Class action lawsuit brought in US against generic-drug makers for colluding to fix prices

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A class action lawsuit was filed early this month by Connecticut and 44 other states against 20 large generic drug companies and 15 senior executives responsible for sales, marketing and pricing for allegedly conspiring as a cartel to fix prices and restrain trade on over 100 generic drugs.

Between 2013 and 2014, of 1,215 generic versions of the most prescribed drugs, prices soared on average more than 400 percent. Some of the more critical medications saw a price hike of more than 1000 percent.

In a prepared statement, Connecticut Attorney General William Tong said, "We have hard evidence that shows the generic drug industry perpetrated a multi-billion-dollar fraud on the American people. We have emails, text messages, telephone records, and former company insiders that we believe prove a multi-year conspiracy to fix prices and divide market share for huge numbers of generic drugs."

This is the second case filed accusing the generic drug industry of perpetrating a multi-billion-dollar fraud against the public. The first complaint had been filed in 2016 against 15 generic drug manufacturers. Many of these drugs treated grave chronic conditions such as diabetes, arthritis, hypertension, and cancers.

The soaring prices for prescription drugs are directly linked to these criminal practices. The suit alleges that for several years these companies have colluded as cartels, avoiding competition, and settling on "fair share" market prices to keep them inflated. In 2018, the pharmaceutical industry spent $27.5 million on lobbying against the pressure to lower prices.

Compounding the storm and stress for the generic drug industry, in a recent expose published in the *New York Times* headlined, "Americans Need Generic Drugs. But Can They Trust Them?" an investigative journalist and expert in Big Pharma, Katherine Eban, has provided a searing critique of the generic drug industry's practice.

According to Eban, "To minimize costs and maximize profit, companies circumvented regulations and resorted to fraud: manipulating tests to achieve positive results and concealing or altering data to cover their tracks. By making the drugs cheaply without the required safeguards and then selling them into regulated and more costly Western markets, claiming that they had followed all the necessary regulations, companies could reap enormous profits."

Just last year, the FDA approved more than 1,000 new generic drugs for sale in the US market. Nearly 40 percent are made in India, and 80 percent of the active ingredients for both brand-name and generic drugs are manufactured abroad. China and India manufacture the majority of these.

An unusually decent FDA safety officer by the name of Peter Baker, since his discovery of fraudulent practices at a Wockhardt Ltd. pharmaceutical plant in India in 2012, has gone on to inspect nearly 100 plants in India and China. His startling findings document that deceptive practices, such as manipulating the results of tests on manufactured drugs, are commonplace with almost 80 percent of drug plants engaged in such behavior.

In her expose, Ms. Eban says, "Interviews with more than 240 people, including numerous whistle-blowers, helped expose what was going on behind the boardroom doors at generic drug companies. Some companies have encouraged data fraud as the most profitable path to securing approvals from regulators and have used deceit to hold the FDA's investigators at bay."

The FDA has feebly defended its practice of giving advanced notice to foreign manufacturing plants for their upcoming inspections. They cite difficulty in obtaining visas and arranging local transportation as reasons. Inspectors arrive as company guests agreeing on inspection dates of selected sites. They are also treated to travel perks, accommodation upgrades, and leisure outings at no cost. And when serious deficiencies are discovered requiring "official action indicated" designation, FDA bureaucrats have downgraded these to "voluntary action indicated" for over 100 Indian plants which meant that drugs from those plants would continue reaching US markets.

In September of 1984, the Drug Price Competition & Patent Term Restoration Act, also known as the Hatch-Waxman Act, was signed into law by then-President Ronald Reagan. This law created a new regulatory pathway for the introduction of generic drugs into US markets, which were until then kept in a

legal stranglehold by Brand-name manufacturers. The legislation intended to encourage innovation while promoting competition between Brand-name and generic drugs to lower prices.

The decade before had seen a rapid escalation of healthcare costs partially due to Medicare expenditures and rapid inflationary stresses. The expansion of hospital expenses and profits with the rapidly developing technology led to corporatizing and integrating hospital systems. Prescription drug spending was also on a rapid rise as a share of GDP and total health spending.

Once the patent on the brand name expired, these generic drugs were placed on a fast track if they could show the FDA they had similar metabolism and effect as their brand-name equivalent. However, there are no measures in place to conduct safety trials on these generics, and none are required. No studies are performed to ensure equivalent effects and adverse outcome evaluation as with brand names beyond their data in the initial application due to the length of time and cost for conducting these trials.

From 1984 to 2018, the rate of prescribing generics climbed from 19 to 90 percent. By 2018, generic drugs accounted for $442 billion of the $1.324 trillion in global pharmaceutical sales. On its present trajectory, according to a BCC Research report, the global market for generic drugs should reach $533 billion by 2021.

In the intervening three decades, the manufacturing sources for generic drugs has shifted from the US and Israel, which led in the 1990s, to countries like India and China which have, presently, surpassed their Western counterparts. While emerging markets have contributed to the global growth of generic markets looking for cheaper substitutes, by 2009 market saturation and tepid economic projections led to consolidation through merger and acquisitions to achieve the appropriate scale to ensure profitability. The top ten generic drug producers now control a 61 percent share of the total revenue.

Politicians have praised the 1984 Hatch-Waxman Act as a boon for the public at large. They note that from 2003 to 2012, generic drugs have saved the US healthcare system $1.2 trillion. However, behind these cost-saving measures has come a catastrophic erosion in assurance and safety for patients using these generic versions. There is considerable anecdotal evidence that when patients were switched to generic medications, their symptoms returned and condition deteriorated. Some have died taking these medications for the prevention of organ rejection after a transplant procedure.

Adding insult to injury, in 2013, a 5 to 4 vote in favor of Mutual Pharmaceutical Co, owned by Sun Pharmaceutical Industries Ltd., the Supreme Court ruled that the state could not sue manufacturers of generic drugs for harm caused by their products, reversing a lower court multi-million-dollar jury awarded decision. Karen Bartlett had suffered a debilitating adverse reaction to a generic anti-inflammatory called Sulindac. She had a toxic reaction that affected 60 percent of her skin, causing open wounds, infections, permeant pain, and near blindness. Writing for the majority opinion, Justice Samuel Alito noted that state laws could not run against federal laws on prescription medicines whose design was approved by the FDA, essentially blocking a patient or their families from suing for harm incurred.

The National Health Expenditure Accounts (NHEA) estimated that US health care spending grew 4.4 percent in 2018 over 2017 reaching $3.65 trillion or over $11,212 per person, accounting for 18 percent of the GDP. Prescription drug spending was up 3.3 percent year over year, mainly due to rising prices and not increased usage. By example, Medicare Part D spending on insulin has increased 840 percent over ten years, rising from $1.4 billion in 2007 to $13.3 billion in 2017. Generic drugs have become indispensable to the objective mathematics of the health care crisis.

Nonetheless, the proportion of generic drugs that are seeing a doubling of their price year-over-year is growing as these manufacturers find therapeutic niches with little competition which they can exploit as well as colluding to fix prices. Insurance carriers, in turn, shift the burden of higher costs to consumers through hiking premiums, deductibles, and copayments.

The logic of establishing the generic drug industry in a capitalist milieu demonstrates that they are fallacious measures that attempt to stabilize the ever-growing contradictions of capitalism that only heighten the crisis down the road. The past three decades have exposed the inevitable development of this industry’s malignant operations and disastrous impacts on the health of the globe. The working class is the only force capable of bringing a rational perspective, utilizing the massive technological gains that have been made, to reorganizing these resources for social need and, importantly, their safety.