JOURNAL OF OPERATIONS MANAGEMENT
ASCM ASSOCIATION FOR SUPPLY CHAIN MANAGEMENT

Call for Papers: Special Issue on

The Operations and Supply Chains of Pharmaceutical Products

Background

The pharmaceutical industry has many unique traits. Drugs with exclusivity fetch high prices and have high operating margins. The majority of drugs (approximately 90% of those consumed in the U.S.) do not have exclusivity; they are generics. Generics often face intense competition and sell at low prices, and are often produced in low-cost locations. Upstream suppliers—those that make active pharmaceutical ingredients (APIs), excipients, and key starting materials (KSMs)—are also often located in low-cost countries, and their operations are opaque to consumers and in some cases even to regulators. New drugs are being approved at an increasing rate, many through accelerated approval routes. At the same time, drug quality problems leading to adverse events and recalls are increasing. Product complexity, industry competition, and operational and supply chain complexities are some probable reasons for drug quality problems (Ball et al., 2018; Anand et al., 2012; Gray et al., 2011).

Federal health regulators play a key role in these operations and supply chains. The Food and Drug Administration (FDA) is the regulator in the U.S., the European Medicines Agency (EMA) in the E.U., and many others exist in different regions of the world. These regulators act with varying levels of coordination. The FDA and the EMA have harmonization agreements in place, while no such agreements exist with other countries such as India or China. Regulators not only control which drugs are approved to be sold but also monitor production and distribution compliance and product quality. Key monitoring activities include facility inspections, collecting and analyzing reported adverse events and product complaints, and overseeing drug recalls.

Pharmaceutical supply chains are also characterized by powerful middlemen, adding another source of complexity. Group purchasing organizations (GPOs), pharmacy benefit managers (PBMs), and distributors often have formed alliances to become powerful actors that influence supply chains, possibly affecting product quality, cost, and availability.

The industry faces numerous operations and supply-chain challenges. Despite the acknowledged quality benefits of collocation of manufacturing and R&D (Gray et al., 2015) and compliance risk when headquarters and plant location are in locations with different primary languages (Gray and Massimino 2014), the pharmaceutical value chain has become increasingly globally dispersed (Motamedi et al., 2021). The opacity of the industry means that consumers find it difficult if not impossible to know where their drugs were produced, so they cannot ascertain the quality history of the firm or plant that manufactured the drug or the quality history of the drug itself (Marucheck et al. 2011; Schulman 2020). Beyond quality concerns, drug shortages are becoming more common. Further, the cost of drugs remains a major public policy and healthcare

economics concern. And, there is a counterfeit supply chain that poses safety concerns for society, as well as profit concerns for the industry. Mail-order pharmacies present another interesting set of operations and supply chain challenges, including ensuring necessary environmental conditions for drug safety in transit.

The industry's operations and supply chains also play a key role in the manufacturing and distribution of billions of doses of vaccines. While largely successful, there were some manufacturing issues (e.g., Emergent Biosolutions manufacturing issues with the Johnson & Johnson vaccine) and supply chain issues (e.g., distribution to lower-income countries) associated with the recent COVID vaccine distribution efforts.

There has also recently been a push by governments to on shore or "friend-shore" manufacturing of critical drugs for national security reasons. For some APIs and KSMs, environmental concerns in high-cost countries present a possible barrier. High labor costs constrain the ability to move the production of many drugs to high-cost countries, possibly mitigated by advanced manufacturing technologies such as labor-reducing automation.

Special Issue (SI) Focus

This special issue (SI) intends to bring to the fore research that examines the operations and supply chains of the pharmaceutical industry. This includes research on how the industry's regulators affect the operations and supply chains. *The research must have a clear focus on operations and supply chains*, but we encourage cross-disciplinary work in the domains of public health, public policy, sustainability, consumer behavior, medicine, pharmacy, and other related disciplines. We also encourage (but do not require) collaborations with manufacturers, buyers, doctors, pharmacists, policymakers, and other practitioners.

We remind researchers to ensure that they adhere to the high standards of the *Journal of Operations Management* (*JOM*) by following the author guidelines. We encourage researchers to review the principles of Responsible Research in Business Management and follow them. We expect that any research published in this SI will serve towards the UN Sustainable Development Goal #3: Ensure healthy lives and promote well-being for all at all ages, either by informing managers or public policymakers about how to improve the production and supply of safe and effective drugs.

Some possible topics include, but are not limited to:

- How can the industry become more transparent? How does the level of opacity influence the operations and supply chains of pharmaceuticals? How does this affect quality, cost, and/or availability? Consumer choice?
- What role do pharmaceutical "middlemen" (GPOs, PBMs, distributors) play, and what role is appropriate to enable high-performing supply chains that produce drugs with high quality and at a low cost to the consumer while minimizing incidents of shortages?
- How do regulators' roles and actions influence supply chain, operations, and quality performance? What is done well and what should be done differently by these regulators to improve quality, availability, and/or cost?
- How are drugs distributed around the globe? How does this distribution approach influence quality, availability, and/or cost? What about mail-order pharmacies?

- What steps can industry and regulators take to reduce counterfeit-drug prevalence?
- How can post-market pharmacovigilance be improved from the firm's and/or regulator's perspective?
- How can regulators ensure drug quality and/or lower drug cost, while not stifling the pace of innovation?
- Which products can be economically produced in high-cost countries? Will advanced manufacturing make this more feasible?
- How do the supply chains of excipients and packaging affect resilience?

Timeline

Submissions must be received by **March 31, 2023**, with first-round decisions targeted by three months after the submission deadline. If they wish, authors may send short abstracts to the editors before the submission deadline for feedback on fit with the SI. We will begin to process submissions as they come in, so earlier submissions are welcome.

We encourage authors intending to submit to this SI to also submit an abstract to and attend the Industry Studies Association's 2023 conference, to be held in Columbus, Ohio, USA in late May, with abstract submissions generally due in mid-January. We hope to have tracks on the pharmaceutical industry and expect to have a plenary session on Operation Warp Speed. Of course, submission of an abstract and attendance at the conference are not necessary for submission to the SI and will not affect editorial decisions.

Guest Editors

Questions may be sent to any, or all, of the SI guest editors, at any time:

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