November 4, 2025

Martin A Makary M.D., M.P.H.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: **Immediately Withdraw Approval of Carbadox**

Dear Commissioner Makary,

We are writing to urge the U.S. Food and Drug Administration (FDA) to immediately withdraw approval of the cancer-causing feed additive carbadox and deny the drug sponsor's request for hearing. The drug, which the Food and Drug Administration, including the Center for Veterinary Medicine (CVM), has identified as being unsafe is linked to serious health risks for humans, food workers, and the environment. Despite clear scientific evidence of its dangers, the drug remains on the market. The FDA's delay in removing carbadox is not only putting public health at risk, but also undermining the agency's role in protecting consumers. It has been nearly two years since the FDA revoked the residue detection method and published its proposal to withdraw approval of Carbadox. Nearly two years without an approved method to test that the drug is being used safely, and nearly two years without an appropriately labeled withdrawal period based on a valid residue detection method. This is unacceptable. As the agency charged with safeguarding public health, the FDA must immediately withdraw approval of carbadox to prevent continued exposure of consumers to this known carcinogen

As a practicing surgical oncologist and researcher who spent more than two decades at Johns Hopkins - authoring influential papers on pancreatic surgery and surgical outcomes - you have built a career focused on improving care and outcomes for patients, including those with cancer. For the many cancer patients and survivors who rely on your vigilance and the general public, you must apply that same scientific rigor to known carcinogens in our food supply.

The use of carbadox in pigs results in carcinogenic residues, including desoxycarbadox (DCBX). These residues can be present in edible portions of the animal and result in an elevated cancer risk in consumers. The sponsor has known since at least 2003 (and the FDA has known since at least 2005) that the residue detection method used to "ensure that residues of carcinogenic concern in edible tissues will not exceed concentrations that represent no significant increase in the risk of cancer to humans"[1] do not provide the needed certainty to protect consumers from a significant increase in the risk of cancer. Since 2005, the FDA has, "provided the sponsor with notice of what is needed to meet the statutory requirements as well as ample time to carry out the necessary studies. To date, CVM has not received data demonstrating the approved method is adequate to measure the residue of carcinogenic concern in compliance with the requirements of FDA regulations or that an alternative analytical method would meet such requirements."[2] For over two decades, the FDA and the drug sponsor have knowingly allowed U.S. consumers to be exposed to a "significant increased risk of cancer." The excessive use of carbadox in the

[1] 88 FR 76759.
[2] Federal Register. "Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method," November 7, 2023. https://www.federalregister.gov/documents/2023/11/07/2023-24548/phibro-animal-health-corp-carbadox-in-medicated-swine-feed-revocation-of-approved-method.

pork supply has also contaminated surface waters[3] and injured workers who are exposed to toxic feed and feed dust containing the carcinogen.[4]

The FDA's own science has long pointed to the dangers of carbadox. The agency's review of the drug has indicated that the risks far outweigh the benefits, and it has called for the removal of carbadox from the market since 2016. Yet, it is now nearly 2026, and we are still waiting for decisive action. In November 2023, the FDA took a step toward resolving this issue by publishing a proposal to withdraw approval for carbadox (Federal Register, November 2023), but the agency must now act swiftly to make this proposal a reality. There is no justification for further delay, especially given that there is no method to determine whether it has been used according to label, and the label itself is compromised since the withdrawal period is based on invalidated data.

Your recent commentaries outline a priority to accelerate cures and eliminate dangerous food additives – restoring "focus on the "F" in FDA". You have stated that the agency has "begun conducting a full inventory of concerning ingredients in the US that are not allowed in other developed countries." And, "plan to apply gold-standard science and common sense to the problem."[5] Yet carbadox - the last remaining approved feed additive known to be carcinogenic, with a substantial body of gold-standard science from the U.S. and around the world clearly documenting its risks – continues to contaminate our food supply. It has also been banned for years in many developed countries, including, but not limited to, the EU, UK, Canada, China, Australia, Brazil and Japan.

Dr. Makary, it is time to put your words into action. Carbadox is low-hanging fruit—the science is clear, the risks are undeniable and urgent, and the FDA has already put in place the necessary framework to remove it from the market. There is no reason to procrastinate. The delay in moving forward with the ban is causing unnecessary harm, and it is long past time for the FDA to take definitive action. Failing to act now would be a betrayal of your stated commitment to improving our food supply and protecting the health of children and all consumers.

We urge you to act swiftly and decisively to ban carbadox. Deny Phibro's request for a hearing, remove carbadox from the market, and protect both consumer and worker health. The science is clear, and the public deserves better than to continue waiting for action on this dangerous drug.

Sincerely,

Alliance for Humane Biotechnology
Antibiotic Resistance Action Center, the George Washington University
Breast Cancer Prevention Partners
Center for Biological Diversity
Consumer Federation of America
Consumer Reports
CURE Childhood Cancer
Earthjustice
Environmental Working Group
Farm Forward
FarmSTAND
Food Animal Concerns Trust
Foodwise
Institute for Agriculture and Trade Policy
Iowa Citizens for Community Improvement
Kewaunee CARES
Mercy For Animals
Northeast Organic Dairy Producers Alliance
Socially Responsible Agriculture Project
Waterkeeper Alliance

[3] Minnesota Department of Health. "Carbadox Screening Profile," July 2016. https://www.health.state.mn.us/communities/environment/risk/docs/guidance/dwec/screening/carbadox.pdf
[4] Baars, A.J. "Carbadox - An Evaluation." Ministry of Agriculture, Nature Management & Fisheries. Department of Agriculture., April 1997.
[5] Makary MA, Prasad V. Priorities for a New FDA. JAMA. 2025;334(7):565–566. doi:10.1001/jama.2025.10116.