Statement for the Record: Doctors for America
House Committee on Oversight and Accountability Hearing:
"Oversight of the U.S. Food and Drug Administration"
April 11, 2024

Thank you, Chairman Comer, Ranking Member Raskin, and distinguished members of the House Committee on Oversight and Accountability, for providing Doctors for America's (DFA) FDA Task Force the opportunity to submit comments for the record regarding ongoing drug shortages. We appreciate your consideration of this important topic at this critical time.

DFA mobilizes doctors and medical trainees to be leaders in putting patients over politics to improve the health of our patients, communities, and nation. We represent 27,000 physicians and medical students in all 50 states, in all areas of specialization. Our impact areas focus on access to affordable care, community health and prevention, and health justice and equity. As a medical advocacy organization, DFA's main purpose is to promote the best evidence-based, scientifically proven, compassionate medical care on an equitable basis to all Americans. Access to effective and safe pharmaceuticals is at the core of our capacity to serve, help, and cure.

As you are aware, prescription medicine shortages have been a chronic, ongoing problem noted by Congress and well-documented and researched. The American Society of Health-System Pharmacists (ASHP) currently lists over 250 drugs on their shortage list, some for as long as eight years. The FDA does try to monitor, manage, and remediate drug shortages. However, the FDA reports that for CY 2022, there were 49 new shortages, 222 prevented shortages, 86 ongoing shortages, and 150 manufacturers generated 1293 notifications. The FDA employs only ten people who do the day-to-day work of preventing and reporting drug shortages. The FDA had additional authorities during the COVID Public Health Emergency to deal with supply shortages, but as beneficial as they were, they were allowed to lapse.

Commonly used medications are in shortage, such as some concentrations of saline, pediatric albuterol, children's Tylenol, Adderall, and some forms of penicillin. Additionally, the current shortage of some generic cancer chemotherapies, which are first-line treatments for lung, breast, bladder, and ovarian cancers, is devastating. Thousands of patients across the country are facing delays in getting these and other treatments for cancer and other life-threatening diseases, with drug shortages in the United States approaching record levels. In response to a nationwide survey sent by the Society of Gynecologic Oncology last year, doctors in 35 states said they had little to no supply of key chemotherapy drugs, even at prominent cancer centers and teaching hospitals. Oncologists are forced to ration their limited supplies of these effective first-line medications, and lives will be shortened and lost. It has been reported that many suppliers, mainly offshore, are floundering. An additional problem lies with the raw materials supply chain, which is complex, opaque, consolidated, offshore, and little monitored for quality.

In this context, DFA wants to emphasize two important areas of responsibility where policy and programs must be significantly improved as soon as possible. As physicians and patient advocates, we find this situation intolerable and an ongoing danger to the health and security of our nation. Solutions will require both legislative action expanding FDA responsibilities, an adequate budget, and a significant federal market intervention.

1. **Shortages are mostly supply-side problems. FDA authority and resources must be enhanced.**

Nearly 80% of manufacturing facilities that produce active pharmaceutical ingredients (API) from raw materials are located outside the U.S., mostly in China and India. The Administration for Strategic Preparedness and Response (ASPR) estimates that 90 to 95 percent of generic sterile injectable drugs used for critical acute care in the U.S. rely on key starting materials from China and India. Between 2010 and 2015, the number of Chinese-based API manufacturers registered with the FDA more than doubled from 188 in 2010 to 445 in 2015. The capacity of the FDA to comprehensively assess the U.S. pharmaceutical supply chain and remediate known causes of shortages for critical drugs is limited by policy and budget. Monitoring the supply chain is a daunting and difficult task. Due to the geographic dispersion of suppliers overseas and lack of agency resources, neither the federal government nor industry has end-to-end visibility of the pharmaceutical supply chain, including key starting materials, APIs, and manufacturers of finished dosages. Although some generic drugs appear to have multiple and diverse drug suppliers, unknown to the FDA, they may, in fact, rely on the same API source or manufacturer. Thus, the universe of actual suppliers for a particular drug may be much smaller than it appears, increasing the risk of shortages.

The FDA is currently unable to assess the percentage of life-supporting and life-sustaining medications with fewer than three manufacturers or rely on only one API supplier because the FDA does not have a list of life-supporting and life-sustaining drugs. The Department of Defense (DOD) and national security are equally reliant on the commercial market for pharmaceutical products. Pharmaceutical supply chain visibility must be increased with real-time assessments, frequent inspections, and interventions or sanctions. At the same time, the President should endorse a reshoring drug manufacturing policy as he has in other sectors. Congress should support and fund expanded domestic manufacturing capabilities for critical generic drug products. The FDA itself has said it needs more legislative authority and a bigger budget from Congress to obtain needed information about drug manufacturing and supply chains. DFA strongly supports this regulatory initiative and augmented authorities, which must be accompanied by substantial budgetary expansion. Additionally, DFA endorses the urgent expansion of domestic pharmaceuticals from API to finished product. This is necessary to protect our patients' health and our nation's resilience and security.

2. **Shortages in generic medications have been created and exacerbated by unacceptable, dysfunctional market behavior on the demand side.**

Some shortages do arise with unanticipated demand due to unexpected morbidities, such as during the COVID pandemic, but issues having to do with reimbursement policies or coverage/formulary determinations by any health insurance company or public payers such as Medicare, Medicaid, CHIP, ACA, Tricare, and the Veterans Administration, and the 340B program have very little to do directly with supply problems. Adjusting public payer payments, formularies, and policies is myopic and will have little effect on the supply and manufacturing problem, which is economically isolated from specific treatment needs required by any health care or insurance system. Cost-saving generic drug approval delays are caused mainly by system manipulation by the manufacturer who holds the original patent.

DFA believes the second major source of generic pharmaceutical shortages is the dysfunctional and perverse impact of market distortions created by the vertically integrated, oligopolistic, profit-maximizing Pharmacy Benefit Managers (PBMs), which are isolated from the harms they create. Consolidation among Group Purchasing Organizations, Prescription Drug Wholesalers, and especially PBMs has significantly contributed to generic drug supply problems by creating market and distribution distortions and excess cost problems. PBMs were initially developed to facilitate the logistics of pharmaceutical distribution while negotiating cost savings. However, with the absence of FTC oversight, by 2020, the three largest PBMs – by now wholly owned and vertically integrated into health insurance

companies – had market dominance: CVS Caremark (CVS bought Aetna for $69B), Express Scripts (bought by Cigna for $54B) and OptumRx (built around the acquisition of the PBM Catamaran is a subsidiary of UnitedHealth Group). The three major PBMs now control nearly 80% of the prescription market (180 million patients).

DFA contends that the oligopolistic, vertically integrated, market-distorting economic power of the PBMs substantially contributed to the development of the generic drug supply problem. In their unfettered quest for profit, intermediary companies like PBMs encouraged high-priced (and highly profitable) brand-name pharmaceuticals and biosimilars. They aggressively tried to limit expenses in contracts with generic drug (low-profit) makers for supplies. They exerted excessive market power to demand increasingly low, rock-bottom prices from generic suppliers. Yet, unlike a customer-facing company like Nike, which also contracts with suppliers worldwide, the drug intermediaries face no accountability when shortages arise. Also, regarding untoward supply chain consolidation, a review by IQVIA, a healthcare analytics company, showed that three buyers account for about 90 percent of generic drug purchases for distribution into the system. The intermediaries, especially the PBMs, have forced generic drug prices to fall by about 50 percent since 2016. These low prices come with a high cost – medication shortages. PBMs force the lowest prices on API and generic medication suppliers, motivating them to cut corners — especially in quality control due to its expensive technical nature - leading to disruptive plant shutdowns and supply shortages when the F.D.A. demands a fix or closure altogether. Overseas suppliers often lack transparency around generic drug quality.

Lately, in various states, Congress, and regulatory agencies, a lot of attention has been paid to PBMs. DFA wants to emphasize that among its other adverse effects on the pharmaceutical system, its market-distorting power has been a major cause of the deterioration of the generic drug supply system. Remediation is the responsibility of the FTC, and DFA recommends immediate legal intervention according to its well-established regulations for national security.

We urge that Congress takes aggressive action this year to tackle drug shortages and implement DFA's recommendations on an expedited basis, including:

1. Passing legislation to expand the FDA's authorities and budget so that it can competently monitor, inspect, and intervene in the supply system for all pharmaceuticals, which, after all, are often life-saving necessities;
2. Create a national "industrial policy" to promote and support the onshoring of the pharmaceutical supply chain.
3. Have the FTC expeditiously exert its known and traditional regulatory authorities to break up PBMs and their market-manipulating economic power.

Thank you for this opportunity to submit this statement for the record. Doctors for America's FDA Task Force looks forward to continuing to work with Congress to identify ways to tackle drug shortages, protect our patients' health, and strengthen our nation's resilience and security. We also look forward to being a resource to this Committee and supporting your work to reach these urgent objectives.