Drug Shortage Crisis: When Generic Manufacturers "Just Say No,"* 93 OR. L. REV. 355, 364 (2014).

102. U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-595, DRUG SHORTAGES: CERTAIN FACTORS ARE STRONGLY ASSOCIATED WITH THIS PERSISTENT PUBLIC HEALTH CHALLENGE 40 (2016), https://perma.cc/AJT4-7GKR.

103. *See* WOSIŃSKA & FRANK, *supra* note 86, at 3 (explaining how GSI quality assurance requires a "multitude of daily management decisions" and associated costs, "including equipment selection, maintenance, quality of materials, staff qualifications,
footnote continued on next page

manufacturing lines" and clean room environments,[104] further exacerbate the dearth of entry in these markets and the reluctance of existing manufacturers to expand production capacity.[105] Other barriers like the cost of obtaining an abbreviated new drug application approval[106] and the need to navigate potential exclusivity agreements when switching suppliers further hinder the market's ability to correct shortages in a timely manner.[107] Moreover, although the Hatch-Waxman Amendments have effectively ensured that approved manufacturers' products are perfect substitutes for each other,[108] other manufacturers' volumes are generally already accounted for in contracts with other buyers, and manufacturing lines often run "24 hours a day, 7 days per week" continuously for years just to keep pace.[109] This is an unnecessarily risky equilibrium for the market. GSI manufacturers "have chosen to meet growing demand by increasing production levels . . . . [and] by running aging production equipment at high capacity" instead of investing in "their manufacturing infrastructure."[110] As a result, like demand for these drugs, GSI supply is also inelastic (in that the quantity supplied is insensitive to the

supervision, process control, and thorough investigations of any manufacturing problems that arise").

104. Hoffman, *supra* note 84, at 5.

105. *See* Lee, *supra* note 101, at 367.

106. *See* Generic Drug User Fee Rates for Fiscal Year 2024, 88 Fed. Reg. 48864, 48864 (July 28, 2023) ("For FY 2024, the generic drug fee rates are [abbreviated new drug application] ($252,453), [drug master file] ($94,682), domestic [active pharmaceutical ingredient] facility ($40,464), foreign [active pharmaceutical ingredient] facility ($55,464), domestic [finished dosage form] facility ($220,427), foreign [finished dosage form] facility ($235,427), domestic [contract manufacturing organization] facility ($52,902), foreign [contract manufacturing organization] facility ($67,902), large size operation generic drug applicant program ($1,729,629), medium size operation generic drug applicant program ($691,852), and small business generic drug applicant program ($172,963).").

107. *See* Am. Soc'y of Health-Sys. Pharmacists, Draft ASHP Guidelines on Selecting Pharmaceutical Manufacturers and Suppliers 19 (2019), https://perma.cc/883J-579T (noting that an agreement may be "exclusive for a product, product line, or supplier"); *see also* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation*, 18 INT'L J. ECON. BUS. 177, 178 (2011) (discussing trends in generic entry).

108. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code); *see* JOHN R. THOMAS, CONG. RSCH. SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER (2016) (explaining that, among other things, "the Hatch-Waxman Act requires generic drug companies to prove that their proposed products are bioequivalent to the brand-name drug").

109. Lee, *supra* note 101, at 365 (quoting J. Woodcock & M. Wosinska, *Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages*, 93 CLINICAL PHARMACOLOGY & THERAPEUTICS 170, 173 (2013)).

110. *Id.* GSI manufacturers justify this as simply "balancing the cost of building redundancy against . . . profit margins." *Id.*

potential market price) and shortages are difficult to resolve through the market alone.[111]

C. Failure-to-Supply Penalties

Economists looking at GSI shortages have therefore proposed failure-to-supply penalties as a potential solution that would "allow reliable suppliers to benefit from higher profit margins, thereby incentivizing investments in the production process."[112] Economic analysis suggests that, compared to other proposals, these penalties are a preferred solution because they yield "the highest increase in consumer welfare"—even above and beyond other proposals like financial incentives to reshore generic drug manufacturing in the United States, where FDA oversight is more effective, or proposals to allow market prices to react more to shortages.[113]

Various structures for these penalties have been proposed—e.g., some fraction of the expected revenue that the manufacturer would have made from the missing quantity or the price difference between the price negotiated in the contract and the price that the buyer had to pay in the market to make up for the missing volumes.[114] The general idea approximates concepts such as opportunity cost damages to make the breached-against party (i.e., the buyer)

111. Policymakers are also aware of the emergence of a gray market, wherein "drugs [enter] the gray market through pharmacies" that "instead of dispensing the drugs in accordance with their state laws, their professional duties, and their contractual obligations, . . . re-[sell] the drugs" at a markup that reflects the market condition of excess demand. CONG. STAFF, 112TH CONG., SHINING LIGHT ON THE "GRAY MARKET": AN EXAMINATION OF WHY HOSPITALS ARE FORCED TO PAY EXORBITANT PRICES FOR PRESCRIPTION DRUGS FACING CRITICAL SHORTAGES 16 (2012). Other government investigations have found that, "[w]hen drugs are in shortage, there are frequently reports of gray market or secondary distributors offering limited quantities of the drugs for sale to health care providers at large markups." OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION & U.S. DEP'T. OF HEALTH & HUM. SERVS., ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES 5 (2011).

112. Anaïs Galdin, Resilience of Global Supply Chains and Generic Drug Shortages 49 (Mar. 20, 2024) (unpublished manuscript) (on file with author); *see* Hoffman, *supra* note 84, at 21 (arguing that "[s]hortages should also be deterred through financial incentives . . . , including . . . failure-to-supply clauses"); Letter from Tom Kraus, Vice President, Am. Soc'y of Health-Sys. Pharmacists, to Cathy McMorris Rodgers, Chair, House Energy & Com. Comm. (Aug. 25, 2023), https://perma.cc/4948-8CCY.

113. Galdin, *supra* note 112, at 5; *see* Lee, *supra* note 101, at 389 (noting that "[i]t is difficult to conceive of a viable approach to ending shortages without manufacturer [financial] incentives").

114. *E.g.*, Galdin, *supra* note 112, at 49 (using "multiples of average expected firms revenues at the market level" to simulate policy counterfactuals); OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 111, at 5 (explaining that failure-to-supply clauses "generally require the manufacturer to reimburse the GPO for the price difference between the negotiated price and purchased price").

indifferent between performance and receiving both the penalty and the second-best contract it could obtain on the market.[115]

However, failure-to-supply penalties already feature regularly in GSI procurement contracts. Typically, Group Purchasing Organizations (GPOs) negotiate contracts with manufacturers on behalf of many different hospitals at once.[116] A simplified[117] outline of the hospital drug supply chain is shown in Figure 2 below for reference.[118] Estimates from the last decade suggest that "some 90% of all hospital purchases"[119] were made through GPOs, and more recent figures suggest that this number has increased to cover purchases by "approximately 97% to 98% of hospitals."[120] To choose a supplier in this market with homogenous goods, the "GPOs use competitive bidding through online reverse procurement auctions to select the lowest-cost supplier for member hospitals."[121] These auctions put downward pressure on prices in the way that

115. For example, existing work in the scholarly literature considers a range of potential penalties—"from minimal penalty rates (0.1 time[s] the average expected firm's revenue in the market [for the missing supply]) that may not necessarily deter any firm from participating" to "penalty levels that may deter most firms from failing to honor their commitments (2.5 times the average expected firm's revenue in the market)." Galdin, *supra* note 112, at 49. Here, the equivalent of opportunity-cost damages would likely be equivalent to a penalty rate in the upper two-thirds of this range: at least one times the breaching firm's expected revenue from the missing supply but potentially higher if the second-best contract available on the market is more expensive.

116. *See infra* Figure 2. In actuality, GPOs generally contract with *labelers*. Galdin, *supra* note 112, at 10 (explaining that "GPOs directly engage with drug labelers to negotiate bulk product prices, aggregating demands from member hospitals to negotiate volume discounts, thus securing drug prices that individual hospitals might not independently obtain"). A drug's labeler may differ from its manufacturer because labelers sometimes outsource manufacturing to other firms. However, this Note abstracts away from this distinction for clarity and will treat labeler and manufacturer as synonymous.

117. As described earlier, this Note abstracts away from several intermediaries who are not as relevant to the discussion at hand. *See supra* notes 83, 116.

118. Figure 2 draws from multiple sources. *See* Cat Weeks, *Hospital Drug Supply Chain* (illustration), *in* Ricky Zipp, *Generic Drugmaker Civica Rx Looks to Upend Hospital Drug Supply Chain*, S&P GLOB. (Mar. 5, 2019), https://perma.cc/3Q35-EBJF; Illustration of Prescription Drug Supply Chain, *in* Alivia Kaylor, *Fundamentals of the Pharmaceutical Supply Chain*, TECHTARGET (Mar. 23, 2023), https://perma.cc/A7L8-M954; *The Generic Supply Chain for Hospital-Administered Medicine* (illustration), *in Generics and Biosimilars Industry Response to COVID-19*, ASS'N FOR ACCESSIBLE MEDS., https://perma.cc/9JE5-L9KA (archived Jan. 3, 2025).

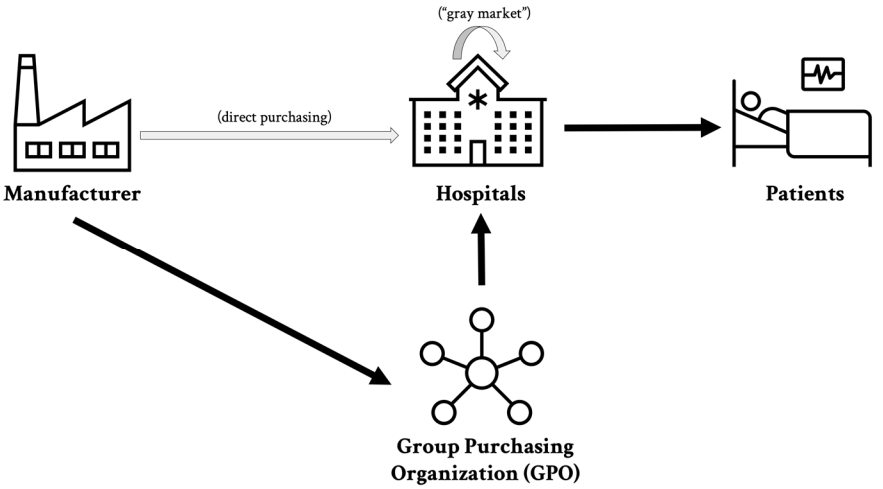
119. Roger D. Blair & Christine Piette Durrance, *Group Purchasing Organizations, Monopsony, and Antitrust Policy*, 35 MANAGERIAL & DECISION ECON. 433, 433 (2014).

120. Brigid C. Flynn, Ling Shen, James E. Littlejohn, Michelle O. Shirak & Natalia S. Ivascu, *Noteworthy Literature in 2018 for Cardiovascular Anesthesiologists and Intensivists*, 23 SEMINARS CARDIOTHORACIC & VASCULAR ANESTHESIA 156, 160 (2019).

121. Galdin, *supra* note 112, at 10.

standard economic theory would predict: driving prices down to marginal cost as long as there are at least two bidders.[122]

Figure 2[123]



Also driving down prices are price adjustment clauses in the procurement contracts.[124] These clauses allow a GPO to switch to a competing manufacturer who offers a lower price as long as they have given the original contracted manufacturer a right of first refusal to match the new price.[125] In addition to downward pressure on prices, these procurement contracts are generally in place for one to three years, thus aggravating price *stickiness* when a shortage occurs.[126]

122. *See id.* This is a standard result of Bertrand competition in a homogenous good market like the one considered here. Mirjam Sarah Salish, *Bertrand Competition*, INOMICS (Jan. 5, 2021), https://perma.cc/H6GK-HMKS (explaining that "Bertrand competition is a model of competition in which two or more firms produce a homogenous good and compete in prices," and that "[t]heoretically, this competition in prices, providing the goods are perfect substitutes, ends with the firms selling their goods at marginal costs and thus making zero profits").

123. Other parties not shown here include biomedical researchers, labelers, wholesalers, distributors, retail pharmacies, insurers, pharmacy benefit managers, etc.

124. OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 111, at 5.

125. *Id.* GPO contracts are voluntary for hospitals, meaning that they can buy off-contract if they find a lower-priced option. Wosińska & Frank, *supra* note 86, at 5; COUNCIL ON MED. SERV., 252-A-18, GROUP PURCHASING ORGANIZATIONS AND PHARMACY BENEFIT MANAGER SAFE HARBOR 1, 8 (2019), https://perma.cc/4PDM-KFZ6.

126. *E.g.*, Wosińska & Frank, *supra* note 86, at 5. Price stickiness describes "the tendency of prices to remain constant despite changes in supply and demand." Pinelopi Goldberg & Rebecca Hellerstein, *Sticky Prices: Why Firms Hesitate to Adjust the Price of Their Goods*, 13 FED. RSRV. BANK N.Y.: CURRENT ISSUES IN ECON. & FIN., Spring 2007, at 1, 1.

The failure-to-supply penalty provisions that are already present in GPO GSI procurement contracts "generally require the manufacturer to reimburse the GPO for the price difference between the negotiated price and purchased price."[127] However, the penalties are rarely enforced in the case of acute shortages because the clauses essentially "provide no reimbursement if there are no alternative sources for the drug."[128] Thus, the market finds itself in a situation where the policy solution proposed by experts is actually in use but rendered ineffective by some combination of legal factors and market realities.

That the clauses offer no reimbursement if the drug is not available elsewhere is a problematic outcome. Failures to supply that occur during market-wide shortages are perhaps *most* costly to a buyer because no second-best option even exists at the time of default. Observers blame U.C.C. section 2-615, which states:

> "[N]on-delivery . . . is not a breach of his duty under a contract for sale if performance as agreed has been made impracticable by the occurrence of a contingency the non-occurrence of which was a basic assumption on which the contract was made."[129]

It is not clear that a manufacturer's nondelivery should always fall under the impracticability exception, however. Although active manufacturing operations are a prerequisite for supplying the market, this exception has generally been read to not apply in cases where the "disruptive event . . . was reasonably foreseeable by the parties at the time of contracting."[130] Today, the potential for quality issues discovered during an FDA inspection to trigger a shutdown and shortage are reasonably foreseeable;[131] buyers and sellers alike have observed this pattern in the market for decades.[132] Moreover, engineering difficulties that make production more difficult or expensive than

127. OFFICE OF ASS'T SEC'Y FOR PLAN. & EVALUATION, *supra* note 111.

128. *Id.*; *see* Woodcock & Wosinska, *supra* note 109, at 173.

129. U.C.C. § 2-615(a) (AM. L. INST. & UNIF. L. COMM'N 1977); *see* OFF. OF ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 111, at 5 (explaining that U.C.C. section 2-615 "suggests that failure to provide contracted products is not a breach of contract if the product is not available in the market").

130. Stephen G. York, *Re: The Impracticability Doctrine of the U.C.C.*, 29 DUQ. L. REV. 221, 222 (1991).

131. *See, e.g.*, Joanne S. Eglovitch, *Cavazzoni: FDA Wants to Prevent Manufacturing Stoppages During Inspections*, REGUL. FOCUS (May 7, 2024), https://perma.cc/TTF9-YTBB (explaining that manufacturers as well as the FDA are aware of this issue and that "[a]s part of FDA's inspection modernization efforts, the agency is piloting a program to enhance communication," and quoting an FDA official who described the program as encouraging "'manufacturers to call [the FDA's] drug shortage team immediately . . . so we . . . don't find ourselves with outright stoppages in the manufacturing of essential drugs like what we have seen over the past year'").

132. *See supra* Figure 1; *supra* notes 85-86.

anticipated have been held as insufficient grounds for excuse by impracticability.[133] In these GSI manufacturing disruptions, production could have been unimpeded if the seller had previously invested sufficient financial capital into equipment and practices that comply with the FDA's CGMP regulations.[134] Thus, blame for the lack of penalty enforcement may not be appropriately placed on the U.C.C.'s impracticability exception.

Courts have occasionally grappled with similar issues and seem to agree with this Note's assessment.[135] For example, AbbVie sought contractual damages, among other things, from Takeda after Takeda failed to deliver on its promised volumes of the cancer drug *Lupron* due to an intermittent shutdown of one of its plants.[136] The shutdown was caused by "a piece of sterilization equipment [that] failed its annual requalification test," which resulted in facility closures and a *Lupron* shortage.[137] Takeda was the drug's sole producer.[138] Delaware awarded damages to AbbVie in relation to its lost profits when downstream customers in *Lupron* market segments switched to products sold by other distributors and "sent [AbbVie]'s market share crashing down, with limited recovery even a year later."[139] The *Lupron* shortage and resulting lawsuit are anomalous because they involve a branded rather than generic sterile injectable.[140] However, the ruling demonstrates at least one judge's

133. *See* United States v. Wegematic Corp., 360 F.2d 674, 676-77 (2d Cir. 1966).

134. *See, e.g.*, NAT'L ACADS. OF SCI., ENG'G & MED., BUILDING RESILIENCE INTO THE NATION'S MEDICAL PRODUCT SUPPLY CHAINS 112 (Wallace J. Hopp, Lisa Brown & Carolyn Shore eds., 2022) (explaining that "[t]he use of outdated technology is common in medical product manufacturing, and it . . . . introduces product errors that can subsequently lead to shortages"). Scholarly research suggests that "[w]hile other industries typically function at an error rate below 3.4 defects per million opportunities, the pharmaceutical manufacturing industry operates at a rate of around 66,000 defects per million opportunities—owing in part to out-of-date manufacturing processes." *Id.* (citing Janet Woodcock & Michael Kopcha, *Quality: The Often Overlooked Critical Element for Assuring Access to Safe and Effective Drugs*, HEALTH AFFS.: FOREFRONT (Mar. 13, 2020), https://perma.cc/8FQW-6T9G).

135. *See* AbbVie Endocrine Inc. v. Takeda Pharm. Co, No. 2020-0953, 2023 WL 5704055, at *1-2 (Del. Ch. Sept. 5, 2023) (discussed below in text accompanying notes 136-39); Watson Lab'ys, Inc. v. Rhone-Poulenc Rorer, Inc., 178 F. Supp. 2d 1099, 1113-14 (C.D. Cal. 2001) (concluding that "the failure [to supply] resulted (at least in part) from the *foreseeable* government shutdown of [the] Centeon [plant]" and holding with respect to the relevance of a force-majeure clause that "when parties expressly contemplate a known risk of a regulatory prohibition, they should be expected to allocate that risk expressly, rather than rely upon a boilerplate clause" (emphasis added)).

136. *AbbVie*, 2023 WL 5704055, at *1.

137. *Id.* at *1-2.

138. *Id.* at *1.

139. *Id.* at *1, 14.

140. *See* Marta Wosińska, *Drug Shortages: A Guide to Policy Solutions*, BROOKINGS (Mar. 13, 2024), https://perma.cc/3YGU-A7X6 (explaining that, "[a]lthough branded sterile

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general unwillingness to interpret shortages caused by manufacturing quality issues as anything other than foreseeable and preventable by the supplier. That being said, litigation is rare—especially in relation to generic rather than branded drugs.[141] As a result, there is no binding authority for this Note to consider or for GSI buyers and sellers to account for when contracting.

Given the uncertainty, it is interesting that GPOs and manufacturers do not contract around this contingency. They continue to tacitly rely on the somewhat hazy default rule of excuse by impracticability.[142] On the one hand, the incentive for drug manufactures is clear. If they think that they will be governed by the default rule—e.g., because the issue is rarely litigated,[143] and they get away without having to pay penalties when a drug is not available on the market most of the time—then they have no incentive to push for a different contractual provision. For these suppliers, any additional provision would likely increase the frequency with which they have to reimburse buyers for failures to supply. Thus, drug manufacturers' failure to contract around the issue is unsurprising. GPOs, on the other hand, as well as their member hospitals, would benefit from more reliable penalties due upon delayed or cancelled performance by manufacturers. Part of GPOs' role in the market is to negotiate not only prices but also "other terms," including those that would cut down on "risk for members."[144] Perhaps GPOs think that the courts would side with them, as with AbbVie, if their losses were ever so significant as to justify litigation to recover damages.[145] Alternatively, bargaining over this additional

injectables face an equally, if not more, complex manufacturing environment, ... high margins earned by their products provide manufacturers with strong incentives to invest in trying to prevent disruptions to those products").

141. As discussed in note 128 above and accompanying text, penalties are rarely enforced, much less enforced *and then also* litigated. Given the thin margins of the generic drugs market discussed in Part IV.B above, it is the case that, at most, generic manufacturers behave as they do when thinking about other types of litigation: "opt[ing] to take . . . payment instead of continuing with litigation . . . . since the success . . . is by no means guaranteed." STUART O. SCHWEITZER & Z. JOHN LU, PHARMACEUTICAL ECONOMICS AND POLICY: PERSPECTIVES, PROMISES, AND PROBLEMS 87, 96 (3d ed. 2018).

142. *See* OFFICE OF ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 111 (noting that, "on average, GPOs recover just 10% of losses due to failure to supply" and attributing this to "[t]he erosion of failure to supply clauses" due to "Section 615 of the Uniform Commercial Code['s] suggest[ion] that failure to provide contracted products is not a breach of contract if the product is not available in the market").

143. *See supra* note 141.

144. Mulcahy & Kareddy, *supra* note 83, at 23.

145. *See* AbbVie Endocrine Inc. v. Takeda Pharm. Co. Ltd., No. 2020-0953, 2021 WL 4302920, at *4 (Del. Ch. Sept. 22, 2021) (finding that "AbbVie has experienced injury sufficient to sustain a finding of liability under appliable law"); *see also* AbbVie Endocrine Inc. v. Takeda Pharm. Co, No. 2020-0953, 2023 WL 5704055, at *3 (Del. Ch. Sept. 5, 2023) (discussing the measure of damages).

provision of a contract may not be worth it to GPOs. Given that joining a GPO is voluntary for hospitals and that hospitals choose their suppliers primarily based on cost, costly contracting around the default rule could lead to higher unit costs for hospitals that cause market share losses for the GPO in the downstream market for members.[146]

Thus, the market may find itself in this equilibrium because neither party to the agreement has an incentive to contract around the problematic default rule. The yearslong duration of these agreements may further aggravate this factor if "[t]he passage of time renders complete contracting both difficult and undesirable" when "the costs of allocating risks deemed unlikely to materialize at all, or only in the distant future, tend to exceed the current value of expected losses from the remote event."[147]

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146. The multi-tiered nature of these healthcare markets makes it difficult for hospitals or GPOs to prioritize outcomes other than unit price. According to experts, "[m]ost hospital payment arrangements for GSI drugs encourage hospitals to minimize spending on them"; take, for instance, Medicare, which bundles GSI drug reimbursement to hospitals with other parts of an inpatient stay. *Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective: Hearing Before the S. Comm. on Fin.*, 118th Cong. 2 (2023) (statement of Marta E. Wosińska, Senior Fellow, Brookings Inst.). Hospitals pressure GPOs to keep prices low. *Id.* GPOs, in turn, pressure manufacturers to keep prices low, which results in the manufacturer cost-cutting measures discussed in Part IV.B above that lead to quality issues and shortages. *See id.* Indeed, a 2014 study concluded that "[a] company must be price competitive to secure business regardless of its ability to show greater reliability. This dominance may act as a disincentive: manufacturers who invest in capacity may not see a market advantage if they cannot also compete on price." AM. HOSP. ASS'N, AM. SOC'Y OF ANESTHESIOLOGISTS, AM. SOC'Y OF CLIN. ONCOLOGY, AM. SOC'Y OF HEALTH-SYS. PHARMACISTS, INST. FOR SAFE MEDICATION PRACS. & PEW CHARITABLE TR., 2014 DRUG SHORTAGES SUMMIT 14 (2014), https://perma.cc/8GLL-CPE4. The study concludes that stronger failure-to-supply penalties can help incentivize quality improvements, but GPOs and other downstream payers must be willing to pay. *Id.* at 16 (recommending that market actors "[i]ncentiviz[e] capacity and reliability through contracts, such as through increased penalties in [failure-to-supply] clauses," inter alia); *see also* Eric Palmer, *Report: 'Carrot and Stick' Needed to Deal with Drug Shortages*, FIERCE PHARMA (Feb. 11, 2015, 3:25 PM), https://perma.cc/C5RL-DJJH (highlighting the potential upside of "a 'carrot and stick' approach with stronger failure-to-supply clauses in contracts so that producers believe it is less expensive to invest in quality than it is to lose contracts" but noting that "payers have to be willing to pay for that quality"). Some commentators also suggest that the GPO system prioritizes manufacturers who can pay hefty "fees" to GPOs rather than those that offer the lowest-cost drug. Phillip L. Zweig & Robert A. Campbell, *Response to "Drug Shortages and the Burden of Access to Care: A Critical Issue Affecting Patients with Cancer"*, 18 CLIN. J. ONCOLOGY NURSING 143, 144 (2014). It is hard to definitively know which explanations are true without copies of GPO contracts that are carefully guarded by the parties as trade secrets. Regardless, no one claims that reliability is the factor being optimized.

147. *See* Gillette, *supra* note 10, at 535. Note that this could also be consistent with the theory presented by Robert Scott, where "rational commercial actors will be motivated by a dominating objective: to reduce the risk of those contingencies over which one or the other has some measure of control," depending on whether one thinks of the

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That is to say that these parties may indeed be optimizing their joint surplus in a manner predicted by standard economics.

Alternatively, perhaps this is simply a case of the "profound path dependence" in contract provisions discussed in Part I above, which reflects a willingness to permit "contractual gaps . . . in even the highest-value transactions between the most sophisticated commercial actors," which can result in inefficient defaults.[148] One explanation for path dependence in this setting is that failure-to-supply provisions in drug supply agreements "can be the most hard fought-over 'what if' in the agreement and, after price and volume, the section of an agreement with a high potential to fracture a customer-supplier relationship."[149] The parties must agree on a large number of issues as part of this provision alone—e.g., the time required to trigger a failure-to-supply event; effects on exclusivity agreements and minimum purchase agreements; and supply disruption causation—on top of the contracted supplier's potential liability for the buyer's cost of procuring from secondary suppliers.[150] Thus, the number of first-order issues that the parties must negotiate over in order to include a failure-to-supply provision at all may lead them to de-prioritize others that they see as low-probability contingencies.

It may also be reasonable to think that the state of other competitors' supply in the market, including the *existence* of other competitors, is "beyond reasonable control" of the manufacturing party.[151] One could spend endless pages debating whether market conditions should be treated as if they were a superseding cause of the buyer's harm. Regardless, rather than leaving it up to default rules or to the courts, the parties could contract around it and decide for themselves whether failing to supply in a shortage should be treated as the manufacturer's fault. This Note argues that, at the very least, failing to supply (for reasons in the party's control) during a shortage should be treated as at least as worthy of penalty as failing to supply when not in a shortage. However, the current approach seems to treat the manufacturer as if entirely

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contingency as the manufacturer failing to supply or the state of the market being in shortage. Scott, *supra* note 10, at 615. The supplier certainly has some control over both, given that it is part of the market; however, that control may be too limited in the market-shortage contingency to induce even a rational firm to contract over it.

148. Nyarko, *supra* note 8, at 4, 24.

149. Hal Craig, *Supply Agreements—Does The 'Failure To Supply' Provision Have To Be So Difficult To Negotiate?*, OUTSOURCED PHARMA (Dec. 26, 2017), https://perma.cc/SG87-D328.

150. *See id.*

151. *Id.* (explaining that "[n]o supplier wants to be penalized for items beyond its control").

blameless during a shortage (e.g., as in a force-majeure event like a natural disaster).[152]

D. Examples of Failure-to-Supply Penalties in Pharmaceutical Product Supply Agreements

To show how supply agreements handle failure-to-supply penalties and the contingencies around such failures, this Note provides four example contracts with failure-to-supply (or inability-to-supply) penalties identified from the Securities and Exchange Commission's (SEC) Electronic Data Gathering, Analysis, and Retrieval (EDGAR) system. These examples are not specific to GPOs. They are the firm-to-firm analogs available from the SEC. However, they are instructive of firms' thinking and contracting about such penalties.[153]

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152. For a discussion of similar foreseeability inquiries during regulator-triggered shutdowns of drug-manufacturing plants in force-majeure defenses, see *Watson Laboratories, Inc. v. Rhone-Poulenc Rorer, Inc.*, 178 F. Supp. 2d 1099, 1113-14 (C.D. Cal. 2001). Note also that under either impracticability or force-majeure, the breaching party pays zero damages because performance is excused. Ayres & Gertner, *supra* note 47, at 731; Richard A. Posner, *Let Us Never Blame a Contract Breaker*, 107 MICH. L. REV. 1349, 1352-53 (2009) (noting that "strict liability for breach of contract . . . allows the parties to specify excuses for failure to perform, such as *force majeure*" or through "default excuse provisions, such as impossibility and frustration"); Richard A. Posner, *The Law and Economics of Contract Interpretation*, 83 TEX. L. REV. 1581, 1585 (2005) (explaining that, "although it is common for contracts to contain a *force majeure* clause, a court will, in the name of impossibility, impracticability, or frustration, read into a contract an implied excuse based on these common law doctrines, unless the contract rejects the excuse").

153. As an input to this Note, all documents from the EDGAR system's 10-Q and 10-K forms that contain the words or phrases "drug," "manufacturing," "supply agreement," and "inability to supply" were reviewed. These materials included agreements with distributors for final drug products and between manufacturers for active pharmaceutical ingredients. These materials excluded amendments as well as contracts involving licensing, commercialization, development, option, technology transfer, promotion, outsourcing, alliance, asset purchase, contract manufacturing, or collaboration agreements. Ideally, one would use a sample of group purchase agreements. However, these are not generally filed with the SEC as material contract exhibits. Material contracts are common 10-Q and 10-K exhibits because SEC Regulation S-K requires the public disclosure of all contracts that are "material to the registrant" that do not occur in the ordinary course of business. 17 C.F.R. § 229.601 (2024). Material contracts are generally those that investors would consider material, so, for instance, a yearslong purchase agreement seems likely to be material, whereas "contracts detailing the purchase of office supplies . . . are not likely to be considered material by investors." James A. Overdahl, *A Researcher's Guide to the Contracts of Firms Filing with the SEC*, 34 J.L. & ECON. 695, 696 (1991). Firms seem not to consider group purchasing agreements material (e.g., they reference group purchasing agreements in their 10-K or 10-Q filings but do not attach those contracts as exhibits). Nonetheless, relevant contracts that can still shed light on this analysis are supply agreements that

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A few different types of penalties are evident in these agreements. For example, in a contract between Aptuit and Zogenix, penalties are defined in what seems to be the standard way: the difference between the actual per-unit cost for Zogenix to purchase from a third-party supplier and the price negotiated in the contract with Aptuit times the number of units implicated by Aptuit's failure to supply.[154] The example agreement between Cosma and Evoke Pharma takes a similar approach.[155] In contrast, the agreement between Charles River Laboratories (CRL) and Tesaro Bio,[156] as well as the agreement between Pharmaceutica International, Inc. (PII) and Adolor,[157] define the failure-to-supply penalty as capped proportionally (e.g., at 110%) of the negotiated supply price.[158] These caps are striking because they seem to admit a

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are similar to group purchasing agreements but that arise between two individual firms.

154. Zogenix, Inc., Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (EX 10.1 to Form 10-Q), § 4.8 (May 9, 2019) ("[I]n the event of, and during the occurrence of, any Inability to Supply, if Zogenix elects to purchase any Drug Substance from a Third Party in order to replace the Drug Substance that Supplier could not deliver to Zogenix hereunder, then Supplier shall pay to Zogenix an amount equal to the product of: (a) the actual per unit cost for Drug Substance paid by Zogenix to such Third Party supplier less the applicable per unit cost for such Drug Substance Zogenix would have paid to Supplier hereunder; times (b) the number of units of Drug Substance actually purchased by Zogenix from such Third Party supplier.").

155. Evoke Pharma, Inc., Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (EX 10.3 to Form 10-Q), app. A (Aug. 15, 2016) ("Seller shall reimburse Buyer for the difference between the purchase price paid by Buyer for the duration of the Supply Interruption . . . and the purchase price . . . for the duration of the Supply Interruption.").

156. Tesaro, Inc., Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (EX-10.4 to Form 10-Q), art. 7.6.2 (May 9, 2017) ("To the extent Client incurs any additional costs or expenses as a result of a delay in or failure by CRL to supply, CRL shall promptly reimburse Client for such additional costs and expenses upon written invoice therefore with reasonable supporting documentation; provided, however, if Client is required to obtain Drug Product from an alternate source, CRL shall not be required to reimburse Client for more than [***] percent([***]%) of the supply price charged by CRL pursuant to Section 8.1 for such alternate supply of Drug Product.").

157. Adolor Corp., Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (EX-10.5 to Form 10-Q), art. 7.7 (Aug. 4, 2004) ("To the extent Adolor incurs any additional costs or expenses as a result of a failure by PII to supply, PII shall promptly reimburse Adolor for such additional costs and expenses upon written invoice therefor with reasonable supporting documentation; provided, however, if Adolor is required to obtain Drug Product from an alternate source, PII shall not be required to reimburse Adolor for more than one hundred ten percent (110%) of the supply price charged by PII pursuant to Section 8.1 for such alternate supply of Drug Product.").

158. Interestingly, the text of the provision in the Adolor-PII agreement is nearly identical to that of the Tesaro Bio-CRL agreement, even though neither party was a party to

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recognition by manufacturers that market prices could skyrocket under industry-wide shortages.

None of these agreements include a provision about what penalty the manufacturer would pay if the buyer cannot purchase from another manufacturer. The Aptuit-Zogenix and Cosma-Evoke Pharma example agreements are silent on the contingency of being unable to purchase from another manufacturer.[159] By specifying a contractual cap, the CRL-Tesaro Bio and PII-Adolor examples seem to acknowledge the possibility of (otherwise uncapped) reimbursement of costs incurred during failures to supply regardless of the ability to purchase from another supplier.[160] However, even these agreements provide no *details* about the specific penalty the manufacturer should pay.[161] Moreover, payment of these penalties is contingent "upon written invoice therefore with reasonable supporting documentation."[162] It seems challenging, if not impossible, to record the intangible but potentially near-infinite costs of a complete inability to procure a product in an invoice or other supporting documentation as required by this provision. So, although the specific approaches to failure-to-supply penalties that firms use may differ, a common thread across these examples is the absence of a clause specifying the amount to be paid by the supplier to the buyer when a significant inability or failure to supply occurs (for reasons other than force-majeure events such as natural disasters) and another supplier is not available in the market to fill the missing quantity.

E. Empirical Evidence from Earnings Calls

To gain additional insight into how pharmaceutical firms think about the penalties, this Note turns next to analyzing the text of a sample of earnings calls.[163] This Note focuses on the set of all (1,870) conference calls that ever mention the word "pharmaceutical" and either "inability to supply," "inability-

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both contracts. *Compare* Tesaro, *supra* note 156, art. 7.6.2, *with* Adolor, *supra* note 157, art. 7.7. This is consistent with the existing literature on "the prevalence of standard boilerplate in corporate documentation" driven by "both learning and network externalities." Marcel Kahan & Michael Klausner, *Standardization and Innovation in Corporate Contracting (Or "The Economics of Boilerplate")*, 83 VA. L. REV. 713, 715-16 (1997).

159. Zogenix, *supra* note 154; Evoke, *supra* note 155.

160. Tesaro, *supra* note 156, art. 7.6.2; Adolor, *supra* note 157, art. 7.7.

161. Tesaro, *supra* note 156, art. 7.6.2; Adolor, *supra* note 157, art. 7.7.

162. Tesaro, *supra* note 156, art. 7.6.2; *accord* Adolor, *supra* note 157, art. 7.7.

163. Tarek A. Hassan, Stephan Hollander, Laurence van Lent & Ahmed Tahoun, *Firm-Level Political Risk: Measurement and Effects*, 134 Q.J. ECON. 2135, 2136 (2019) (explaining that "[t]he vast majority of U.S. listed firms hold regular earnings conference calls with their analysts and other interested parties, in which management gives its view on the firm's past and future performance and responds to questions from call participants").

to-supply," "failure-to-supply," "failure to supply," "FTS," or "shortage" and that were held in conjunction with an earnings release by firms listed in the US. These transcripts were pulled from the Capital IQ Transcripts database of earnings calls made between January 1, 2008 and January 30, 2024.[164] This sample includes some firms that are not relevant to the discussion.[165] Therefore, Standard Industrial Classification (SIC) codes were manually identified for each company, and the relevant subset of transcripts is focused on firms in the relevant industries listed in Table 1 below.[166] This results in a sample of 752 transcripts associated with 286 firms.[167] Industries are then grouped by role (e.g., supplier, wholesaler, pharmacy, hospital, other). Overall, 5.1% of these transcripts mention failures-to-supply, 1.2% mention inabilities-to-supply, and a striking 95.9% mention shortages.[168]

164. This database is housed within Wharton Research Data Services (WRDS) and assembled by S&P Global and, according to the WRDS data dictionary, "provides historical conference call transcripts from around the world, covering approximately 8,000 public companies." WHARTON RSCH. DATA SERVICES, https://perma.cc/54M4-75RF.

165. Industries that are included in the initial set of earnings calls but dropped at this point include, for example, X-Ray Apparatus & Tubes & Related Irradiation Apparatus; Steel Works, Blast Furnaces & Rolling & Finishing Mills; Surgical & Medical Instruments & Apparatus; Orthopedic, Prosthetic & Surgical Appliances & Supplies; Arrangement of Transportation of Freight & Cargo; Services-Testing Laboratories, etc. It is understandable why these industries might have discussed the keywords during earnings calls; however, they are not relevant to the focus of this Note.

166. SIC codes are self-reported by firms in their disseminated EDGAR filings. *Standard Industrial Classification (SIC) Code List*, SEC, https://perma.cc/T4QB-9FTV (last updated June 3, 2021).

167. In this step, firm conferences presentations are also excluded, as these are not precisely comparable to the earnings calls discussed elsewhere.

168. See the calculations in the "overall" row of Table 1.

Table 1

SIC Code	Number of Transcripts	% Mentioning Failure-to-Supply	% Mentioning Inability-to-Supply	% Mentioning Shortage
Suppliers 2833: Medicinal Chemicals & Botanical Products 2834: Pharmaceutical Preparations 2835: In Vitro & In Vivo Diagnostic Substances 2836: Biological Products (No Diagnostic Substances)	581	6.0%	1.0%	95.3%
Wholesalers 5122: Wholesale-Drugs, Proprietaries & Druggists' Sundries	39	5.1%	0.0%	94.9%
Retail Pharmacies 5912: Retail-Drug Stores and Proprietary Stores	46	2.2%	4.3%	9.6%
Hospitals and Medical Offices 6324: Hospital & Medical Service Plans 8011: Services-Offices & Clinics of Doctors of Medicine 8062: Services-General Medical & Surgical Hospitals, NEC 8093: Services-Specialty Outpatient Facilities, NEC	17	0.0%	0.0%	100.0%

Other 8071: Services-Medical Laboratories	13	0.0%	0.0%	100.0%
Other 8731: Services-Commercial Physical & Biological Research	56	0.0%	1.8%	100.0%
Overall	752	5.1%	1.2%	95.9%

Taking a closer look at the text of these transcripts, it is particularly informative to focus on how *suppliers* think about failures to supply, given that they discuss these events in their earnings calls at a relatively high rate. A manual review of the 581 transcripts from suppliers[169] reveals that their references to supply failures fall into five broad categories. First, some suppliers talk about how they are "doing everything [they] can to stay away from any failure to supply type clauses in contracts."[170] Second, a few talk about their competitors' inability to supply the market as a good thing for their own bottom line.[171] Third, many mention an increase or decrease in supply issues and resulting penalties to explain lower or higher profitability in the last

169. This sample corresponds to the first row of Table 1 above.

170. *See, e.g.*, Thomas Werner, Hospira Inc., Q3 2012 Earnings Call (Nov. 7, 2012), https://perma.cc/QQU8-BPET (answering a question about concessions in recent GPO contracts with a discussion of how "[n]et-net, we view the renegotiation of these 3 GPO contracts to be neutral to positive," and how "in terms of concessions relative to manufacturing, I would say that we're doing everything we can to stay away from any failure to supply type clauses in contracts"); Elliot Wilbur, Akorn Operating Co., 2018 Earnings Call (Feb. 28, 2019), https://perma.cc/M7G4-9RUC (wondering "with respect to failure to supply provisions of some of your contracts . . . . how easily you can extract yourself from some of those").

171. *See, e.g.*, Paul Bisaro, Watson Pharmaceuticals Inc., Q4 2008 Earnings Call (Feb. 19, 2009), https://perma.cc/3RJT-2EYL (noting that, "with KB's [ph] current inability to supply both their brand and generic products, we are now the only supplier of Micro-K for the market"); Robert Matsuk, Glenmark Pharmaceuticals Ltd., Q3 2019 Earnings Call (Feb. 15, 2019), https://perma.cc/RG49-MKKZ (answering a question about peer companies' shift in focus from price to supply reliability with an explanation implying that competitors are still experiencing failures to supply and that Glenmark is benefitting as a result, noting that "on the product supply side . . . we kind of see, depending on the product, right, certain times we'll see a need to supply more depending on the situation," that "we'll see an ability to increase market share because of some supply problems," and that "I don't want to make any comments on failure to supply"); Douglas Boothe, Akorn Operating Company LLC, 2018 Earnings Call (Feb. 28, 2019), https://perma.cc/96F9-AE2U (expecting "a combination of the failure to supply to come down and greater throughput will help drive our top line and our bottom line results throughout the course of 2019").

quarter.[172] Fourth, a few talk about trying to enforce their own suppliers' obligations to supply.[173] Finally, some firms talk about steps they are taking to try to avoid failure-to-supply penalties, such as carrying extra inventory.[174] Thus, it seems as though failure-to-supply penalties can provide a strong incentive for manufacturers to avoid supply disruptions ("which potentially can drive [a firm] into bankruptcy"[175]) such that some companies even publicly discuss trying to avoid the provisions entirely.[176] However, this analysis relies on a selected sample. The piece *missing* from these conversations is the set of cases where the penalties were zero due to market-wide shortages such that baseline profitability was unaffected and discussion of such penalties with shareholders was unwarranted. Suffice it to say that, when failure-to-supply penalties do bind, firms find them to be a strong incentive against risky behavior that might result in a supply problem, but this is not the case when such penalties are excused.

172. *See, e.g.*, Thomas Werner, Hospira Inc., Q1 2011 Earnings Call (Apr. 26, 2011), https://perma.cc/FW7C-9KDH (answering a question about the state of the firm's propofol segment by flagging that performance was not as good in Canada as in the United States because "we did incur in the quarter some failure to supply penalties with respect to Canadian propofol"); Werner, *supra* note 170 (explaining that "[o]ur margins in the quarter were a little bit lower than we had initially expected" in part because of "failure to supply penalties, all related back to the quality issues and the supply issues"); Bryan M. Reasons, Impax Laboratories Inc., Q2 2016 Earnings Call (Aug. 9, 2016), https://perma.cc/4KMX-2V97 (noting that "[o]n the Generic side, lower failure-to-supply claims and trade accounts receivable reserves decreased expenses by approximately $6 million").

173. *See, e.g.*, Larry Hsu, Impax Laboratories Inc., Q3 2010 Earnings Call (Nov. 2, 2010) https://perma.cc/W7Y6-F7Y5 (noting that "[w]e are seeking to enforce Shire's obligation to supply Impax with product pursuant to our agreement"); Larry Hsu, Impax Laboratories Inc., Q4 2010 Earnings Call (Feb. 24, 2011) https://perma.cc/RE2U-D93P (relaying that "we announced litigation against the Shire, seeking to enforce their contractual obligation to supply Impax with product").

174. *E.g.*, Arthur Przybyl, ANI Pharmaceuticals, Inc., Q4 2018 Earnings Call (Feb. 27, 2019) https://perma.cc/F3F5-2M5J (explaining that "[w]e carry $40 million worth of inventory on the books for a $200-million revenue base business in order to avoid those failure-to-supply penalties"); Harvey Berger, ARIAD Pharmaceuticals, Inc., Shareholder/Analyst Call (June 26, 2012) https://perma.cc/9H8A-ZZ6A (answering a question about manufacturing by explaining that "we are working with multiple suppliers in different locations in and out of Europe to be able to do that. So obviously, to prevent the potential of undersupply, inability to supply, we're very attuned to that. We are not going to fail because of things like that. Because that's in our control").

175. Przybyl, *supra* note 174.

176. Werner, *supra* note 170.

F. The Case for Regulatory Disincentives upon Breach Due to Inability to Supply

GPOs and member hospitals are not the only ones harmed by incomplete provisions on failure-to-supply penalties during market-wide drug shortages. At the end of the day, "patients still need their therapies."[177] To the extent that experts think enforceable penalties could give manufacturers an incentive to address the quality issues that result in drug shortages before they become a problem, incomplete contracting has helped cause a realization of "the worst fears of patients" when, for example, "some people with aggressive cancers have been unable to get the treatment they need."[178] That is to say that, whether the underlying reasons for incomplete contracting are sophisticated or unsophisticated, these agreements can end up benefitting corporate entities "at the expense of the . . . patient."[179]

Given this reality, GSI manufacturers' failures to supply may be an appropriate setting for the type of regulatory solution discussed in Part III above. Specifically, failure-to-supply penalties may be best implemented through government regulation rather than a contractual provision. A recent set of pharmaceutical company interviews done by Pew Charitable Trusts suggests that "drug shortages could be reduced with improvements in . . . the relationships between a manufacturer, a provider, and *regulators*."[180] Moreover, imposing financial penalties on pharmaceutical firms is nothing new. A recent study found that the Department of Justice (DOJ), SEC, EPA, and state attorneys general together issued approximately $33 billion in fines to pharmaceutical firms from 2003 to 2016 (the equivalent of about $2.4 billion in fines each year on average) for things like "providing kickbacks and bribes, knowingly shipping adulterated or contaminated drugs

177. Craig, *supra* note 149.

178. Christina Jewett, *'I'm Scared to Death.' Behind the Shortage Keeping Cancer Patients from Chemo*, N.Y. TIMES (Dec. 19, 2023), https://perma.cc/A764-CXQ4.

179. COUNCIL ON MED. SERV., *supra* note 125, at 8. These contracts may benefit not only the manufacturers and GPOs who are parties to the contract but also hospitals. Hospital participation is voluntary, suggesting that they reveal their preference (at least relative to the outside option of negotiating on their own) for these GPO contracts by joining them. In contrast, patients do not have a substantive say in manufacturers' choice to cut costs in production, GPOs' failure to contract around the default rule on failures to supply when the drug cannot be procured elsewhere, hospitals' choice to join a GPO as a member, or hospitals' choice to (not) purchase a drug on the gray market during a shortage. They are left with what is available after the manufacturer, GPO, hospital, insurer, and government have made their own choices according to their own surplus functions.

180. PEW CHARITABLE TRS., DRUG SHORTAGES: AN EXPLORATION OF THE RELATIONSHIP BETWEEN US MARKET FORCES AND STERILE INJECTABLE PHARMACEUTICAL PRODUCTS: INTERVIEWS WITH 10 PHARMACEUTICAL COMPANIES 7 (2017) (emphasis added).

to pharmacies, and marketing drugs for unapproved uses."[181] In January 2013, the DOJ warned that it would take "an especially hard look whenever patients are placed at an unacceptably high risk of harm by . . . violations of [CGMPs]" and indicated a willingness to impose penalties in excess of $500 million in one recent case against Indian generic drug manufacturer Ranbaxy.[182]

However, the DOJ's ability to penalize companies for CGMP violations in the Ranbaxy case arose out of an interpretation of the False Claims Act (FCA) that was subsequently curbed by a Fourth Circuit decision the following year.[183] In *Rostholder v. Omnicare*, a former employee of a pharmaceutical services provider brought an FCA claim that the firm had sought government (Medicare and Medicaid) reimbursement for drugs that violated CGMP regulations.[184] Judge Barbara Milano Keenan held that, because CGMP compliance is not required for reimbursement, "Omnicare did not make any false statement merely by distributing adulterated products that were reimbursed, and the [former employee] could not state a claim under the FCA."[185] A similar result subsequently came out of *United States ex rel. Campie v. Gilead Sciences, Inc.*:

> [*United States* ex rel. *Hendow v. University of Phoenix*, 461 F.3d 1166, 1168 (9th Cir. 2006)] does not stand for the proposition that a falsehood told to a governmental regulatory agency can form the basis of FCA liability simply because the fraudulently induced action of that agency was part of a causal chain that ultimately led to eligibility for payment from the payor agency. Such causation is insufficient to state a claim under the FCA.[186]

As a result, it is now much more difficult for the DOJ to bring actions against manufacturers under the FCA for CGMP violations.

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181. Denis G. Arnold, Oscar Jerome Stewart & Tammy Beck, *Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities*, 324 J. AM. MED. ASS'N 1995, 1995-96 (2020).

182. Eric Sussman & Terra Reynolds, *cGMP Enforcement and Compliance in the Wake of Rostholder*, BLOOMBERG L.: PHARMA & LIFE SCIS. (July 22, 2015, 2:41 PM PDT), https://perma.cc/S82F-WTNQ (quoting Maame Ewusi-Mensah Frimpong, Deputy Assistant Att'y Gen., U.S. Dep't of Just., Address at the 2013 CBI Pharmaceutical Compliance Congress (Jan. 29, 2013), https://perma.cc/J3E3-AXED); Press Release, U.S. Dep't of Just., Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA (May 13, 2013), https://perma.cc/3U82-YDUH.

183. *See* Sussman & Reynolds, *supra* note 182; United States *ex rel.* Rostholder v. Omnicare, Inc., 745 F.3d 694, 703 (4th Cir. 2014).

184. *Rostholder*, 745 F.3d at 697. The FDA takes the view that "[i]f a company is not complying with CGMP regulations, any drug it makes is considered 'adulterated' under the law." *Facts About the Current Good Manufacturing Practices (CGMP)*, U.S. FDA (2023), https://perma.cc/ET8X-XCG9.

185. Sussman & Reynolds, *supra* note 182.

186. No. C-11-0941 EMC, 2015 WL 106255, at *10 (N.D. Cal. Jan. 7, 2015).

The FDA may be a more promising imposer of such penalties. The FDA issues Warning Letters, as discussed in Part IV.A above.[187] However, in addition to Warning Letters, the FDA can request recalls, bring seizure or injunction cases, and even "bring criminal cases because of CGMP violations, seeking fines and jail time" for both violations of the regulations.[188] Technically speaking, the "FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action, except in a few specifically defined areas" not relevant to the discussion here.[189] Nonetheless, "Warning Letters are issued to achieve voluntary compliance and to establish prior notice;" they are an *advisory* rather than an *enforcement* or *regulatory* action.[190] Although financial penalties could be concurrent, Warning Letters are generally the FDA's first step unless the violation is repeated, intentional, flagrant, presents a reasonable possibility of injury or death, intentional, or willful.[191] Since 2009, 46% of drug product inspections have resulted in the need for voluntary action, and 27% have resulted in a posted citation.[192] Figure 3 shows that these rates have been relatively constant over time. Given the persistently high frequency with which issues are discovered during inspections, the current approach's focus on warnings rather than enforcement action may be failing to disincentivize the type of fast-and-loose manufacturing practices that end up causing shortages and the potential for patient injuries while left undiscovered by inspections.[193]

187. These well-meaning Warning Letters about CGMP regulation violations are generally what trigger plant shutdowns and shortages. *See* Eglovitch, *supra* note 131 (noting that "enhanc[ing] communication between the investigators, the drug shortage team, and the compliance team . . . . on an ongoing basis and before, during and after an inspection" may help mitigate plant shutdowns).

188. *Facts About the Current Good Manufacturing Practices (CGMP)*, *supra* note 184.

189. U.S. FDA, *supra* note 95, ch. 4, at 3.

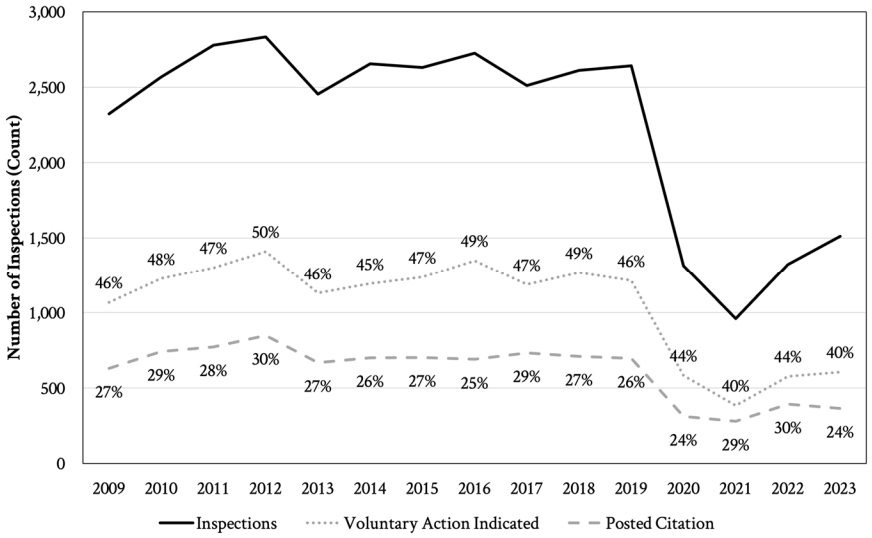
190. *Id.*; U.S. FDA, MAN-000007, REGULATORY PROCEDURES MANUAL ch. 4, at 8-9 (6th rev. 2021), ch. 6, at 5, https://perma.cc/2JWL-Y6NR.

191. U.S. FDA, *supra* note 95, ch. 4, at 4.

192. *Inspections*, U.S. FDA, https://perma.cc/7KDE-QSHY (archived Jan. 4, 2025).

193. For instance, in *In re Valsartan, Losartan, & Irbesartan Products Liability Litigation*, patients were "prescribed and used varying doses of Defendants' [valsartan-containing drugs to treat high blood pressure] for several years." MDL No. 2875, 2021 WL 100204, at *4 (D.N.J. Jan. 12, 2021). An FDA inspection later revealed CGMP violations that had caused the defendants' drugs to contain "probable human carcinogens," creating an increased "risk that [the patients] will develop cancer." *Id.*

Figure 3
FDA Inspections and Outcomes by Year: Drug Products FY 2009 to 2023



Voluntary compliance could be achieved even *before* a Warning Letter is issued if the financial incentives were structured to rationalize the cost-benefit analysis of safe manufacturing practices prior to an FDA inspection. The CGMP regulations are, after all, publicly available and accessible in 21 C.F.R. § 210-12.[194] Therefore, although Warning Letters may be helpful to show knowing violations in subsequent litigation, they are not strictly necessary "to establish prior notice" for a subsequent regulatory or enforcement action.[195] The FDA could impose the type of penalty discussed above alongside the Warning Letters to both encourage safe manufacturing practices generally and to decrease the likelihood of shortages triggered by FDA inspections that uncover violations. That most firms resolve the issues in the Warning Letter only after inspection but prior to monetary penalties being imposed suggests that these financial incentives would motivate better behavior among generic drug manufacturers.[196] After all, whether contractual or regulatory, "[t]he

194. U.S. FDA, *supra* note 95, ch. 4, at 31; *Current Good Manufacturing Practice (CGMP) Regulations*, U.S. FDA, https://perma.cc/5N4G-L84U (last updated Dec. 29, 2023).

195. *See Advisory Action Letters*, U.S. FDA, https://perma.cc/LJW6-T2YR (last updated May 1, 2023).

196. This is not necessarily true for nongeneric manufacturers, which are much more profitable than their generic peers. For example, the FDA fined Wyeth-Ayrest Pharmaceuticals, Inc. $4,155,000 in early 2002 after filing a Consent Decree of Condemnation and Permanent Injunction in 2000. *Bioresearch Monitoring Program: Warning Letter Issued to Clinical Investigator*, U.S. FDA (Mar. 1, 2016),
footnote continued on next page

remedy available against a breaching party will, of course, influence that party's decision whether to breach."[197]

Thus, the FDA may find it helpful in combatting drug shortages (and CGMP violations more broadly) to include civil monetary penalties alongside Warning Letters. Regulators could answer many of the questions that failure-to-supply contract provisions struggle to grapple with, such as supplier fault and the appropriate penalty. In doing so, regulatory penalties could ensure both that merchant parties can negotiate contracts efficiently and that any time a plant must temporarily shut down manufacturing, such as due to cost-cutting on good manufacturing practices, there is a financial consequence to deter such behavior.

V. Potential Risks and Reasons for Cautious Implementation

A risk with such penalties is that transaction costs will be higher and chill economic activity. However, the *regulatory* response to incomplete provisions would be unlikely to increase contracting costs given that parties would not need to contract around the default rule. The regulatory action that would follow a failure-to-supply would function like an immutable rule (but applied only when the context is deemed appropriate by regulators).[198] At worst, if the penalties are poorly calibrated, they "will motivate sellers to inform lawmakers of the problem and convince them to reform the rules"—either the U.C.C. rules or the FDA's regulatory power.[199]

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https://perma.cc/3W8J-TSZJ. These penalties were imposed "with respect to [Wyeth-Ayrest's] manufacture of drug and biologic (vaccine) products." *Id.* The Consent Decree resulted from an FDA inspection months earlier; Wyeth-Ayrest ultimately closed "a portion of its Marietta facility to address the issues raised during the inspection and to make other facility improvements." *Wyeth-Ayrest Laboratories Signs Consent Decree with FDA*, PHARM. ONLINE (Oct. 4, 2000), https://perma.cc/3CDR-GYMU. However, in 2000, Wyeth-Ayrest earned nearly $11 billion for its parent company, American Home Products (AHP), as indicated in AHP's March 2001 Message to Stockholders. John R. Stafford & Robert Essner, *Message to Stakeholders*, Am. Home Prods. (Mar. 6, 2001), https://perma.cc/K7H6-3JV5. Thus, the penalties that resulted from even this relatively extreme case amounted to less than 0.04% of Wyeth-Ayrest's revenue in the year the violations were discovered by the FDA inspection.

197. *See* A. Mitchell Polinsky, *Risk Sharing Through Breach of Contract Remedies*, 12 J. LEGAL STUD. 427, 427 (1983).

198. In the broader consideration of default rules versus immutable rules, legal scholars and academics suggest that "immutable rules are justifiable if society wants to protect . . . parties outside the contract [due to externalities]" and are "justified only if unregulated contracting would be socially deleterious" because the people harmed "cannot adequately protect themselves." Ayres & Gertner, *supra* note 5, at 88.

199. James Gibson, *Boilerplate's False Dichotomy*, 106 GEO. L.J. 249, 286 (2018).

The regulatory penalties discussed here also raise the possibility of parties taking safeguards that exceed the level of "efficient precautions."[200] For example, a manufacturer may spend too much money (relative to the potential social harm of not doing so) on quality control, equipment maintenance, or inventory to ensure that it does not violate warranties or supply requirements.[201] This concern relates to the familiar problem of defensive medicine among doctors who fear medical malpractice liability.[202] In the extreme, this could drive down industry profits to the point that firms exit and the industry becomes under-served or highly concentrated among only the largest suppliers. Indeed, counterfactual simulations from economic research predict this type of outcome "under large penalties [for failure-to-supply]" because "the cost of disruptions may become prohibitive for locations experiencing large supply shocks."[203]

However, this concern about inefficient precautions supports penalty-imposition by regulators, who can tailor the penalties to act as a deterrent but impose an amount specific to a firm's condition. This is an advantage of a regulatory rather than statutory or contractual solution to this problem. After all, "[t]he state generally does not tailor the contents of the law to people's [and firms'] characteristics and traits."[204] Moreover, the risk of over-precaution is relatively low in the pharmaceutical failure-to-supply penalty case discussed above because the penalties (when contracted over) are already defined as equivalent to the full value of the product in the market (i.e., "all of the losses actually caused by the defect" or supply event), which a regulator could emulate and thereby align with traditional law and economics conclusions of

200. Richard Craswell, *The "Incomplete Contracts" Literature and Efficient Precautions*, 56 CASE W. RSRV. L. REV. 151, 163 (2005) (exemplifying efficient precautions as a builder who "reduced the likelihood of using the wrong brand of pipe" by "spen[ding] more time and effort monitoring its purchase of supplies," or a product manufacturer who "reduce[d] the frequency of defective products by spending greater amounts on quality controls").

201. *See* Monu Bedi, *Contract Breaches and the Criminal/Civil Divide: An Inter-Common Law Analysis*, 28 GA. ST. U. L. REV. 559, 584-85 (2012) (explaining that, for example, "[i]mposing criminal [rather than civil] punishment may . . . prompt drivers to take additional inefficient precautions (e.g., driving very slowly)" and noting that "[t]he net effect here is the increase of inefficient activity").

202. *See generally* Daniel Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine?*, 111 Q.J. ECON. 353 (1996) (discussing concerns that physicians practice defensive medicine).

203. Galdin, *supra* note 112, at 51. Despite this, of the policies simulated, failure-to-supply penalties still yield "the most substantial reduction in the fraction of unfulfilled demand and the likelihood of shortages, for reasonably small penalty thresholds." *Id.* at 50.

204. Ariel Porat & Lior Jacob Strahilevitz, *Personalizing Default Rules and Disclosure with Big Data*, 112 MICH. L. REV. 1417, 1418 (2014).

optimal liability and precaution in incomplete contracts more broadly.[205] Thus, a regulatory solution to incomplete contracting that harms consumers can be designed to have the desired effect (e.g., shortage deterrence) without necessitating inefficient precaution.

Conclusion

In summary, GSI shortages exemplify situations where merchants engage in incomplete contracting that harms everyday consumers who are not themselves parties to the agreement. Whether commercial parties fail to contract around these rules for economically rational reasons, such as the costs of contracting, or economically irrational reasons, such as path dependence in contract drafting, merchant parties seem content with the status quo. However, this status quo can result in significant welfare losses, such as medical patients being unable to obtain necessary medications.

Therefore, there is a compelling case for regulators to step in to fill the gap with tools like civil money penalties that would provide an incentive to invest in robust manufacturing processes where failure-to-supply clauses that ultimately result in zero-dollar penalties fall short. Further work is needed to identify details like the optimal level and mode of implementation for such regulatory action. This Note simply opens the door to such work by identifying situations where default rules fall short and where regulatory and contractual tools can complement each other to improve the well-being of members of society who are otherwise at the whim of corporate contracts and the incentives created therein.

This Note also brings ideas from the legal and economics scholarly literatures into more direct conversation with each other—taking lessons from robust economic simulations of how firms would respond to policy changes and combining them with insights from legal scholars about problems that could arise when amending the current legal regime and how economists' proposed solutions might be constrained or enhanced by existing legal structures. Thus, it goes beyond the standard conceptualization of law and economics as "the economic analysis of law"[206] and moves toward an idea of the field as "research where legal and economic dimensions *intersect*."[207]

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205. *See* Craswell, *supra* note 200, at 164 (citing Lewis A. Kornhauser, *Reliance, Reputation, and Breach of Contract*, 26 J.L. & ECON. 691 (1983)).

206. *See* Paul H. Rubin, *Law and Economics*, ECONLIB, https://perma.cc/KP2R-DEZE (archived Jan. 4, 2025).

207. *See European Journal of Law and Economics*, SPRINGER NATURE, https://perma.cc/5U6W-5A8S (archived Jan. 4, 2025) (emphasis added).