Re-Shoring of Generic Drug Global Supply Chain: An Exploratory Economic Analysis

Z. John Lu * and Ya-Chen Tina Shih

Posted Date: 14 February 2026

doi: 10.20944/preprints202602.1157.v1

Keywords: generic drug supply chain; cost of goods sold; operating profit margins; cobb-douglas production function; total factor productivity; cost increase

 doi:10.20944/preprints202602.1157.v1

Article

Re-Shoring of Generic Drug Global Supply Chain: An Exploratory Economic Analysis

Z. John Lu [1,2,*] and Ya-Chen Tina Shih [1]

[1] University of California, Los Angeles

[2] California State University, Channel Islands

* Correspondence: zjohnluucla@ucla.edu

Abstract

Low generic drug prices in the US have benefited from offshoring production to low-cost overseas plants in countries with a strong manufacturing base, such as China and India. However, the ongoing quality control and reliability issues with the supply chain of generic drugs have engendered discussions on the merits of "re-shoring". This study examines the potential economic impact of re-shoring generic drug production from China and India back to US/EU. We use a convenience sample of ninety publicly traded generic drug manufacturers headquartered in China (43), India (32), and the US and Europe (15). All firms have at least one production plant inspected by the US Food and Drug Administration between 2017 and 2019. Nearly 90% are vertically integrated and manufacture both active pharmaceutical ingredients and final drug formulations for generic drugs. The US/EU-based firms face significantly higher labor compensation costs, and experience lower operating profit margins compared to China- and India-based firms. We estimate a Cobb-Douglas production function of generic drugs for each region, using the real value of cost of goods sold (COGS) and the real value of total capital stock as input factors, and the real value of sales as output. We employ a fixed effect regression model for each region. We find that output is more responsive to change in COGS among China- and India-based firms, but less responsive in US/EU-based firms, while the output response to capital stock is greater in the latter. We use the same production function to estimate total factor productivity (TFP), a measure of overall production efficiency. The 95% confidence intervals for estimated TFP in each region overlap, suggesting TFP is not statistically significantly different across regions. We project the COGS for generic drugs will rise by at least 35-40% if production is reshored from China or India. Findings from our analyses highlight an urgent need for more in-depth economic analyses on how reshoring may increase costs and ultimately prices for generic drugs in the US/EU.

Keywords: generic drug supply chain; cost of goods sold; operating profit margins; cobb-douglas production function; total factor productivity; cost increase

1. Introduction

The Drug Price Competition and Patent Restoration Act passed by Congress in 1984, also known as the Hatch-Waxman Act, made an important contribution to equitable and affordable healthcare in the US. Since 2020, ninety percent of all dispensed prescriptions are filled with generic drugs which only account for less than 15% of the total spending on pharmaceutical products. In addition, prices of generic drugs in the US are among the lowest in the developed world (IQVIA 2020; Mulcahy et al. 2021), indicative of the fierce price competition in the US market.

There are two distinct stages in the pharmaceutical production process. The first stage is the production of Active Pharmaceutical Ingredients (APIs) that provide a drug's essential chemical components. The API process utilizes a series of chemical and biochemical synthesis to convert key starting materials into intermediates and then API, using several chemical agents to facilitate the

 doi:10.20944/preprints202602.1157.v1

synthesis, such as catalysts, reagents, and solvents. The second stage is the Final Drug Formulation (FDF) process in which API materials are combined with inert substances and reconstituted to produce a final product for consumers (Shivdasani et al. 2021). For a specific API, there could be several different formulations for the final product (tablets, capsules, or injections, etc.). The two production stages for generic drugs are often carried out in different facilities, either owned by the same firm, or by different firms. Several studies estimate that over 50% of the total oral generic drug cost can be attributed to the API production stage (Arnum 2006; Bumpas and Betsch 2009; Fortunak et al. 2014; Hill, Barber, and Gotham 2018).

Low US generic drug prices have benefited substantially from offshoring production to low-cost overseas plants in countries with a strong manufacturing base, such as China and India. In 2020, 29%, 16% and 13% of the generic API plants approved by the Food and Drug Administration (FDA) – meaning they are certified to manufacture products for the US market - are in India, China, and the US, respectively (White House Report 2021, p. 216; Socal et al. 2023). For plants making FDFs, 37% of FDA-approved facilities are in the US, while 26% and 8% are in India and China (ibid p. 217), respectively. In 2024, more than 60% of oral generic FDFs (by quantity) for the US market are manufactured in India alone (Wosinska 2025). US-based generic firms may import foreign-made APIs which are made into FDFs domestically or just import foreign-made FDFs (which most likely have already used foreign-made APIs) to be packaged and sold in the US (Cuddy, Lu, and Ridley 2023). More than 40% of injectable generic FDFs (by quantity) for the US market are still made in the US, followed by India, Europe, and China (Wosinska 2025).

The FDA does not directly test the quality of APIs or FDFs. Instead, it relies on periodic facility inspections to ensure a plant's adherence with Good Manufacturing Practices (GMPs). The offshoring of production sites en masse has presented a significant logistical and resource burden on the FDA (Schweitzer 2008). Since the contaminated heparin API crisis in 2008, the FDA has significantly increased resources for foreign plant inspections (GAO 2024). Starting in the late 2010s, the number of annual FDA inspections of foreign-based plants surpassed that of domestic inspections before the COVID-19 pandemic reversed this trend (Chenoweth, Liu, and Lu 2024).

India- and China-based firms account for a substantial portion of total foreign inspections since 2009. The FDA inspection data shows that a higher share of China- and India-based plant inspections results in plants receiving the Official Action Indicated (OAI) designation – indicating plants having serious deficiencies in compliance with GMP standards - compared to US based plants – even though foreign plant inspections are typically pre-announced (Gray, Roth and Leiblein 2011; Almeter et al 2022; FDA 2023). Nevertheless, a substantial number of deficiencies in GMP adherence in foreign plants continues to persist, and reports of substandard generic drugs sold in the US market are steadily on the rise (Frank, Mcguire, and Nason 2021; FDA 2025).

The ongoing quality control and reliability issues with generic drugs, along with national security concerns that a potentially strategic adversary may be controlling the US medicinal supply lines, have engendered much discussion on the necessity of "re-shoring" of generic drug production back to the US (White House Report 2021; Schulman, Kumar, and Adashi 2023). The obvious trade-off is that costs of labor (and possibly materials) will be higher, perhaps substantially, following re-shoring which in turn may lead to higher generic drug prices in the US. To our knowledge, there has been no systematic study on the magnitude of this trade-off. It is our hope that our study, preliminary as it may be, will encourage follow-on studies to fill this urgent knowledge gap.

We select generic manufacturers based in China, India, and the US and Europe (including the UK) from publicly available data in the period from 2017 to 2019. We do not use data from 2020 to 2023 due to the large-scale production interruptions from the Covid-19 pandemic. We examine the supply chain characteristics, estimate labor costs and material costs in the production stage, and calculate annual operating profit margins for firms based in each region. We lump US and Europe as one region to increase the sample size, and because most generic firms based in the US and Europe sell majority of their products in this region, and the organizational, managerial, and cost structures in these firms are similar.

 doi:10.20944/preprints202602.1157.v1

We use a standard 2-factor Cobb-Douglass production function to estimate the output elasticity of each factor for firms based in each region. We also utilize the C-D function to estimate the overall production efficiency by region. We then provide some estimates on how much the COGS for generic drugs sold in the US/EU may rise when the production is re-shored from China- or India-based firms.

2. Data and Methods

2.1. Firm Selection

Our analytical dataset is a convenience sample of generic drug-producing firms based in China, India, or the US/Europe that meet the following criteria:

1. Each firm owns at least one plant that was inspected by the FDA at least once between 2017 and 2019. The FDA maintains an on-going plant inspection database with inspection records on worldwide manufacturing facilities making food, cosmetics, devices, blood products, and pharmaceuticals for exports to the US market (FDA 2024A). We obtain information on drug plant inspections by selecting the Project Area tab of "Drug Quality Assurance" in the database. The owner firm of the plant is typically identified.
2. All selected firms must produce primarily generic drugs (either API or FDF exclusively, or both), according to the annual report. Some firms may have a small share of revenue coming from different lines of business (such as specialty drugs, or OTC drugs), but in many cases exact figures are not available. In those cases, we may err on the side of over-identifying generic firms to achieve a reasonable sample size.
3. The owner firm must have been publicly traded in at least one year during the period 2017-2019, on either a domestic (e.g., Shanghai Stock Exchange or SSE, Bombay Stock Exchange or BSE) or global stock exchange (e.g., New York Stock Exchange or NYSE, London Stock Exchange or LSE). This is to ensure we obtain firms' financial information in at least one year.
4. Annual reports (ARs) for each selected firm must be publicly available and will be used to collect supplemental information such as location of manufacturing plant(s), number of employees and labor compensation. Majority of the Chinese firms' ARs are written in Chinese, so some translation was performed by a research assistant fluent in Chinese. All US/EU and Indian firms publish ARs in English.

When selecting firms, the location of the headquarters of the owner firm is used as its base country, regardless of whether the firm also owns manufacturing plant(s) in other countries. Thus, the term China-based refers to a firm headquartered in China. Most plants owned by a firm are in the country the firm is headquartered in. Based on the readings of each annual report, we classified each firm into one of three categories: primarily generic API manufacturer, primarily generic FDF manufacturer, or both (meaning the firm is vertically integrated).

The final dataset includes a total of 43 China-based generic firms (129 firm-years), 32 Indian-based firms (95 firm-years), and 15 US/EU-based firms (44 firm-years). While most China- and India-based firms report financial information in their respective local currencies, all but one of the 15 US/EU firms report financial figures in USD. Please refer to Appendices 1-3 for the full list of firms included.

2.2. FDA Global Plant Inspection Record

Relying on a publicly available database containing FDA global drug manufacturing plant inspection records from 2008-2022, the Inspection Classification Database (FDA 2024A), we trace each plant inspection to the owner firm of the plant in that year. The plant location (country) is provided in the database, and the headquarter location (country) of the owner firm is obtained from the firm's annual report. We obtain the total number of plant inspections (all locations) each owner firm is subject to during 2017 - 2019.

 doi:10.20944/preprints202602.1157.v1

There are three possible outcomes from each plant inspection conducted by the FDA (FDA 2024B). The most favorable one is the classification of "No Action Indicated" or NAI, implying that the plant has an acceptable profile of compliance with GMP, and there is no issue that may warrant a regulatory action. Next is the classification of "Voluntary Action Indicated" or VAI, which indicates that some minor issues are discovered in the inspection, but the firm is expected to address them voluntarily, and a follow-up regulatory action may occur. The worst outcome is the classification of "Official Action Indicated" or OAI, signaling that serious compliance violations are found and the FDA will most likely take regulatory action, such as issuing a warning letter about the plant. The owner firm must respond to an OAI designation with a correction plan subject to FDA's assessment and approval. Failure to timely and properly respond could lead to product seizures or being placed on import ban list, as well as legal actions. We calculate the share of inspections resulting in an OAI designation for each owner firm.

2.3. Firm Operating Profitability

A firm's operating profit margin (or operating income margin) is defined as follows:

$$\text{Operating Margin}_{i,t} = (\text{Revenue}_{i,t} - \text{Cost of Goods Sold}_{i,t} - \text{Operating Expense}_{i,t})/\text{Revenue}_{i,t} \quad (1)$$

The subscript t denotes the year between 2017 to 2019 and i denotes individual firms. Costs of Goods Sold (COGS) are variable costs and include both labor and material costs in the production stage. Operating expenses (OE) typically include Selling and General Administration or SGA (including staff salaries and benefits, supplies and materials, space and equipment tied to SGA), Research and Development or R&D (including salaries and benefits, supplies and materials, space and equipment tied to R&D), Depreciation and Amortization (if applicable), and other operating expenses (e.g., software development, legal fees, etc.). Figures for COGS and OE are provided in the Consolidated Income Statement contained in the ARs or obtained online from a Yahoo Finance Premium subscription (which goes back to as early as 1985 or a firm's founding year, whichever is more recent). We calculate the operating profit margin in each year as well as for the entire 3-year period.

2.4. Estimation of Production Function for the Generic Drug Industry

We use a 2 factor Cobb-Douglas production function (Cobb and Douglass 1928) to characterize a typical generic drug production process, as follows:

$$Q = A * V^{\alpha} * K^{\beta} \quad (2)$$

In the original model specification by Cobb and Douglass, Q represents output, V represents labor and K capital stock in the production stage. Following the modern adoption in De Loecker, Eeckhout, and Unger (2020), in our model Q is the real (inflation-adjusted) net annual sales revenue, V the real value of COGS, and K the real net value of property, plant and equipment (NPPE). We use country specific GDP deflators (base year = 2019) and 2019 foreign exchange rates to calculate the real values (in USD$) for all three variables. The exponents α and β represent the output elasticity with respect to V and K, respectively. A is the Total Factor Productivity (TFP), which measures the combined efficiency of V and K in the production stage (Comin 2006).

Coefficients α and β can be estimated empirically by natural-log-transforming ($\log_e$ or ln) both sides of (2):

$$\ln Q = \ln A + \alpha \times \ln V + \beta \times \ln K \quad (3)$$

We use the Ordinary Least Square regression to estimate α, β and the intercept, lnA.

We include a firm-level fixed effect and a time variable in our region-specific model, specified in equation (4) below:

$$\ln Q_{i,t} = \ln A + \alpha \ln V_{i,t} + \beta \ln K_{i,t} + \gamma T_{i,t} + \text{FirmFE}_i + \varepsilon_{i,t} \quad (4)$$

 doi:10.20944/preprints202602.1157.v1

where t denotes year, i denotes individual firm, and ε is the error term. The variable T takes on the value of 1, 2, and 3, corresponding to the year 2017, 2018, and 2019, respectively. This regression will be run for each region separately. In addition to estimating the output elasticity to variable inputs embodied by COGS (α) and NPPE (β) in equation (4), the estimate for the intercept (lnA) and its natural antilog will provide the estimate for A, the TFP, in each region.

2.5. Estimate for Increase in COGS if Re-shoring Production from China or India

Let the old (offshored) unit COGS be denoted as C_o, then $C_o = W_o + M_o$ where W_o is the unit labor cost and M_o the unit material cost with offshored production. Similarly, let $C_n = W_n + M_n$ be the new (re-shored) unit COGS, unit labor, and material cost with re-shored production, respectively. If we can obtain estimates for W, M in China-, India-, and US/EU-based firms, the ratio of new to old unit costs for COGS, R_1, is given by

$$R_1 = (W_n + M_n)/(W_o + M_o) \quad (5)$$

Our task is to find reliable sources for estimates for W and M in both settings. We make a simplifying assumption that the unit material cost for generic drug production is the same across regions and will not change following re-shoring. We reason that any US/EU-based generic drug producer should be able to source materials from anywhere in the world, and energy costs in China and India fluctuate greatly and may even be higher than what is in the US, a major producer of energy. If there is no overall productivity difference between firms located in different regions, W_n and W_o then represent the productivity-adjusted unit labor costs. Thus:

$$R_1 = (W_n + M_o)/(W_o + M_o).$$

If we can estimate the ratio of unit material to unit labor costs during the *offshored* production stage, denoted as m, R_1 becomes

$$R_1 = (W_n + mW_o)/(W_o + mW_o) \quad (6)$$

It is easy to see that R_1 rises with W_n, the unit labor cost in the region where production is re-shored to. Differentiating R_1 with respect to m, it is not difficult to show that R_1 also rises with lower m – meaning that COGS will rise faster if re-shoring is from the region where material is less expensive relative to labor. As it is easier to find sources for unit labor cost in all three regions, our main task becomes how to estimate m, the ratio of unit material to unit labor costs during *offshored* production.

2.6. Unit Labor Compensation Cost in Generic Drug Manufacturing in China, India, and the US/EU

We look for data on total labor compensation cost, which includes both direct wages and fringe benefits such as retirement, vacation, and health benefits, etc. for firms located in each region. For China-based firms, we rely on both firms' ARs and Moomoo.com, a Hong Kong based and Nasdaq listed global investment and trading platform with operations in China, the EU, Japan, US, and Singapore and Australia (Moomoo 2025). Information on total labor compensation costs (including benefits) paid by firms is provided in the category of "Staff behalf paid" (under the Cash Flow tab), and the number of employees is consistently provided in the ARs. We then calculate the average annual labor cost *per employee* for each firm. Many of the India-based firms included provide figures for total labor compensation, total material costs and total number of employees in the ARs, allowing us to estimate the average annual labor cost *per employee* as well.

However, average labor cost *per employee* is different from average labor cost *per production worker*, and in most industries the latter is less than the former. We cannot directly obtain the labor cost per production worker from financial statements. However, the ratio of average annual labor cost per production worker to average annual labor cost per employee in China- and India-based

 doi:10.20944/preprints202602.1157.v1

manufacturing sectors is publicly available (U.S. Bureau of Labor Statistics or USBLS 2013, National Bureau of Statistics of China 2020).

For US/EU-based firms, data on labor or material costs is rarely provided in ARs. We turn to USBLS (2020), which provides random survey data on wage and number of employees by type of positions in most industrial sectors classified by the North American Industry Classification System (NAICS). The code value of 325400 represents the Pharmaceutical and Medicine Manufacturing Industry. Although this code includes both the branded and generic drug sectors, we reason that wages for production workers are unlikely to be much different between them. We choose 16 positions related to drug production and calculate a weighted (by number of employees in each position) average of annual labor wage. The same BLS data also show benefits is around 42% of annual wages for private sector workers, allowing us to estimate the total annual labor compensation.

To obtain the hourly labor compensation cost (i.e., unit labor cost), the annual compensation figure is divided by 2,000 hours in all three regions. It turns out for the EU countries represented in our sample, the average hourly labor cost in the manufacturing sector is similar to the US (Eurostat 2023).

2.7. Unit Material Cost and Unit COGS in Generic Drug Manufacturing in China, India, and the US/EU

Some, but not all India-based firms report total labor and total material costs separately. However, the figures usually include costs from all the divisions in a firm, including production, sales, general administration, R&D, etc. Because most of the total material costs come from production, but not so for the total labor costs, the ratio of firm-wide material to labor costs is not a good measure of such a ratio in only the production stage.

As most China-based firms are domestic and report the number of production workers each year, we use the estimated unit labor cost described in the last section to estimate the total labor costs in the production stage, which is unit labor cost multiplied by number of employees. We then estimate the total material costs in the production stage by subtracting total labor costs from the COGS and compute the ratio of the two to produce an estimate for m – the ratio of unit material to unit labor costs. Assuming the unit material cost and overall productivity in generic drug production are the same across regions, we estimate the unit COGS in as follows:

Let $C_a = W_a + M_a = W_a + mW_a$ be the unit COGS for China-based firms. Then, $C_i = W_i + M_i = W_i + mW_a$ will be the unit COGS for India-based firms, and $C_u = M_u + W_u = W_u + mW_a$ the unit COGS for US/EU-based firms. As W_a, W_i, W_u and m are all estimable, C_a, C_i, and C_u are estimable. Plugging in the estimated unit COGS in each region in equation (6) then produces a preliminary estimate for how much COGS will rise following re-shoring (from China to US/EU, and from India to US/EU).

3. Results

3.1. Characteristics of Publicly Traded Generic Drug Manufacturers Inspected by the FDA

Tables 1A – 1C provide key summary statistics on public generic firms based in each country over the period 2017-2019. While Table 1A focuses on key financial characteristics, 1B examines organizational characteristics, and 1C looks at subgroups defined by the vertical structure and whether a firm is entirely domestic (i.e., without any plant located outside the region where the headquarters is located). In general, less financial data are available for US/EU-based firms.

Table 1. A. Financial Characteristics of FDA Inspected, Public Generic Manufacturing Firms: 2017-2019*.

Characteristic	China-based Firms (n=43 firms, 129 firm-years)	India-based Firms (n=32 firms, 95 firm-years)	US/EU-based Firms# (n=15 firms, 44 firm-years)
	Mean (Median)		

 doi:10.20944/preprints202602.1157.v1

Annual Revenue per Firm (in millions)	$676.7 ($351.9)	$775.5 ($286.6)	$4,042 ($2,114)
Employees per Firm	4,503 (2,998)	7,552 (3,418)	9,489 (3,285)
Cost of Goods Sold (COGS) as % of Sales	50.5 (52.1)	45.6 (44.6)	56.3 (56.2)
Operating Expenses (OE) as % of Sales	33.3 (30.2)	42.3 (44.6)	37.4 (33.0)
Capital Stock per Employee	$82,900 ($71,500)	$61,900 ($50,600)	$157,200 ($127,900)
Per Employee Annual Labor Compensation Cost^	$16,300 ($14,800)	$20,000 ($14,100)	NA
Production Workers Share of Total Employment^	47.7% (47.3%)	NA	NA
Material to Labor Cost Ratio *in Production*^	10.25 (8.52)	NA	NA

*All financial figures are in 2019 USD. Currency Conversion: 1 USD=6.91 RMB, and 1 USD=70.42 INR. (https://data.oecd.org/conversion/exchange-rates.htm). #Of the 15 selected firms based in US-EU, one firm each is based in the UK, Germany, and Switzerland, and 3 firms are legally domiciled in Ireland and one in Israel but with most of their operations being US based. ^Data for 2019 only.

Table 1. B. Organizational Characteristics of FDA Inspected, Public Generic Manufacturing Firms: 2017-2019.

Characteristic	China-based Firms (n=43 firms)	India-based Firms (n=32 firms)	US/EU-based Firms (n=15 firms)
Mean Only (except Number of FDA Inspections)			
% Firms with >1 Plants in US*	7.0	43.8	93.3
% Firms with >1 Plants in China*	100	25.0	46.7
% Firms with >1 Plants in India*	2.3	100	60.0
% Firms without any foreign plant* (Domestic Production Only)	90.7	56.3	20.0
% Firms producing BOTH API and FDF* (Vertically Integrated)	88.4	84.4	86.7
% Firms Both VI and Domestic Only*	79.1	40.6	13.3
% Firms producing API only*	11.6	12.5	0.0
% Firms producing FDF only*	0	6.3	20.0
Number of FDA plant inspections (mean/median)#	1.88 (1)	6.38 (4)	6.5 (6)

 doi:10.20944/preprints202602.1157.v1

% of inspections resulting in FDA letter of "Official Action Indicated" (OAI) #	13.1	8.6	4.4

*Data for 2019 only #Over 3 Years 2017-2019.

Table 1. C. Selected Characteristics of FDA Inspected, Public Generic Manufacturing Firms: By Vertical Structure and Geography of Operation*.

Characteristic	China-based Firms (n=43)		India-based Firms (n=32)		US/EU-based Firms (n=15)	
	VI (n=38)	Domestic (n=39)	VI (n=27)	Domestic (n=18)	VI (n=13)	Domestic (n=2)
	Mean (Median)					
Employees per Firm (2019)	4,901 (3,245)	4,482 (3,011)	8,429 (4,411)	3,689 (1,693)	4,618 (2,775)	Too few data points
No. of FDA Inspections (3 years)	2.0 (1)	1.9 (1)	7.0 (4)	4.2 (3.3)	6.8 (5.5)	
% of Insp Resulting in OAI letter (3 years)	9.5 (0)	14.4 (0)	10.1 (0)	4.2 (03)	4.0 (0)	
COGS as % of Sales (3 years)	48.9 (49.6)	50.3 (52.1)	43.7 (42.3)	51.0 (53.6)	55.6 (55.2)	
OE as % of Sales (3 years)	35.5 (34.0)	33.8 (32.4)	44.9 (45.7)	39.3 (38.9)	33.5 (30.4)	
Per Employee Annual Labor Compensation Cost^	$16,900 ($15,400)	$15,700 ($14,700)	$21,600 ($15,700)	$12,000 ($12,100)	NA	NA
Material to Labor Cost Ratio in *Production*^	10.76 (8.46)	10.38 (8.52)	NA	NA	NA	

*All financial figures are in 2019 USD. Currency Conversion: 1 USD=6.91 RMB, and 1 USD=70.42 INR. (https://data.oecd.org/conversion/exchange-rates.htm) ^Data for 2019 only.

As indicated in Table 1A, the average annual revenues among US/EU-based firms are about 5-6 times larger than those based in India and China, and these firms also tend to have more employees. The COGS as a percentage of annual sales is the highest in US/EU-based firms, and lowest in India-based firms, while the share of the operating expenses (OE) is just the reverse with India-based firms being the highest. The US-based firms have the highest capital stock per employee, and India-based firms the lowest. The annual per employee labor compensation cost estimated in our study is over $16,000 for China-, and $20,000 for India-based firms. In China-based firms, nearly 50% of the employees work in the production stage. We estimate that in China-based generic drug firms, the ratio between unit material to labor costs in the production stage averages above 10 (median = 8). Such ratios for India- and US/EU-based firms are not estimable due to data limitation.

We note in 1B that substantial differences between China- and India-based firms in the propensity to have at least one manufacturing plant located in the US: 7% vs. 44%, respectively. In addition, 25% India-based firms have at least one manufacturing plant in China, while only 1 out of 43 China-based firms has a plant in India. Forty-seven percent and 60% of the US/EU- and India-based firms respectively have at least one manufacturing plant in China. While most China-based

 doi:10.20944/preprints202602.1157.v1

firms (91%) are domestic in manufacturing, nearly half and 80% of US/EU- and India-based firms respectively are global in manufacturing capacity. About nine out of 10 firms in all regions produce both APIs and FDFs, with a very small minority of firms in each region producing either API or FDF only, indicating vertical integration in the generic drug global supply chain is quite common. On average, US/EU- and India-based firms receive a similar number of FDA inspections over the study period, which is much higher than that received by China-based firms. The US/EU-based firms have the lowest inspection failure rate (i.e., resulting in an OAI designation by the FDA), while China-based firms have the highest rate.

Table 1C presents some key statistics from subgroup analyses based on a firm's vertical structure and whether production is exclusively domestic. As most China-based firms are both vertically integrated (VI) and produce only domestically (D), results by subgroup are not different, with the exception being the FDA inspection failure rate: VI firms experience a lower failure rate compared to the D firms (9.5% vs. 14.4%). While a large majority of India-based firms are VI, slightly more than half of the firms operate domestically only, and these D firms on average have less employees, are inspected less often, and have a lower failure rate. More importantly, the per employee annual labor compensation cost in the domestic only Indian firms is much lower than that in the VI firms ($12,000 vs. $21,600). This is likely because many India-based VI firms operate globally and therefore incur significantly higher labor costs.

3.2. Unit Labor Compensation Cost

Table 2 provides estimates for *per employee* annual labor compensation cost, *per production worker* annual and hourly labor compensation cost in 2019. Note that the estimates for China- and India-based firms are for those with exclusively domestic plants. This is to ensure labor cost estimates in the two countries are not biased upward by inclusion of those firms that own US/EU-based plants (and presumably pay higher wages). For the US/EU-based firms, we obtain the weighted average of hourly wages plus 42% for benefits for 16 types of position related to the drug production stage in the U.S. Pharmaceutical and Medicine Manufacturing Industry. As expected, the labor cost advantages enjoyed by China- and India-based firms are substantial: the US/EU-based firms grapple with an average hourly labor cost for production workers that is more than 9 times of that in India-based firms (mean of $34.5 vs. $3.80 in 2019), and nearly 5 times of that in China-based firms (mean of $34.5 vs. $6.95 in 2019). Our estimates on the hourly labor compensation cost are quite similar to those from previous studies (BCG 2019, Huang, Sheng, and Wang 2021, The Reshoring Initiative 2022, and Cui and Li 2023).

Table 2. Estimated Annual Labor Compensation Cost per Production Worker: Domestic Generic Manufacturing Firms in China, India, and the US.

Country-based, Firm Type	Annual Labor Costs per *Employee* (W+B)	Annual Labor Costs per *Prod Worker* (W+B)	Hourly Labor Costs per *Prod Worker* (W+B) Annual Hours Worked = 2,000	Sources and Assumptions for Estimation
	Mean (Median)			
China-based Firms with exclusively Domestic Plants	$16,900 ($15,400)	$13,900 ($12,600)	$6.95 ($6.30)	2019 ARs or Moomoo.com; Reported labor costs divided by total workers = per worker cost; Production worker in manufacturing earns 82% of all worker average*
India-based Firms with exclusively	$12,000 ($12,100)	$7,600 ($7,600)	$3.80 ($3.80)	2019 ARs; Reported labor costs divided by total workers = per worker

 doi:10.20944/preprints202602.1157.v1

Domestic Plants				cost; Production worker in manufacturing earns 63% of all worker average**
U.S. General Pharma: all firms	$106,800 ($85,300)	$69,000 ($64,100)	$34.5 ($32.05)	2019 wage statistics for the US pharma industry – by type of position# Weighted annual wage average for production worker is calculated (using wage and share of employment in each position related to production; total = 16). Add 42% for benefits to the wage cost.##

* National Bureau of Statistics of China. *Average Annual Wage of Employed Persons in Different Positions in Enterprises above Designated Size in 2019*. Published on May 18, 2020. (https://www.stats.gov.cn/english/PressRelease/202005/t20200518_1746069.html.). ** U.S. Department of Labor, Bureau of Labor Statistics. *International Labor Comparisons: India's Organized Manufacturing Sector*. Published on August 28, 2013. (https://www.bls.gov/fls/india.htm). #These positions include crushing/grinding/blending workers, packaging and filling machine operators, testers, samplers, technicians, repair and maintenance workers, planning clerks, first-line supervisors and managers, etc. See the U.S. Department of Labor, Bureau of Labor Statistics. *Occupational Employment and Wage Statistics (OEWS) Survey May 2020*. https://www.bls.gov/oews/2020/may/naics4_3250A1.htm. NAICS = 325400. ##U.S. Department of Labor, Bureau of Labor Statistics June 18, 2020: *Employer Costs for Employee Compensation – March 2020*. https://www.bls.gov/news.release/archives/ecec_06182020.pdf). Benefits = 42% of annual wages for private sector workers.

3.3. Profit Margin in FDA Inspected, Public Generic Drug Manufacturers

As shown in Table 3, with a 3-year average rate of 16.1%, firms based in China enjoy the highest operating margin during this period, in comparison to 12.5% for firms based in India, and only 6.3% for firms based in the US/EU (China vs US $p<0.01$; India vs US $p<0.05$). Examining each year separately and focusing on all firms, we see that while the margins across the three regions are quite comparable in 2017, the average margins in 2018 begin to diverge while the medians are still close, and by 2019 both the average and median margins in US/EU-based firms fall significantly below those in China- and India-based firms which hold steady in all 3 years. The VI firms and D firms have similar profit margins as all firms in China and India, while the VI firms based in US/EU appear to have higher margins than those in all firms, but the sample size is too small for hypothesis testing.

Table 3. Operating Profit Margins in FDA Inspected, Public Generic Manufacturing Firms, 2017-2019.

	China-based			**India-based**			**US/EU-based**		
Period	**All Firms (n=43)**	**VI Firms (n=38)**	**Domestic (n=39)**	**All Firms (n=32)**	**VI Firms (n=27)**	**Domestic (n=18)**	**All Firms (n=15)**	**VI Firms (n=13)**	**Domestic (n=3)**
	Mean % (Median %)								
2017	16.4 (14.2)	16.0 (13.4)	16.3 (14.2)	11.4 (12.6)	11.2 (13.0)	8.9 (8.2)	10.9 (14.3)	14.2 (14.5)	Too few data points

 doi:10.20944/preprints202602.1157.v1

2018	15.4* (12.8)	15.1 (12.6)	15.2 (12.8)	12.4* (12.8)	12.0 (12.9)	10.2 (11.0)	6.2* (13.8)	13.2 (15.7)
2019	16.6* (14.8)	15.5 (13.8)	16.5 (14.8)	13.5* (13.4)	12.8 (13.5)	11.4 (12.1)	1.5* (7.9)	5.1 (8.4)
3 yr average	16.1* (14.2)	15.5 (13.1)	16.0 (13.6)	12.5* (12.9)	12.0 (13.0)	10.2 (11.2)	6.3* (12.6)	11.0 (14.3)

*China- vs US/EU-based: p<0.01; India- vs. US/EU-based: p<0.05 (comparison of means only).

Note that there is only one missing firm-year observation each for India- and US-EU based firms, and none for China-based firms. Out of a total of 90 generic firms and 269 firm-year observations in this period, there are 10 (11.1%) *firms* with at least one annual negative operating margin, and 22 (8.2%) *firm-years* which have a negative *annual* operating margin. Five of 15 (33.3%) US/EU-based firms have at least one negative annual operating profit margin, while only 2 (4.7%) of China-based and 3 (9.4%) of India-based firms have any negative margin during this period (p<0.01 US vs. China or India).

3.4. Production Function, Output Elasticity, and Total Factor Productivity in Generic Drug Firms

Tables 4A to 4D contain estimates for the Cobb-Douglas production function for the generic drug industry, including 1) α, the output elasticity to variable inputs (measured by COGS and consist of labor and materials); 2) β, the output elasticity to fixed inputs (measured by NPPE and consists of property, plants, and equipment); 3) γ which measures the YEAR effect; and 4) lnA, the natural log of Total Factor Productivity. These estimates are separately obtained for each region and based on type of firms: all firms (4A), VI firms only (4B), firms producing domestically only (4C) and globally (4D), provided a minimum sample size of thirty firm-years is reached. Each regression also contains a firm fixed effect.

Table 4. A. Estimation of C-D Production Function for FDA Inspected, Public Generic Drug Manufacturers in Each Region: 2017-2019.

Parameter	China-based	India-based	US/EU-based
α (mean, std. err.)	0.697 (0.057)*	0.693 (0.056)*	0.486 (0.073)*
β (mean, std. err.)	0.042 (0.050)	0.128 (0.055)**	0.284 (0.073)*
γ (mean, std. err.)	0.074 (0.011)*	0.030 (0.001)*	-0.008 (0.012)
lnA (Constant)	1.930 (0.126)*	1.653 (0.371)*	2.314 (0.627)*
Firm Fixed Effect	Y	Y	Y
R^2	0.893	0.963	0.972
N	129	95	44

*p<0.01; **p<0.05. Panel Regression Model Specification: $\mathbf{lnQ_{i,t} = lnA + \alpha\, lnV_{i,t} + \beta\, lnK_{i,t} + \gamma\, T_{i,t} + FirmFE_i + \varepsilon_{i,t}}$. i: index for firm; t: index for year. Q: Inflation Adjusted Sales. V: Inflation Adjusted COGS; K: Inflation Adjusted NPPE. T=1 (year=2017), 2 (2018), and 3 (2019).

Table 4. B. Estimation of C-D Production Function for FDA Inspected, Vertically Integrated Public Generic Drug Manufacturers in Each Region: 2017-2019.

Parameter	China-based	India-based	US/EU-based

 doi:10.20944/preprints202602.1157.v1

α (mean, std. err.)	0.683 (0.058)*	0.677 (0.055)*	0.495 (0.058)*
β (mean, std. err.)	0.058 (0.052)	0.277 (0.068)*	0.314 (0.063)*
γ (mean, std. err.)	0.072 (0.011)*	0.020 (0.009)**	-0.005 (0.011)
lnA (Constant)	1.987 (0.266)*	0.989 (0.437)**	2.175 (0.543)*
Firm Fixed Effect	Y	Y	Y
R^2	0.895	0.975	0.971
N	114	81	38

*p<0.01; **p<0.05.

Table 4. C. Estimation of C-D Production Function for FDA Inspected, Domestic Public Generic Drug Manufacturers in Each Region: 2017-2019.

Parameter	China-based	India-based	US/EU-based
α (mean, std. err.)	0.719 (0.062)*	0.868 (0.098)*	Too few data points
β (mean, std. err.)	0.047 (0.055)	0.056 (0.070)	
γ (mean, std. err.)	0.071 (0.013)*	0.024 (0.014)	
lnA (Constant)	1.805 (0.298)*	1.007 (0.456)**	
Firm Fixed Effect	Y	Y	
R^2	0.880	0.903	
N	117	53	

*p<0.01; **p<0.05. Panel Regression Model Specification: $\mathbf{lnQ_{i,t} = lnA + \alpha\, lnV_{i,t} + \beta\, lnK_{i,t} + \gamma\, T_{i,t} + FirmFE_i + \varepsilon_{i,t}}$. i: index for firm; t: index for year. Q: Inflation Adjusted Sales. V: Inflation Adjusted COGS; K: Inflation Adjusted NPPE. T=1 (year=2017), 2 (2018), and 3 (2019).

Table 4. D. Estimation of C-D Production Function for FDA Inspected, Global Public Generic Drug Manufacturers in Each Region: 2017-2019.

Parameter	China-based	India-based	US/EU-based
α (mean, std. err.)	Too few data points	0.603 (0.059)*	0.521 (0.091)*
β (mean, std. err.)		0.251 (0.089)*	0.265 (0.143)***
γ (mean, std. err.)		0.028 (0.012)**	-0.017 (0.014)
lnA (Constant)		1.701 (0.646)**	2.333 (0.863)**
Firm Fixed Effect		Y	Y
R^2		0.984	0.982
N		42	35

*p<0.01; **p<0.05; ***p<0.10.

Because most China-based firms are VI and produce in domestic plants only, estimates by firm type are very similar, and show that China-based firms have a high output elasticity to labor and materials, but a low elasticity to capital stock, and have a positive YEAR effect on Total Factor Productivity (TFP). There are only 4 China-based firms which operate globally, so no estimates are provided for this group (4D). On the other hand, most US/EU-based firms are VI and produce in globally located plants, so estimates by firm type are also similar, showing that these firms have a larger output elasticity to capital stock and a smaller elasticity to labor and materials, compared to

 doi:10.20944/preprints202602.1157.v1

China- and India-based firms. Due to a very limited sample size, there are no estimates for US/EU-based firms which produce D (Table 4C).

The data for India-based firms is more variable. By firm type, these firms all have a high output elasticity to labor and materials that is similar in size to China-based firms. Most India-based firms have a positive YEAR effect which is smaller than China-based ones. The output elasticity to capital stock in VI firms based in India is quite similar to that in US/EU-based VI firms (Table 4B; 0.277 vs. 0.314 respectively). Furthermore, the elasticity is comparable between India- and US/EU-based globally producing firms (Table 4D; 0.251 vs. 0.265, respectively). However, the estimated elasticity is much lower and is remarkably similar between China- and India-based D firms (Table 4c; 0.047 vs. 0.056, respectively).

Regardless of firm type, the estimate for lnA is numerically larger in US/EU, followed by China and then India. Therefore, the TFP (measured by the antilog of lnA) in US/EU-based firms is numerically larger. Nevertheless, the 95% confidence interval for TFP in each region overlaps, as can be seen in Table 5. Taken together, these results indicate that the difference in overall productivity between US/EU- and China- or India-based firms is not statistically significant.

Table 5. Estimates for Total Factor Productivity (TFP) in Generic Drug Production in Each Region: 2017-2019.

Type of Firms	China-based (C)	India-based (I)	US/EU-based		
			Raw	TFP Ratio of US/EU to China	TFP Ratio of US/EU to India
	Mean (95% Confidence Interval = Mean +/- 1.96 x SE)			Ratio of Mean to Mean Only	
All Public Firms Inspected by FDA	6.890 (5.355, 8.864)	5.223 (2.487, 10.968)	10.115 (2.886, 35.446)	1.468	1.937
VI Firms	7.294 (4.284, 12.420)	2.691 (1.122, 6.443)	8.802 (2.971,26.076)	1.207	3.270
Domestic Firms	6.080 (3.350, 11.034)	2.737 (1.100, 6.814)	NA	NA	NA
Global Firms	NA	5.479 (1.504, 19.925)	10.309 (1.835, 57.916)	NA	1.882

3.5. Increase in COGS if Re-shoring Production from China or India

With the assumption that the unit material cost in the production stage is similar across the three regions, we can estimate the rise in unit COGS by using Equation (6) as follows:

$$R_1 = (W_n + mW_o)/(W_o + mW_o) \quad = (W_u + mW_o)/(W_o + mW_o)$$

where "n" denotes new region, which is US/EU (denoted by "u"), and "o" denotes old region which is either China (denoted by "c") or India (denoted by "i"). W is the unit labor cost, which we estimate with hourly labor compensation for domestic firms based in the three regions: W_u = \$34.5/hour, W_i = \$3.80/hour, and W_c = \$6.95/hour (Table 2; mean estimates).

First, we estimate R_1 – indicating the re-shoring is from China. The coefficient m for China-based domestic only firms is estimated and provided in Table 1C. Using mean estimates throughout, we calculate R_1 as follows:

 doi:10.20944/preprints202602.1157.v1

$$R_1 = (W_u + mW_c)/(W_a + mW_c) = (34.5 + 10.38x6.95)/(6.95 + 10.38x6.95) = 1.35$$

Therefore, if generic drug production is reshored from China to US/EU, our study estimates the COGS will rise by 35% (see Table 6).

Table 6. Estimates for Unit COGS in Public, Generic Drug Firms in China, India, and US/EU, Assuming Same Unit Material Cost and Productivity in Production across Regions.

		Region Firm Is Based		
		China (domestic only)	India (domestic only)	US/EU
		Mean Estimates Only		
A	Unit Material to Labor Cost Ratio (Table 1C)	10.38	NA	NA
B	Unit Labor Cost ($/hr) (T. 2)	$6.95	$3.80	$34.5
C	Unit Material Cost ($/hr) (A x B for China; assumed same across regions)	$72.14	$72.14	$72.14
D	Unit COGS ($/hr) (A + C)	$79.1	$75.94	$106.6
Ratio of COGS (US to C or I)		1.35	1.40	

Using mean estimates for W and m, we calculate R_1 if re-shoring from India as follows:

$$R_1 = (W_u + mW_c)/(W_i + mW_c) = (34.5 + 10.38x6.95)/(3.8 + 10.38x6.95) = 1.40$$

Thus, COGS will rise by 40% if generic production is reshored from India to US/EU (Table 6).

4. Discussion

Our study offers a few important observations regarding the economics of generic drug supply chain and the potential economic impact of re-shoring production from China/India to US/EU. First, among larger and publicly traded firms, the global generic drug supply chain is characterized by vertical integration, wherein firms produce both APIs and FDFs for generic drugs. This is true regardless of where a firm's headquartered is based in China, India, or the US/EU. The extent of supply chain globalization differs across region, with almost 80% of China-based firms being exclusively domestic, compared to only 13% of the US/EU-based firms, and 41% of the India-based firms.

While the operating profit margins in China- and India- based firms are stable or even rising during the period from 2017 to 2019, US/EU-based generic firms experience a significant and rapid decline in profitability, in comparison to both China and India. In 2019, the mean operating profit for all US/EU-based firms in our study is barely positive (1.5%). In comparison, the mean 2019 operating margin for the 15 largest *branded* drug firms in the world (with the vast majority being US/EU-based) is more than 25% (IQVIA 2020; Ledley et al. 2020). It is therefore no surprise that, at the time of this writing, seven out of the 15 US/EU-based public generic firms have either filed for Chapter 11 bankruptcy or have been merged with another firm (Appendix 3).

 doi:10.20944/preprints202602.1157.v1

Third, the output elasticity to labor and materials is very similar between all firms based in China and India, both of which are higher than that in US/EU-based firms. On the other hand, US/EU-based firms enjoy a higher output elasticity to capital stock, especially compared to China-based firms. In India, both the VI firms and firms with global manufacturing operation possess an output elasticity to capital stock very similar to that in comparable US/EU-based firms, while firms with strictly domestic manufacturing operation experience a similar output elasticity to capital stock to comparable China-based firms.

We cannot uncover any evidence in this study that total productivity is higher in US/EU-based generic firms. This stands in contrast to majority of economic literatures showing US firms in many industries (though generic drug industry not included) possessing higher TFP than their Chinese and Indian counterparts - which allows them to partially offset the disadvantage in labor costs (Hsieh and Klenow 2009; Zhu 2012; Boeing, Mueller, and Sandner 2016). In our view this finding should not come as a surprise, because both India and China have spent years honing manufacturing capabilities in the generic drug sector, whereas in the US/EU region, this sector has experienced significant capital erosion, leading to accelerated consolidation and firm exit (Frank, Mcguire, and Nason 2021).

Lastly, we note a substantial financial disincentive for reshoring generic drug production. We estimate that the COGS could increase by 35-40% if production is reshored from a China- or India-based firm, respectively, even assuming material costs stay the same. Exactly how much of the increase in COGS will be factored into a price hike for generic drugs likely depends on the extent of market power the generic firms possess, existing laws regulating price hike such as the Inflation Reduction Act, and the availability of government subsidies (Wosinska 2025).

Three limitations in our study warrant some further discussions. First, our sample contains 90 publicly trade and relatively large generic firms which produce APIs, FDFs, or both. While these included firms do not represent the entire global generic drug industry, their combined global sales reached USD$114.6B in 2019. In the same year, the US final generic drug market, which primarily represents the FDFs, is USD$115B, and the x-US market is around USD$74B (Statistica 2024). Therefore, firms included in our study account for over 60% ($114.6B/$189B) of the total generic drug sales in 2019. Second, because BLS does not have a unique classification code for generic drug manufacturers, the labor compensation cost for production workers in US/EU-based firms includes branded firms. This may affect the precision of our estimates. Third, thus far our study has been exclusively on COGS, which represents variable costs. Reshoring certainly would require substantial capital investment to upgrade and expand the current manufacturing capacity to handle the enormous increase in domestic output (McKinsey 2024; Wosinska 2025). A detailed study is urgently warranted to further investigate this issue.

5. Conclusion

Publicly traded generic drug firms based in China and India are mostly vertically integrated, producing both APIs and FDFs for generic drugs. The US/EU-based firms face a significant disadvantage of higher labor costs (by nearly 5 and 9 folds, respectively). There is no evidence that this disadvantage may be partially offset due to higher productivity in US/EU-based firms. Therefore, reshoring from China or India will lead to substantially higher COGS for generics. If compelled to reshore, it is unclear how US generic firms can sustain the business without substantial governmental support or significant price increase. Substantial new expenditures to expand capital structures will further increase the cost of reshoring.

The economic benefits derived from a globalized generic drug supply chain are reflected in the projected higher costs associated with reshored production. While various arguments have been made that pharmaceutical supply is essential to the United States and that it should be entirely or mostly a domestic enterprise, findings from our research suggest there will be significant costs in doing so. To build a sustainable business model for the generic drug industry in the US/EU, any policy decision must incorporate the difficult trade-offs faced by manufacturers.

 doi:10.20944/preprints202602.1157.v1

Acknowledgments : We would like to thank Samson Seligman (California State University, Channel Islands), Charity Chuan-Mei Custance (Northern Arizona University) for capable research assistance in collecting primary data for this study, especially those financial statements and annual reports written in Chinese. Special thanks to Professor Bill Comanor and seminar participants at the UCLA Seminar on Pharmaceutical Economics and Policy, and Professor Ted Frech at the Department of Economics, UCSB, for their insightful comments on earlier drafts. .

Appendix A. List of China-Based Generic Firms in the Analysis

Firm Name	**Headquarter Location (City, Province*)**	**Year Established**	**Stock Symbol**
Apeloa Pharmaceuticals	(Dongyang, Zhejiang)	1989	000739.sz
Aurisco Pharma	(Tiantai, Zhejiang)	1998	605116.ss
BrightGene Bio-Medical Technology Co.	(Suzhou, Jiangsu)	2001	688166.ss
Changzhou Qianhong Biopharmaceuticals	(Changzhou, Jiangsu)	1971	002550.sz
CSPC Pharma Group	(Shijiazhuang, Hebei)	1997	1093.hk
Fuan Pharma Group	(Chongqing*)	2004	300194.sz
Grand Pharma Group	(Hong Kong)	1995	0512.hk
Hainan Haiyao Pharma	(Haikou, Hainan)	1965	000566.sz
Hainan Poly Pharma	(Haikou, Hainan)	1992	300630.sz
Hainan Shuangcheng Pharma	(Haikou, Hainan)	2000	002693.sz
Huadong Medicine Co.	(Hanzhou, Zhejiang)	1993	000963.sz
Huapont Life Sciences	(Chongqing*)	1992	002004.sz
Hubei Goto Biopharma	(Xiangyang, Hubei)	2006	300966.sz
Humanwell Healthcare	(Wuhan, Hubei)	1993	600079.ss
YiChang HEC ChangJiang Pharma	(Yichang, Hubei)	2001	1558.HK
Jiangxi Fushine Pharma	(Jingdezhen, Jiangxi)	2002	300497.sz
Jiangsu Lianhuan Pharma	(Yangzhou, Jiangsu)	1999	600513.ss
Jiangxi Synergy Pharma	(Fengxin, Jiangxi)	2004	300636.sz
Livzon Pharma Group	(Zhuhai, Guangdong)	1985	1513.hk
Nanjing King-Friend Biochemical Pharma	(Nanjing, Jiangsu)	2000	603707.ss
North China Pharma	(Shijiazhuang, Hebei)	1992	600812.ss
Pharmablock Sciences	(Nanjing, Jiangsu)	2006	300725.sz
Porton Pharma Solutions	(Chongqing*)	2005	300363.sz
Shandong Lukang Pharma	(Jining, Shandong)	1966	600789.ss
Shandong Xinhua Pharma	(Zibo, Shandong)	1943	0719.hk

 doi:10.20944/preprints202602.1157.v1

Tianjin Chase-Sun Pharma	(Tianjin*)	1996	300026.sz
Tianjin Tianyao Pharma	(Tianjin*)	1999	600488.ss
United Lab International	(Hong Kong)	1990	3933.hk
Zhejiang Huahai Pharma	(Huahai, Zhejiang)	1989	600521.ss
Zhejiang Ausun Pharma	(Taizhou, Zhejiang)	2010	603229.ss
Zhejiang Hisun Pharma	(Taizhou, Zhejiang)	1956	600267.ss
Zhejiang Hisoar Pharma	(Taizhou, Zhejiang)	1966	002099.sz
Zhejiang Jiuzhou Pharma	(Taizhou, Zhejiang)	1973	603456.ss
Zhejiang Medicine Company	(Shaoxing, Zhejiang)	1997	600216.ss
Zhuhai Rundu Pharma	(Zhuhai, Guangdong)	1997	002923.sz
Zhejiang Starry Pharma	(Hangzhou, Zhejiang)	1997	603520.ss
Zhejiang Tianyu Pharma	(Huangyan, Zhejiang)	1993	300702.sz
Zhejiang Xianju Pharma	(Taizhou, Jiangsu)	1972	002332.sz
Zhejiang Yongtai Technology	(Linhai, Zhejiang)	1999	002326.sz
Zhejiang NHU Co.	(Shaoxing, Zhejiang)	1999	002001.sz

*There are four autonomous municipalities in China: Beijing, Chongqing, Tianjin, and Shanghai.

Appendix B. List of Indian-Based Generic Firms in the Analysis

Full Name	**Headquarter Location (City)**	**Year Established**	**Stock Symbol**
Aarti Drugs Ltd	(Mumbai)	1984	AARTIDRUGS.NS
Ajanta Pharma Ltd	(Mumbai)	1973	AJANTPHARM.BO
Alembic Pharma Ltd	(Vadodara)	1907	APLLTD.NS
Alkem Laboratories Ltd	(Mumbai)	1973	ALKEM.NS
Anuh Pharma Ltd	(Mumbai)	1960	ANUHPHR.BO
Aurobindo Pharma Ltd	(Hyderabad)	1986	AUROPHARMA.NS
Bal Pharma Ltd	(Bengaluru)	1987	BALPHARMA.NS
Biocon Ltd	(Bengaluru)	1978	BIOCON.NS
Cadila Healthcare Ltd	(Ahmedabad)	1952	CADILAHC.NS
Cipla Ltd.	(Mumbai)	1935	CIPLA.NS
Dishman Carbogen Amcis Ltd	(Ahmedabad)	1983	DCAL.NS
Dr. Reddy's Laboratories Ltd	(Hyderabad)	1984	RDY
Glenmark Pharma Ltd	(Mumbai)	1977	GLENMARK.NS
Granules India Ltd	(Hyderabad)	1991	GRANULES.NS
Hikal Ltd	(Mumbai)	1988	HIKAL.NS

 doi:10.20944/preprints202602.1157.v1

Indoco Remedies Ltd	(Mumbai)	1945	INDOCO.BO
IOL Chemicals and Pharmaceuticals Ltd	(Ludhiana)	1986	IOLCP.NS
Jubilant Generics Ltd	(Noida)	2013	JUBLPHARMA.NS
Kopran Res Lab Ltd	(Mumbai)	1986	KOPRAN.NS
Laurus Labs Ltd	(Hyderabad)	2005	LAURUSLABS.NS
Lupin Ltd	(Mumbai)	1968	LUPIN.NS
NATCO Pharma Ltd	(Hyderabad)	1981	NATCOPHARM.NS
Neuland Lab Ltd	(Hyderabad)	1984	NEULANDLAB.NS
Orchid Pharma Ltd.	(Chennai)	1992	ORCHPHARMA.NS
Shilpa Medicare Ltd	(Raichur)	1987	SHILPAMED.NS
Strides Pharma Sci Ltd	(Bengaluru)	1990	STAR.BO
Sun Pharma Industy Ltd	(Goregaon)	1983	SUNPHARMA.NS
Syngene International	(Bengaluru)	1993	SYNGENE.RS
Torrent Pharma Ltd	(Ahmedabad)	1971	TORNTPHARM.NS
Unichem Lab Ltd	(Mumbai)	1944	UNICHEMLAB.NS
Wanbury Ltd	(Navi Mumbai)	1988	WANBURY.NS

Appendix C. List of US-Based Generic Firms in the Analysis

Full Name	**Headquarter Location**	**Year Established**	**Stock Symbol**
Akorn Inc[$]	U.S.	1981	AKRX
Amneal Pharmaceuticals Inc	U.S.	2002	AMRX
Amphastar Pharma Inc	U.S.	1996	AMPH
Ani Pharmaceuticals	U.S.	2001	ANIP
Cambrex Corporation[#]	U.S.	1981	CBM
Endo International plc[$*]	U.S./Ireland	1997	ENDP
Hikma Pharmaceuticals	UK	1978	HKMPY
Lannett Co. Inc[#]	U.S.	1942	LCIN
Mylan Pharmaceuticals Inc[#]	U.S.	1961	MYL
Mallinckrodt Pharmaceuticals[$*]	U.S./Ireland	1867	MNK
Perrigo Company plc*	U.S./Ireland	1887	PRGO
Sandoz Group AG	Switzerland	1886	SDZ
STADA Arzneimittel AG[#]	Germany	1985	SAZ
Telligent, Inc	U.S.	1997	TLGT
Teva Pharma Industries Ltd	U.S./Israel	1901	TEVA

*Registered tax status to Ireland, but primary operations remain in the U.S. [#]No longer an independent and public firm at time of this writing [$]Filed for Chapter 11 bankruptcy protection at time of this writing.

 doi:10.20944/preprints202602.1157.v1

References

Almeter PJ: Isaacs JT, Hunter AN,et al (2022). "FDA Approaches in Monitoring Drug Quality, Forces Impacting the Drug Quality, and Recent Alternative Strategies to Assess Quality in the US Drug Supply." *J Pharm Innov*;17(2): 269-282.

Balog, M (2024). "The Generic Drug Supply Chain from the Perspective of an Insider," Presentation at the UCLA Seminar on Pharmaceutical Economics and Policy, May 16, 2024.

BBC (2024). "Trump threatens 100% tariff on BRICS nations if they try to replace dollar." https://www.bbc.com/news/articles/cgrwj0p2dd9o (accessed December 12, 2024).

Bertrand M, Hsieh CT and Tsivanidis N. "Contract Labor and Firm Growth in India" *The BECKER FRIEDMAN INSTITUTE FOR ECONOMICS*, Research Briefs published on Aug 23, 2021. https://bfi.uchicago.edu/insight/research-summary/contract-labor-and-firm-growth-in-india/ (accessed June 5, 2025).

Boeing P, E Mueller, and P Sandner (2016). "China's R&D explosion – analyzing productivity effects across ownership types and over time." *Research Policy*, Vol. 45, No. 1, pp. 159-176.

Boston Consulting Group (2019). "Getting a Grip on COGS in Generic Drugs." https://www.bcg.com/publications/2019/getting-a-grip-on-cogs-in-generic-drugs(accessed February 20, 2025).

Bumpas J and E Betsch (2009). *Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines*. Health, Nutrition and Population (HNP) discussion paper; World Bank, Washington, DC. © World Bank.

Chenoweth M, XY Liu and ZJ Lu (2024). "Asymmetric Information in the US Generic Drug Market: Predictors of FDA Plant Quality Inspection Outcomes in an Interim Analysis." Published by the 99th Annual Conference of the Western Economic Association International, July 2024.

Chit A, A Chit, M Papadimitropoulos, et. al. (2015). "The Opportunity Cost of Capital: Development of New Pharmaceuticals." *The Journal of Healthcare Organization, Provision, and Financing*, May: 1-5.

Cobb, CW and Douglas, PH. (1928). "A Theory of Production." *American Economic Review*. Vol. 18 (Supplement): 139–165.

Comin, D (2006). "Total Factor Productivity". *NBER Working Paper* # 11928.

Comin, D and S Mulani (2006). "A Theory of Growth and Volatility at the Aggregate and Firm Level," *NBER Working Paper* # 11503.

Conti, R and E Berndt (2020). "Four Facts Concerning Competition in US Generic Prescription Drug Markets." *International Journal of the Economics of Business*, Vol. 27.

Cuddy E, Lu YP, and Ridley DB (2023). "FDA Global Drug Inspections: Surveillance of Manufacturing Establishments Remains Well Below Pre-COVID-19 Levels." *Health Affairs* 42, No. 12: 1758-1766.

Cui C and Li LS (2023). "Trade policy uncertainty and new firm entry: Evidence from China." *Journal of Development Economics*, Vol. 163, June 2023, pp. 1030-1093.

De Loecker JD, J Eeckhout, and G Unger (2019). "The Rise of Market Power and the Macroeconomic Implications. Online Appendix." *The Quarterly Journal of Economics*, December 10, 2019.

De Loecker JD, J Eeckhout, and G Unger (2020). "The Rise of Market Power and the Macroeconomic Implications," *The Quarterly Journal of Economics*, Vol. 135, pp. 561-644.

Ederhof M, Nagan V and Rajan M (2017). "An Empirical Analysis of Capacity costs." Center for Economic Studies (CES) Research Paper CES17-26. CES.Working.Papers@census.gov (last accessed on June 5, 2025)

Eurostat (November 2023). "Labour cost structural statistics – levels." https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Labour_cost_structural_statstics_-_levels (last accessed on June 5, 2025).

Frank RG, Mcguire TG, and Nason I (2021). "The Evolution of Supply and Demand in Markets for Generic Drugs." *The Milbank Quarterly*, 99 (3): pp. 828-852.

Fortunak JM, OMA de Souza R, Kulkarni AA, etc. (2014). "Active pharmaceutical ingredients for antiretroviral treatment in low- and middle-income countries: a survey." *Antiviral Therapeutics*, 19 (03): 15-29.

Government Accountability Office (2024). "Drug Safety: FDA Has Faced Persistent Challenges Overseeing Foreign Drug Manufacturing." Feb 06, 2024.

 doi:10.20944/preprints202602.1157.v1

Gray JV, Roth AV, and Leiblein MJ (2011). Quality risk in offshore manufacturing: Evidence from the pharmaceutical industry. *Journal of Operations Management*; 29 (7-8):737-52.

Hall, R and C Jones (1999). "Why Do Some Countries Produce So Much More Output per Worker than Others?" *The Quarterly Journal of Economics*, Vol. 114, pp. 83-116.

Hill A, M Barber, and D Gotham (2018). "Estimated costs of production and potential prices for the WHO Essential Medicines List." *BMJ Global Health*, 3 (1).

Hsieh CT and PJ Klenow (2009). "Misallocation and manufacturing TFP in China and India." *The Quarterly Journal of Economics*, vol. 124, No. 4, pp. 1403-1448.

Huang Y, Sheng L, and Wang C (2021). "How did rising labor costs erode China's global advantage?" *Journal of Economic Behavior and Organization*, vol. 183, March 2021, pp. 632-653.

IQVIA 2020. "Operating Margin Dynamics for Life Sciences Companies." *IQVIA Institute Research Brief*, August 17, 2020.

IQVIA 2024. "Overview of the Active Pharmaceutical Ingredient Market." *IQVIA Chemical Intelligence Brief*. February 2024.

Ledley FD, McCoy SS, Vaughan G, and Cleary EG (2020). "Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies." *Journal of the American Medical Association*, Vol. 323 (9), pp. 834-843.

Lu, ZJ and Comanor, WS (2020). "U.S. Pharmaceutical Markets: Expenditures, Health Insurance, New Products and Generic Prescribing from 1960 to 2016." *International Journal of the Economics of Business*, vol. 27(1), pages 1-26.

McKinsey & Company (2024). "Decarbonizing API Manufacturing: Unpacking the Cost and Regulatory Requirements." June 26. https://www.mckinsey.com/industries/life-sciences/our-insights/decarbonizing-api-manufacturing-unpacking-the-cost-and-regulatory-requirements. Accessed February 27, 2025.

Moomoo (2025). The Next-Gen Online Trading Platform. https://www.moomoo.com/us/about (last accessed June 5, 2025)

Mulcahy, AM et al. (2021). "International Prescription Drug Comparisons." *RAND Research Report*, 2021, p. 28.

National Bureau of Statistics of China. *Average Annual Wage of Employed Persons in Different Positions in Enterprises above Designated Size in 2019*. Published on May 18, 2020. https://www.stats.gov.cn/english/PressRelease/202005/t20200518_1746069.html (last accessed June 5, 2025)

The Reshoring Initiative (2022). *The Reshoring Initiative 2022 Data Report*. https://reshorenow.org/content/pdf/2022_Data_Report.pdf (accessed June 5, 2025).

Schulman, KA, Kumar WM, and Adashi EY (2023). "Ensuring Access to Generic Medications in the US." *Health Affairs Forefront*, September 12, 2023.

Shivdasani Y, Kaygisiz NB, Berndt ER, and Conti RM (2021). "The geography of prescription pharmaceuticals supplied to the USA: levels, trends, and implications." *Journal of Law and the Biosciences*, 1-28.

Socal MP, Ahn K, et al. (2023). "Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients." *Health Affairs*, 42 (3): 407-415.

Statista (2024). "Worldwide Generic Prescription Drug Sales 2012-2026." Dec 10, 2024. (last accessed January 2025).

U.S. Department of Health and Human Services. *Understanding Recent Trends in Generic Drug Prices*, January 27, 2016 (ASPE).

U.S. Department of Labor, Bureau of Labor Statistics: *Employer Costs for Employee Compensation – June 18, 2020*. https://www.bls.gov/oes/2020/may/naics4_3250A1.htm. (last accessed October 2024).

U.S. Department of Labor, Bureau of Labor Statistics. *International Labor Comparisons: India's Organized Manufacturing Sector*. Published on August 28, 2013. https://www.bls.gov/fls/india.htm (last accessed June 5, 2025).

U.S. Food and Drug Administration. "Frequently Asked Questions about Drug Shortages." https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages. (Last accessed January 2025).

 doi:10.20944/preprints202602.1157.v1

U.S. Food and Drug Administration (2024A). "Inspection Classification Database." https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database. (Last accessed December 2024.)

U.S. Food and Drug Administration (2024B). "FDA's Risk-Based Approach to Inspections." https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/fdas-risk-based-approach-inspections (Last accessed December 12, 2024).

U.S. Food and Drug Administration (2023). "Overview of Drug Manufacturing Inspections." *Understanding FDA Inspections and Data Webinar*. September 6. Slides 34-35. https://www.fda.gov/drugs/news-events-human-drugs/understanding-fda-inspections-and-data-09062023 (last accessed May 2025).

Van Arnum, P. (2006). "The Changing Fortunes of APIs," *Pharm. Technol*. **31** (1), 52–58.

White House Report (2021). "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-based Growth". The White House, Washington, DC.

Zhu, XD (2012). "Understanding China's growth, past, present, and future." *Journal of Economic Perspective*, vol. 26, no. 4, pp.103-124.