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PREDICTING PHARMACEUTICAL SUPPLY-CHAIN DISRUPTION USING SOURCING, CAPACITY, REGULATORY, AND DEMAND SIGNALS

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ABSTRACT

Drug shortages and supply-chain interruptions pose significant risks to patient care, disrupt clinical decision-making, and generate substantial operational costs for health systems, often preceded by observable signals in sourcing, manufacturing capacity, regulatory quality events, and demand volatility. Current pharmaceutical supply-chain risk management largely relies on manual monitoring, retrospective shortage reporting, and simple threshold-based escalation, which are limited in their ability to integrate heterogeneous signals or detect emerging disruption patterns that deviate from historical events. To address these limitations, this article proposes a conceptual predictive model designed to estimate the probability and timing of pharmaceutical supply-chain disruptions, with a focus on sourcing risks, manufacturing capacity constraints, regulatory inspection signals, and demand-side volatility. The approach leverages a gradient-boosted classification model trained on historical shortage events and aligned time-series predictors, including features such as supplier concentration, plant capacity utilization, enforcement action indicators, drug-specific demand trends, and seasonality. Conceptually, the model would function as an early warning system for high-risk supply nodes, ranking contributing factors to enable targeted mitigation before shortages impact patients. By integrating operational, regulatory, sourcing, and demand signals, this predictive framework has the potential to shift pharmaceutical supply-chain management from reactive response to proactive resilience planning, enhancing medicine availability and strengthening public health preparedness.

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Introduction

Pharmaceutical shortages arise from interacting vulnerabilities across sourcing, manufacturing, quality, distribution, and demand, rather than from a single isolated failure. Empirical work on drug shortages has linked disruption risk to manufacturing quality failures, production reliability, and supply-chain fragility [1], while broader shortage analyses emphasize how raw-material constraints, market concentration, and regulatory delays can compromise access to essential medicines [2]. Surveys of hospital pharmacy practice show that shortages repeatedly affect medication substitution, procurement effort, and clinical continuity [3]. These patterns indicate that current early-warning systems remain too reactive when they depend mainly on shortage declarations after supply has already deteriorated.

The pharmaceutical supply chain is surrounded by data streams that could support earlier detection, including sourcing records, manufacturing schedules, quality inspection histories, demand forecasts, and inventory signals. Regulatory strategies for medicines shortages increasingly recognize the need to connect manufacturing and market authorization information with supply-continuity monitoring [4]. Hospital-level optimization studies further show that inventory and replenishment information can be structured for shortage prevention rather than only for stock control [5]. However, these data streams are often fragmented across regulatory authorities, manufacturers, wholesalers, and health systems, limiting their use in integrated predictive analytics.

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Supervised machine learning offers a framework for learning disruption precursors from historical events and combining heterogeneous operational signals into a unified risk estimate. Predictive studies using pharmacy and shortage data suggest that machine learning can help identify drugs at elevated risk before conventional monitoring would escalate them [6], and related validation work has shown how shortage-management prediction can be framed as a practical decision-support problem [7]. In broader supply-chain settings, artificial intelligence has been proposed for risk detection, disruption classification, and resilience planning when conventional models are too rigid for complex networks [8]. These findings motivate a pharmaceutical-specific model that links sourcing, capacity, regulatory, and demand information in a single predictive workflow.

The central thesis of this manuscript is that a predictive model integrating sourcing, capacity, regulatory, and demand features could forecast pharmaceutical supply-chain disruptions before they materialize. A model trained on historical shortage events could assign a disruption probability to each product or product family over a future planning horizon, while also explaining which signals drive the risk score [9]. Simulation-based studies of epidemic disruption show that supply-chain impacts can propagate through production and distribution networks before they are visible downstream [10]. Therefore, an early-warning model should be designed not merely to classify risk, but to support timely procurement, quality, manufacturing, and allocation decisions.

Background

Pharmaceutical Supply-Chain Structure and Vulnerabilities

Pharmaceutical supply chains combine global sourcing of active pharmaceutical ingredients, specialized excipient supply, regulated manufacturing, quality release, distribution, and clinical demand fulfillment. Their vulnerability is amplified when products depend on single-source materials, limited production lines, or geographically concentrated manufacturing capacity [1]. Medicines-shortage reviews note that disruptions may originate upstream in raw-material supply, inside manufacturing through quality or capacity problems, or downstream through demand shocks and distribution bottlenecks [2]. This structure makes just-in-time inventory efficient under stable conditions but fragile when supplier failure, regulatory action, or demand escalation occurs.

Signals of Impending Disruption: Sourcing and Capacity

Sourcing and capacity indicators are central to disruption prediction because they describe the physical ability of the supply network to absorb shocks. Reliability-oriented pharmaceutical supply-chain models show that limited redundancy, insufficient buffer inventory, and constrained manufacturing capacity can increase shortage susceptibility [1]. Supplier vulnerability modeling in the pharmaceutical context also suggests that external hazards can affect upstream supply nodes and cascade into product availability risks [11]. A predictive system should therefore encode supplier concentration, alternate-source availability, utilization pressure, overtime patterns, downtime logs, and maintenance-related capacity interruptions as time-varying risk signals.

Regulatory Signals as Leading Indicators

Regulatory events can function as leading indicators when they reveal quality-system weaknesses that may later constrain production or importation. Medicines-shortage policy analyses emphasize that regulatory agencies increasingly monitor manufacturing and market signals because quality or compliance failures can precipitate supply interruptions [4]. Conceptually, warning letters, import alerts, repeat inspection deficiencies, and enforcement actions can be encoded as structured features representing recent quality-system stress. In a predictive model, these indicators should be temporally lagged so that the algorithm learns whether regulatory deterioration precedes later shortage declarations rather than simply coinciding with them.

Table 1 shows key regulatory events that can serve as leading indicators of potential medicine shortages, with examples and their relevance to predictive modeling.

Table 1. Regulatory Indicators as Leading Predictors of Medicine Shortages

Regulatory Event Type	Example(s)	Relevance to Predictive Modeling	Temporal Consideration
Warning Letters	FDA Warning Letter to manufacturer	Signals potential quality-system weaknesses	Should be lagged to detect predictive value
Import Alerts	Suspension of imported batches	Indicates compliance issues affecting supply	Use previous regulatory periods to model effect
Repeat Inspection Deficiencies	Multiple inspection observations	Highlights chronic quality failures	Lagged data helps determine causality
Enforcement Actions	Consent decrees, fines, recalls	Reflects systemic compliance or manufacturing problems	Incorporate temporal lag before shortages
Market & Manufacturing Signals	Production delays, recall trends	Combined with regulatory data to capture supply stress	Lagged to test if deterioration precedes shortage

Demand Fluctuations and Market Dynamics

Demand volatility can convert a manageable supply constraint into a shortage when prescription volumes, seasonal disease patterns, or emergency stockpiling exceed planned replenishment. Pandemic-era healthcare supply-chain research shows that epidemic outbreaks can rapidly alter demand and require more adaptive demand-management systems. Vaccine and emergency preparedness studies similarly illustrate how sudden public-health demand interacts with supply limits, allocation rules, and distribution capacity [12]. A pharmaceutical disruption model should therefore include rolling demand averages, trend changes, volatility measures, and seasonality indicators to capture the demand-side contribution to shortage risk.

Machine Learning in Supply-Chain Risk Management

Machine learning has been applied to supply-chain risk management as a way to recognize nonlinear relationships, combine diverse predictors, and update risk estimates as new data arrive. Reviews of artificial intelligence in supply-chain risk management describe applications in risk identification, disruption monitoring, and decision support [8]. Network-based learning has also been used to infer hidden supply-chain relationships, which is relevant when pharmaceutical sourcing dependencies are not fully transparent [13]. The gap for pharmaceutical operations is a product-level model that blends operational, regulatory, sourcing, and clinical demand data into an interpretable disruption forecast.

Model Development Overview

High-Level Disruption Prediction Framework

The proposed framework treats each pharmaceutical product or product family as a monitored unit with periodic snapshots of sourcing, capacity, regulatory, and demand information. Predictive work on drug shortages has already framed shortage risk as a supervised learning problem in which historical shortage labels can be connected to preceding product-level signals [6]. In this article, the model would output a disruption probability over a future planning horizon rather than a deterministic shortage declaration. The probability should be interpreted as a decision-support signal that can trigger review, contingency planning, and mitigation before the disruption becomes operationally severe.

Figure 1 illustrates the proposed early-warning architecture by linking fragmented sourcing, capacity, regulatory, and demand signals to temporally aligned features, calibrated disruption probability, interpretable risk attribution, and cross-functional mitigation playbooks.

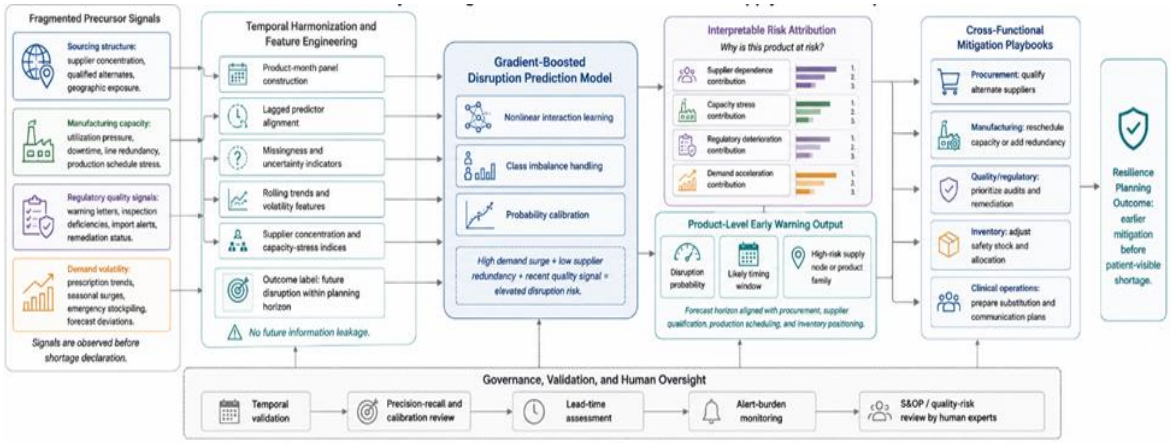

Figure 1. Predictive Early-Warning Architecture for Pharmaceutical Supply-Chain Disruption.

Core Input Features

Core input features should represent the major pathways by which pharmaceutical supply becomes fragile: supplier dependence, manufacturing capacity stress, regulatory quality deterioration, and demand acceleration. Supplier and capacity features can be informed by reliability models that emphasize redundancy, inventory, and production constraints [1], while regulatory features can reflect the role of quality oversight in shortage prevention [4]. Demand features should include product-level volume trends, seasonality, and abnormal surges, consistent with healthcare supply-chain models that incorporate epidemic-driven demand changes. The resulting feature vector should be mixed-type, time-indexed, and designed to remain useful even when some signals are delayed or incomplete.

Design Principles

The model should be designed for actionable lead time, interpretability, adaptability, and compatibility with regulated supply-chain governance. Because shortage prediction is useful only when it supports mitigation, the forecast horizon should align with procurement, supplier qualification, production scheduling, and inventory redistribution cycles rather than with immediate crisis response [7]. Interpretability is especially important because supply-chain managers must understand whether a risk score is driven by supplier concentration, capacity pressure, regulatory enforcement, or demand volatility. Adaptability

is also necessary because disruption patterns can change during crises, as shown by pandemic-related supply-chain research on epidemic impacts and resilience [10].

Data Sources and Feature Engineering

Compilation of a Disruption Dataset

A disruption dataset would link official drug shortage entries and internal company shortage records to historical time-series features describing the months before each event. Prior predictive work demonstrates the feasibility of using pharmacy and shortage-related data to construct models for drug shortage prediction and management [6, 7]. The longitudinal panel should align each product-month with sourcing, capacity, regulatory, and demand variables available at that time, so that the model learns from information that would have been visible before the disruption. This design supports realistic evaluation because it separates early-warning information from later shortage outcomes.

Sourcing and Capacity Features

Sourcing features should quantify dependence on limited suppliers, geographic concentration, and the availability of qualified alternatives. Pharmaceutical supply-chain reliability research supports representing redundancy, inventory, and production constraints as drivers of shortage vulnerability [1], while supplier vulnerability analysis shows how external shocks to upstream nodes can affect product continuity [11]. Capacity features should include production volume trends, utilization pressure, downtime, maintenance status, and line redundancy, transformed into indicators that can be compared across products. Supplier concentration could be expressed through indices such as a Herfindahl-Hirschman-style measure, while capacity stress could be represented through deviations from normal operating patterns.

Regulatory and Demand Features

Regulatory features should encode inspection and enforcement signals as temporally ordered indicators, including recent warning letters, import alert status, repeat deficiencies, or remediation activity. Shortage-management policy literature supports treating regulatory and quality information as part of proactive supply-continuity monitoring [4]. Demand features should summarize prescription or sales trajectories through rolling averages, trend changes, seasonality, and volatility descriptors, building on healthcare demand-management research that links sudden demand shifts to supply-chain strain. Together, these features would allow the model to distinguish products at risk because of upstream supply weakness from those at risk because demand is rising faster than replenishment capacity.

Table 2 organizes the proposed predictor domains into a feature-engineering framework that links observable sourcing, capacity, regulatory, demand, and inventory signals to specific disruption mechanisms and planning decisions.

Table 2. Feature Engineering Framework for Pharmaceutical Supply-Chain Disruption Prediction

Predictive Signal Domain	Representative Variables	Feature Engineering Logic	Disruption Mechanism Captured	Expected Decision Use
Sourcing concentration	Number of active suppliers, API supplier count, excipient-source dependency, single-source status, qualified-alternate availability	Convert supplier dependence into concentration indices, binary single-source flags, and redundancy scores	Captures vulnerability created when few suppliers or limited qualified alternates restrict substitution options	Prioritize alternate-source qualification, supplier diversification, and procurement contingency planning
Geographic sourcing exposure	Supplier region, manufacturing country, port dependency, regional hazard exposure, cross-border dependency	Encode regional concentration, multi-region redundancy, and exposure to geopolitical, climate, or transport disruption	Identifies products vulnerable to localized shocks that may propagate through upstream supply nodes	Guide geographic diversification and risk-adjusted sourcing review
Manufacturing capacity pressure	Capacity utilization, overtime use, production schedule compression, batch backlog, planned shutdowns, maintenance events	Generate rolling utilization trends, deviations from baseline, and capacity-stress flags	Detects when limited manufacturing slack reduces the ability to absorb demand changes or supplier delays	Trigger production rescheduling, line prioritization, and capacity-buffer review
Production reliability	Batch failure rate, release delays, downtime frequency, yield variability, line redundancy	Summarize recent production instability using lagged failure and delay indicators	Captures operational fragility before a formal shortage is declared	Support root-cause investigation, manufacturing risk review, and targeted reliability improvement
Regulatory quality signals	Warning letters, inspection deficiencies, import alerts, repeat observations, remediation status	Encode regulatory events as temporally lagged severity and recency indicators	Represents quality-system deterioration that may constrain production, release, or importation	Prioritize supplier audits, quality remediation, and regulatory-risk escalation

Demand trend	Prescription volume, order volume, sales demand, hospital utilization, procurement requests	Calculate rolling averages, month-over-month growth, and demand acceleration indicators	Detects demand-side pressure that may exceed replenishment capacity	Adjust forecasts, procurement quantities, and allocation planning
Demand volatility and seasonality	Seasonal peaks, epidemic-related demand spikes, emergency stockpiling, forecast error	Generate seasonality-adjusted volatility metrics and abnormal-surge indicators	Identifies products at risk when demand becomes unstable or abruptly elevated	Support safety-stock adjustment, surge planning, and clinical substitution preparedness
Inventory and replenishment signals	Days of supply, fill rate, backorder frequency, wholesaler availability, replenishment lead time	Convert inventory status into lagged depletion trends and replenishment-risk measures	Detects downstream deterioration that may signal emerging availability stress	Inform inventory positioning, redistribution, and early communication with clinical users
Missingness and uncertainty	Unreported capacity values, delayed regulatory updates, incomplete demand feeds, proprietary supplier data gaps	Include missingness indicators and confidence flags rather than assuming absence of risk	Distinguishes true low-risk conditions from incomplete visibility	Direct human review toward products with high risk or poor data observability
Historical shortage label	Official shortage declaration, validated internal shortage event, product-family disruption	Align outcome labels to future planning windows after predictor observation dates	Enables supervised learning while preserving early-warning temporal structure	Train and evaluate the model for forward-looking disruption prediction

Predictive Model Architecture

Model Choice – Gradient-Boosted Trees

Gradient-boosted tree models are appropriate for this conceptual architecture because pharmaceutical disruption data are likely to be tabular, mixed-type, nonlinear, and incomplete. Prior drug-shortage prediction studies indicate that machine learning can be applied to pharmacy and shortage datasets for operational risk identification [6], while broader pharmaceutical supply-chain optimization work has used machine-learning methods to support planning under complex constraints [14]. Gradient-boosted models would be expected to capture interactions such as high demand volatility becoming more concerning when supplier redundancy is low. Their outputs can also be paired with explanation methods, which is important when predictions must inform regulated operational decisions.

Input Feature Vector and Temporal Alignment

Each product-month would be represented by a feature vector containing lagged sourcing, capacity, regulatory, and demand variables that were observable before the forecast date. Temporal alignment is essential because predictive studies can otherwise overstate usefulness by allowing future information to leak into the training record [9]. Official shortage declarations or validated internal shortage records would define the outcome label, while upstream predictors such as regulatory events or supplier changes would be shifted backward to preserve the early-warning structure. This approach is consistent with disruption modeling in broader supply chains, where forward-looking simulation and prediction require careful separation of precursor signals from realized outcomes [10].

Output: Disruption Probability and Forecast Horizon

The model would output a calibrated probability that a product or product family will experience a supply-chain disruption within a defined future window. Predictive shortage-management work supports framing model output as a risk signal that can help prioritize attention rather than as a replacement for expert judgment [7]. Calibration would be important because managers may use the probability to compare products, set escalation thresholds, and decide when to activate mitigation playbooks. The forecast horizon should be long enough to support supplier qualification, procurement adjustment, inventory positioning, and production rescheduling, but short enough to remain connected to current operational signals.

Handling Imbalanced and Noisy Disruption Data

Imbalance in Disruption Events

Disruption prediction is naturally imbalanced because most marketed pharmaceutical products are not in shortage during routine planning cycles. Machine-learning studies of drug shortage prediction show that this imbalance must be addressed so that the model does not simply learn to classify most products as stable [6, 15]. A conceptual implementation could use class-weighted learning, threshold tuning, or sampling strategies to make rare disruption events more influential during training. The objective would not be to maximize alerts, but to preserve sensitivity to plausible early-warning patterns while limiting unnecessary operational burden.

Dealing with Noisy and Missing Signals

Pharmaceutical supply-chain data are often noisy because regulatory signals may be delayed, capacity indicators may be proprietary, and demand records may vary across markets or channels. Predictive models for hospital drug shortages and pharmaceutical supply chains show that usable signals can be assembled from imperfect operational data, but they must be

engineered carefully to avoid dependence on unavailable or inconsistent fields [16, 17]. Missing regulatory or capacity values should therefore be treated as informative uncertainty rather than automatically interpreted as low risk. Robust feature engineering would emphasize stable summaries, lagged trends, and transparent missingness indicators.

Temporal Validation and Avoiding Over-Optimism

Temporal validation should mimic real deployment by training on earlier periods and evaluating on later periods, rather than randomly mixing observations across time. Pandemic-focused supply-chain research demonstrates that disruption patterns can shift abruptly, making retrospective random validation especially vulnerable to overly optimistic conclusions [18]. A forward-time evaluation would test whether the model could have identified emerging risks using only information available before the disruption. This structure is also important for regulatory and quality signals, where later enforcement or shortage knowledge must not influence earlier predictions.

Model Interpretability and Supply-Chain Decision Support

Explaining Disruption Predictions to Supply-Chain Managers

Interpretability is essential because pharmaceutical supply-chain managers must understand why a model assigns elevated risk to a specific product. Machine-learning models for resilient pharmaceutical supply chains increasingly emphasize decision support rather than opaque automation [19, 20]. Explanation methods such as feature-attribution summaries could show whether a prediction is driven mainly by supplier concentration, capacity stress, regulatory deterioration, or demand volatility. Such explanations would help managers distinguish between a product that needs supplier diversification and one that requires inventory repositioning or quality remediation.

From Risk Score to Mitigation Playbook

A disruption probability becomes operationally useful only when it maps to specific mitigation actions. Blockchain- and machine-learning-based resilience models for drug and equipment supply chains highlight the value of linking risk visibility to coordination, traceability, and response planning [21]. If the main risk driver is single-source API dependence, the playbook could prioritize alternate supplier qualification; if the driver is rising demand volatility, it could support safety-stock adjustment or allocation planning. This decision-oriented interface would turn model output into structured managerial action rather than a passive dashboard signal.

Table 3 translates interpretable model explanations into supply-chain mitigation playbooks, governance safeguards, and evaluation indicators for practical resilience planning.

Table 3. Interpretation-to-Mitigation Matrix for Model-Guided Pharmaceutical Supply-Chain Resilience Planning

Dominant Model Explanation Pattern	Operational Interpretation	Primary Stakeholders	Recommended Mitigation Playbook	Governance Safeguard	Evaluation Indicator
High supplier concentration with limited qualified alternates	Product availability depends on a fragile sourcing base with minimal substitution flexibility	Procurement, supplier management, quality assurance, regulatory affairs	Begin alternate-supplier qualification, review API/excipient dependency, negotiate backup supply agreements, assess dual-sourcing feasibility	Confirm that supplier-risk data are current and that model explanations are not based on outdated vendor records	Reduction in single-source exposure; time required to activate alternate supplier
Capacity utilization surge with production-line redundancy gaps	Manufacturing network has limited slack and may not absorb schedule shocks or demand increases	Manufacturing operations, S&OP, production planning, technical operations	Reschedule high-risk products, reserve backup production slots, evaluate overtime or contract manufacturing options, review maintenance timing	Require S&OP review before major production-priority changes	Lead time gained before shortage; number of preventable production conflicts identified
Recent regulatory or quality deterioration drives risk	Compliance or quality-system signals may later restrict production, importation, or batch release	Quality assurance, regulatory affairs, supplier quality, compliance leadership	Prioritize supplier audits, accelerate corrective actions, increase quality monitoring, prepare regulatory communication plans	Ensure human review of enforcement-event severity and remediation context	Time from regulatory signal to quality-risk review; proportion of high-risk cases with documented action
Demand acceleration with otherwise stable supply	Supply base may be adequate under normal conditions but insufficient under surge demand	Demand planning, commercial operations, procurement, pharmacy operations	Update forecasts, increase safety stock, revise allocation logic, prepare clinical substitution pathways for essential medicines	Require review of demand anomaly source before escalating supply actions	Forecast-error reduction; alert lead time before inventory depletion
Combined sourcing fragility	A product with limited redundancy is exposed	Cross-functional shortage committee,	Activate integrated contingency planning:	Escalate to multidisciplinary review	Number of days of usable warning;

and demand volatility	to rapid demand changes, creating high shortage potential	procurement, clinical operations, S&OP	alternate sourcing, inventory repositioning, demand prioritization, and clinical communication	because mitigation requires coordinated action	mitigation completion before stockout
High disruption probability but weak explanation clarity	Model detects risk, but the available signals do not provide a clear causal pathway	Data science, supply-chain analytics, risk governance, domain experts	Conduct manual case review, inspect missing data, compare with external intelligence, avoid automatic escalation without explanation	Flag as "review required" rather than treating probability alone as sufficient	Percentage of high-risk alerts with actionable explanation
High uncertainty due to missing proprietary or delayed data	Risk estimate may be limited by incomplete visibility rather than true operational stability	Data governance, manufacturers, wholesalers, regulators, supply-chain leadership	Improve data-sharing agreements, add confidence scores, prioritize products with critical clinical dependence	Document data completeness and restrict overinterpretation of low-risk scores	Data completeness rate; number of critical products with insufficient visibility
Recurrent moderate risk across multiple months	Product shows persistent vulnerability even without a single acute trigger	S&OP, procurement, quality, portfolio risk management	Add product to resilience watchlist, review long-term sourcing strategy, assess market concentration and lifecycle constraints	Periodically reassess thresholds to avoid alert fatigue	Persistence-adjusted risk trend; watchlist conversion to mitigation action
Low probability but high clinical criticality	Model risk appears low, but patient-care consequences of disruption would be severe	Clinical pharmacy, medical leadership, procurement, emergency preparedness	Maintain contingency stock, define substitution protocols, monitor more frequently despite low predicted probability	Override model ranking using clinical criticality criteria	Coverage of essential medicine contingency plans
Model alert burden exceeds operational capacity	Prediction system may generate more alerts than teams can realistically evaluate	Supply-chain leadership, analytics governance, S&OP committee	Tune thresholds, prioritize by clinical criticality and lead time, group alerts by product family, suppress redundant alerts	Monitor alert fatigue and require periodic threshold recalibration	Precision-recall balance; number of alerts reviewed per planning cycle

Integration Into Pharmaceutical S&Op And Risk Management

Embedding in Sales & Operations Planning (S&OP) Cycles

The proposed model should be embedded into recurring S&OP cycles so that risk predictions are reviewed alongside demand forecasts, production plans, inventory positions, and supplier constraints. Pharmaceutical and vaccine supply-chain modeling studies show that resilience depends on coordinated planning across procurement, manufacturing, distribution, and demand management [12, 22]. Monthly model updates could support cross-functional review of high-risk products and prompt adjustments to sourcing, scheduling, and allocation plans. In this setting, the model would complement human planning judgment by highlighting products whose risk profile has changed before conventional shortage escalation occurs.

Supporting Regulatory and Quality Risk Assessments

The model output could also support quality risk management by linking supplier quality signals to supply-continuity risk. Lessons from hospital pharmacy crisis preparedness emphasize that shortage resilience requires earlier coordination among pharmacy, procurement, quality, and external stakeholders [23]. Regulatory and quality teams could use model explanations to prioritize supplier audits, remediation follow-up, or contingency planning for products exposed to repeated compliance signals. This integration would help connect quality oversight with commercial continuity, rather than treating regulatory risk and supply risk as separate domains.

Evaluation Strategy

Predictive Performance

Predictive performance should be evaluated with metrics suitable for rare disruption events, including discrimination, precision-recall behavior, and probability calibration. Prior drug-shortage prediction research supports evaluating whether a model can rank products by future shortage risk and support practical shortage-management decisions [6, 7]. Calibration is particularly important because the model's probability output would be used to compare products and prioritize mitigation effort. Evaluation should be performed on temporally held-out data so that the assessment reflects how the model would behave in prospective use.

Lead Time and Alert Burden

Evaluation should also consider whether alerts arrive early enough to support action and whether the number of alerts remains manageable for supply-chain teams. Empirical evidence on drug-shortage drivers suggests that causes may accumulate gradually across manufacturing, market, and sourcing conditions, creating opportunities for earlier warning when signals are

monitored together [24]. Supplier-side risk modeling further supports assessing whether upstream vulnerability indicators can provide useful warning before downstream disruption becomes visible [25]. The model should therefore be assessed not only for statistical accuracy, but also for whether its alerts are timely, explainable, and operationally tolerable.

Impact on Supply-Chain Resilience

The most meaningful evaluation would examine whether model-informed decisions strengthen pharmaceutical supply-chain resilience over time. Research on intertwined supply networks argues that resilience should be expanded toward viability and survivability, especially when disruptions propagate across connected supply and demand systems. A practical evaluation could compare shortage management before and after model implementation using historical controls, while avoiding claims of causal impact until prospective validation is completed. The expected contribution would be a more proactive risk-management process that identifies vulnerable products, supports mitigation planning, and reduces dependence on reactive crisis response.

Limitations

Data Access and Confidentiality

A major limitation is that many of the most predictive signals are proprietary, including detailed supplier audit findings, internal capacity forecasts, production-line downtime, and procurement constraints. Pharmaceutical shortage research shows that public data can support useful risk analysis, but it may not fully capture the internal operational realities that determine whether a product can be supplied continuously [1, 9]. Data-sharing barriers may therefore limit portability across manufacturers, wholesalers, regulators, and health systems. The model's usefulness would depend on governance arrangements that protect confidential information while allowing timely integration of risk-relevant signals.

Black-Swan Events and Rapidly Shifting Markets

A second limitation is that historical training data may not contain examples of unprecedented disruptions, such as novel pandemics, sudden trade embargoes, extreme weather shocks, or abrupt geopolitical restrictions. COVID-19 supply-chain studies show that epidemic disruptions can create demand and supply patterns that differ substantially from routine operating conditions [10]. A predictive model should therefore be paired with scenario analysis, stress testing, and expert review rather than treated as a complete substitute for resilience planning. This limitation is especially important for products with fragile sourcing structures or highly concentrated manufacturing networks.

Conclusion

The proposed predictive model would integrate sourcing, manufacturing capacity, regulatory, and demand-side signals to estimate the probability of pharmaceutical supply-chain disruption before shortages become clinically visible. It would transform fragmented operational data into an early-warning risk score for products and product families.

Its main strength is multi-modal data fusion across domains that are often monitored separately. By combining interpretable risk drivers with a planning-oriented forecast, the model could support supplier qualification, inventory adjustment, production scheduling, and quality risk management.

Important challenges remain around data confidentiality, cross-market generalization, and model robustness during unprecedented disruption events. These limitations mean that the model should support expert judgment and scenario planning, not replace them.

Future progress will require pre-competitive data sharing, collaborative pilots, and prospective validation across diverse pharmaceutical supply networks. Such collaboration could help determine whether predictive analytics can reduce shortage risk and improve medicine availability in practice.

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