Pharmacists’ Commitment to Patient Safety and Compounding Quality

November 12, 2012

As national organizations of pharmacists caring for patients in all settings, we offer our deepest sympathy and condolences to patients and families affected by the fungal meningitis outbreak due to contaminated injectable products. The pharmacy profession is dedicated to ensuring patient safety and access to quality medications that meet patients’ needs. Based on our understanding of this tragedy, the entity involved was engaged in unauthorized manufacturing of drug products, not traditional pharmacy compounding.

Compounding is integral to all aspects of pharmacy practice. Pharmacists compound medications in response to a prescription from a physician or other prescriber to customize a patient’s therapy and meet patient-specific needs. Patients may receive compounded medications when they have a need for a customized medication, when a drug shortage or product discontinuation occurs, when the needed strength or dosage form is not available from a manufacturer, or when an allergen-free version of a medication is needed. Pharmacists also compound prescriptions for veterinary needs.

Patients must continue to have access to high quality compounded medications that are not available from a manufacturer. Pharmacists working in all practice settings such as hospitals and health systems, community pharmacies, long-term care and assisted-living, and the facilities serving our nation’s uniformed services work to ensure that quality compounding standards are met and to comply with state board of pharmacy regulations. Importantly, all practice settings and health professionals providing sterile compounding must follow quality standards. Pharmacies and pharmacists may also be held to accreditation and certification requirements when compounding preparations to further ensure quality and compliance.

The undersigned national pharmacy organizations and our colleague state pharmacy associations are committed to working with state legislatures, and state boards of pharmacy which regulate the practice of pharmacy. In addition, we will work with Congress, the Food and Drug Administration (FDA) which regulates pharmaceutical manufacturing, and the Drug Enforcement Administration (DEA) which regulates controlled substances. We will also collaborate with physicians, other prescribers, and key stakeholders to prevent further tragedy.

We are a resource for policymakers and stakeholders in identifying a clear delineation between drug manufacturing and traditional pharmacy compounding. We will advocate for state pharmacy boards and FDA to have the resources they need for enforcement, and to ensure an appropriate balanced approach for public safety and continued access to compounded medications.

Thank you.

Academy of Managed Care Pharmacy
American College of Apothecaries
American Association of Colleges of Pharmacy
American Pharmacists Association
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists

College of Psychiatric and Neurologic Pharmacists
International Academy of Compounding Pharmacy
National Association of Chain Drug Stores
National Alliance of State Pharmacy Associations
National Community Pharmacists Association
Media Contacts

Academy of Managed Care Pharmacy
Neal Learner
(703) 683-8416 ext 608
nlearner@amcp.org

American College of Apothecaries
Ed Hesterlee
(901) 383-8119
ed@acainfo.org

American Association of Colleges of Pharmacy
Gerry Romano
(703) 739-2330 x1010
gromano@aacp.org

American Pharmacists Association
Michelle Fritts
(202) 429-7588
mfritts@aphanet.org

American Society of Consultant Pharmacists
Lynne Batschon
703-739-1300 ext 141
lbatshon@ascp.com

American Society of Health-System Pharmacists
Ellen Wilcox
(301) 664-8621
ewilcox@ashp.org

College of Psychiatric and Neurologic Pharmacists
Brenda Schimenti
(402) 476-1677
bschimenti@cpnp.org

International Academy of Compounding Pharmacy
David A. Ball
(617) 243-9950
david@ballcg.com

National Association of Chain Drug Stores
Chrissy Kopple
(703) 837-4266
NACDSmedia@nacds.org

National Alliance of State Pharmacy Associations
Rebecca Snead
(804) 285-4431
rsnead@naspa.us

National Community Pharmacists Association
Kevin Schweers
(703) 838-2682
kevin.schweers@ncpanet.org