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ASBM Statement on FDA Commissioner's Comments Regarding Compounded Medicines

The Alliance for Safe Biologic Medicines (ASBM) welcomes FDA Commissioner Marty Makary's comments on the social media platform X affirming that "the FDA cannot verify the quality, safety, or effectiveness of non-approved drugs" and warning that the agency will "take swift action against companies mass-marketing illegal copycat drugs." These remarks accurately reflect ASBM's longstanding concern regarding large-scale compounding pharmacies that copy FDA-approved medicines while sidestepping the FDA's rigorous safety, quality, and oversight standards that protect patients.

While ASBM is encouraged by the Commissioner's words, we remain concerned that insufficient action has been taken to date to rein in abuses by large-scale compounding pharmacies. We urge the FDA to follow these statements with strong enforcement actions that signal large-scale compounders cannot operate outside FDA oversight or scrutiny.

Philip Schneider, Chair of ASBM's Advisory Board and a former president of the American Society of Health-System Pharmacists (ASHP), echoed Commissioner Makary's concerns and praised the FDA for calling attention to the issue.

> Compounding pharmacies play a critical role in our medication delivery system - particularly during drug shortages or when patient-specific factors require a customized formulation. But when compounded drugs are mass-produced to copy FDA-approved therapies, they bypass standards for quality, consistency, and accountability that cannot be replicated outside the FDA approval process.

Schneider and fellow ASBM advisory board member Ronald Jordan, past president of the American Pharmacists Association (APhA) and Dean Emeritus at the Chapman University College of Pharmacy have written extensively on the risks of inappropriate compounding and have conducted educational courses at colleges of pharmacy nationwide on the topic. Jordan highlights the importance of FDA oversight for compounded medicines:

> "The U.S. drug supply is probably the safest in the world because of the FDA's standards for drug manufacturing - but the public should know that these standards don't apply to compounders, and those that do are not consistently enforced. On a continuum of risk, U.S. drug manufacturers would be on the low end for risk and pharmacy compounders would be on the high end."

To support and educate policymakers, pharmacists, and the public on the issue, ASBM has launched SafeRxCompounding.org, a dedicated microsite that tracks the rapidly evolving compounding landscape. The site aggregates original analysis, expert commentary, news coverage, and peer-reviewed research, and provides links to relevant federal and state legislation addressing unsafe or unlawful compounding practices. More information is available at **SafeRxCompounding.org**.