Generic drug shortages in the US, particularly chemotherapy agents, reach historic highs

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Dr. William Dahut, chief scientific officer for the American Cancer Society and professor of medicine at Uniformed Services University of the Health Sciences in Bethesda, Maryland, remarked on the ongoing dire shortage of critical chemotherapy agents, "If these drugs are not available, people are going to get inferior care. That's the bottom line. These aren't third- or fourth-line drugs where there are multiple other agents around. These are used up front for people you are trying to cure."

The US Food and Drug Administration has indicated that there are 295 active drug shortages in the US, a 30 percent increase since 2021. Twenty-three of these are chemotherapies, making them fifth in the top five drug classes with active shortages.

People are being delayed or denied these treatments, which means that they will not be cured and their lives cut short. In fact, one of the key predictors of how patients will do is if they get the right dose of drugs on the right schedule. A study published in the *BMJ* (formerly the British Medical Journal) in November 2020 found that a one-month delay increased the risk of dying by 6 to 13 percent.

The American Cancer Society recently highlighted the important fact that innovations in cancer treatments have led to a 33 percent decline in cancer mortality since 1991. The organization estimates that the US can see around 1.9 million new cancer cases in 2023. Given the current shortages in cancer treatments have no foreseeable end, the question arises whether such trends will become of historic precedence.

Dr. Amanda Fader, president of the Society of Gynecologic Oncology, warned, "This is in my opinion a public health emergency because of the breadth of individuals it affects and the number of chemotherapy agents that are in shortage right now."

Dr. Fader is speaking of agents like carboplatin and cisplatin, drugs discovered more than three decades ago that have continued to prove their resilience in the treatment of various cancer types, which include leukemias, lymphomas, colon, breast, lung and ovarian. They are also generic drugs that cost pennies to manufacture but generate razor-thin profit margins.

Generic drugs account for 90 percent of all drugs used domestically, but account for only 17 percent of drug spending, costing on average $9 per treatment. Generic drugs are also one of few areas where costs have not risen faster than inflation. The economic environment for nationally based manufacturing is so unappealing that life-saving drugs are being produced abroad by only one or two pharmaceuticals for world-wide consumption. When there are temporary halts to production, the social cost is incalculable.

As many in the industry have noted, given the costs associated with these generic drugs and their ultra-narrow profit margins, it is difficult to compete against pharmaceuticals based in countries such as India or China. Additionally, these lead to safety issues as regulatory oversight of the manufacturers is at times nonexistent.

Resulting incidents include the discovery of industrial solvents and antifreeze agents in medications, which has led to deaths of the children receiving them. In March, the Centers for Disease Control and Prevention (CDC) released a health care-associated infections alert on an outbreak of an extensively drug-resistant strain of Pseudomonas aeruginosa traced back to EzriCare or Delsam Pharma's artificial tears, affecting 68 people across 16 states. Three people died, some went blind and several had to have their eyeballs removed.

Much of the profits for these generic drugs goes to Pharmacy Benefit Managers or PBMs, middlemen who eat up almost 50 percent of the drug costs. The three largest PBMs—CVSHealth (including Caremark and Aetna), the Express Scripts business of Cigna, and the OptumRx business of UnitedHealth Group—control nearly

80 percent of all commercial drugs sales, constituting a veritable monopoly or cartel.

According to Commonwealth Fund, “PBMs are companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers. By negotiating with drug manufacturers and pharmacies to control drug spending, PBMs have a significant behind-the-scenes impact on determining total drug costs for insurers, shaping patients’ access to medications, and determining how much pharmacies are paid.”

As such, these PBMs force generic drugmakers to accept their rates or stop production altogether due to lack of profitability because they are unable to compete with India, whose labor costs are far lower. Over the past 10 years, dozens of generic drug manufacturers have closed and the current generic manufacturing capacity is running at 50 percent of what could be produced.

Such was the case when in February Akorn Pharmaceuticals, an American generic pharmaceuticals manufacturer based in Lake Forest, Illinois, filed for Chapter 7 bankruptcy and summarily laid off around 450 employees at its plant in Decatur, with employees given a one-day notice to pack-up their belongings and vacate the premises. Such sudden disruptions in the availability of vital medications have had a far-reaching impact on patient care and distressed health care workers.

In a letter to the workers, Akorn CEO Douglas Boothe wrote, “Because the company has insufficient liquidity to continue its operations, continue to seek a buyer and continue to retain its workforce, the company will file cases under Chapter 7 of the US Bankruptcy Code. In connection with that filing, the company must shut down all operations and terminate all of its employees.”

On the growing crisis of the chronic drug shortages in the US, which have reached a five-year high, Bloomberg recently reported that the White House has assembled a “covert group” of experts led by the Domestic Policy Council and National Economic Council to supposedly tackle the problem.

According to the sources speaking with Bloomberg on condition of anonymity, “[T]he agency [FDA] has been cooperating with the White House but can’t fix the supply problems alone because larger market forces are driving generic drugmakers out of business, contributing to shortages. The companies that buy drugs in bulk pit manufacturers against each other and drive down prices, which shrinks drugmakers’ margins.”

Given the extremely narrow profit margins on such generic drugs, the logic of capitalist production means that the inherent value attributed to these medications in terms of lifesaving capacity is less than the pennies it costs to produce them. Accordingly, the White House is looking for market mechanisms that can introduce further efficiencies to entice some companies to undertake production while at the same time developing new regulations to improve quality control, including “announced FDA inspections.”

In response to these potential changes, Teva Pharmaceutical Industries, one of the world’s major generic drug manufacturers with 2022 revenues of $14.9 billion, wrote on social media, “The security of the American generic drug supply can only be ensured by addressing the root cause of shortages and implementing sustainable economic and regulatory policies. Adding burdensome additional regulations on an already struggling industry facing tremendous downward pricing pressures, will only further exacerbate drug shortages.”

Indeed, fragile global supply chains and the heavy reliance on China and India for active pharmaceutical ingredients (APIs) led the chairman of the Energy and Commerce Committee’s Subcommittee on Oversight and Investigations, Rep. Morgan Griffith from Virginia, to declare last week during a hearing on the root causes of drug shortages “a national security risk.”

In other words, these massive pharmaceuticals, whose stocks are held in the grip of the financial aristocracy, demand unlimited public funds from the US government and promises to fortify the supply chains secured through aggressive foreign policy, including military action to ensure profits continue to flow undisturbed. Simply put, the international working class is being held hostage by the corporations allowing these shortages of life-saving treatments to persist.

The more than $110 billion that has been mustered to pursue the deadly NATO-led conflict in Ukraine against Russia confirms that these drug shortages are essentially driven by capitalist economic interests.