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December 13, 2006

Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Prescription Drug Marketing Act Pedigree Requirements

Dear Commissioner von Eschenbach:

We, the undersigned companies and trade associations, write to express our concerns with the Prescription Drug Marketing Act ("PDMA") pedigree requirements and to ask the FDA to work with us and the Congress to enact amendments to the PDMA to provide greater protection to the public and to assure continuity to the drug supply chain. PDMA was enacted specifically to avoid risks that counterfeit, adulterated, misbranded, subpotent or expired drugs were being sold to the American public. Especially given the preliminary injunction adopted by a New York federal district court, it is critical that we all work together at the earliest possible time to achieve these objectives.

As we noted in our letter to the FDA on October 20, 2006 (attached hereto), we are committed to assuring the safety of our products in the marketplace. We appreciate that the Compliance Policy Guide 160.900 ("CPG") and accompanying Questions and Answer guidance issued by the FDA recognizes that ADRs should provide pedigree information to downstream distributors, noting that "to further advance the shared goals of protecting the public health, FDA encourages all parties in the prescription drug supply chain to cooperate fully by providing pedigrees and information to trading partners for each sale, transfer, or trade of prescription drugs."

However, because the FDA could only "encourage" ADRs to provide pedigrees, rather than "require" them to do so, ADRs may either refuse to provide pedigrees to non-ADR distributors or offer to provide pedigrees on uneconomic terms. The FDA's guidance indicates that it recognizes the importance of allowing non-ADR an appropriate method to distribute products and provide the required pedigree; however, we also recognize that the FDA lacks the legal authority to require ADRs to provide pedigrees to non-ADR distributors.

Without doubt, there is an enhanced risk to public safety when ADRs are exempted from pedigree requirements. FDA's own criminal enforcement agents can attest to this. In a case

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developed by FDA agents, for example, an employee of H.D. Smith, an ADR, pleaded guilty in 2004 to involvement in a scheme relating to counterfeit Lipitor. And while denying complicity in the scheme, H.D. Smith agreed to pay more than \$2 million in civil forfeiture to the federal government.

In addition to these public safety concerns, the anticompetitive effects stemming from the pedigree requirements will hinder the ability of many small doctors' offices, rural pharmacies, veterinary clinics, and hospitals to acquire needed medications. Because Authorized Distributors of Record ("ADRs") are not required to provide pedigree to non-ADR distributors, thousands of non-ADR distributors who supply smaller and rural operations may be forced under the law to cease conducting business, leaving only a few ADRs left to supply the thousands of customers we currently supply.

We have begun working with members of Congress to adopt a change to the PDMA that would put legal force behind the FDA's "encouragement" to ADRs to provide pedigrees. After the adoption of the preliminary injunction, it is even more critical that we work together to revise the PDMA to provide greater protection to the public and to assure continuity of the drug supply chain.

We ask you to formally indicate to Congress that you support changes in the PDMA that provide FDA with immediate authority to safeguard the public by requiring all wholesale distributors to provide drug pedigrees on all sales to other suppliers. We will call your Office soon to arrange a meeting to discuss our request in further detail and to learn more about FDA's position on this matter. We and thousands of other important businesses in the drug supply network look forward to working with you toward our common goal.

Respectfully submitted,

American Veterinary Distributors Association (including 22 veterinary distributors)

National Coalition of Pharmaceutical Distributors (NCPD)

National Distribution & Contracting, Inc. (representing 280 member medical and dental distributors)

A.F. Hauser, Inc.
Valparaiso IN

ACME Health Products, Inc.
Bartlett, TN

Advanced Medical Sales, Inc.
Laguna Hills, CA,

Advantage Medical Supply Co.
San Antonio, TX

Alpha Scientific Medical, Inc.
La Verne, CA

American Medical Supplies & Equipment, Inc.
Miami, FL

Andromedex Corporation
Frederick, MD

Apex Pharmaceuticals, Inc.
Valencia, CA

Apothevax
St Paul, MN

Atlantic Biologicals
Miami, FL

Beck-Lee, Inc.
Bridgeport, CT

BioPharm Solutions, Inc.
San Marcos, CA

Birmingham Medical Alliance, Inc.
Birmingham, AL

Bloodhound Medical, Inc.
San Luis Obispo, CA

C. D. Smith Company Medical Supplies
Las Vegas, NV

Carolina Pharmaceuticals
Ridgeland, SC

Center Medical Supply
Kalamazoo, MI

D & H Wholesale Medical, Inc.
Ruston, LA

DIT Healthcare
Cincinnati, OH

Diversified Pharmaceuticals, Inc.
Owings Mills, MD

DOSCO Medical
Newbury Park, CA

DTR Medical Wholesale, Inc.
East Hanover, NJ

Dubin Medical, Inc.
San Diego, CA

Global Medical
Miami, FL

Golden State Medical Supply, Inc.
Valencia, CA

Grogan's Healthcare Supply
Lexington, KY

Hanna's Pharmaceutical Supply Co., Inc.
Wilmington, DE

Harford Health Services, Inc
Bel Air, MD

Harrison HealthCare, Inc
Baltimore, MD

HyGen Pharmaceuticals, Inc.
Bellevue, WA

IMCO
Daytona Beach, FL

Independent Medical Co-Op (IMCO)
Daytona Beach, FL

Kreisers Inc.
Sioux Falls, SD

Lake Erie Medical & Surgical Supply, Inc.
Temperance, MI

Liberty Health Supply Inc.
Rochester, NY

Lighthouse Pharmaceutical Services, Inc.
Garden City, GA

Louisiana Wholesale Drug
Sunset, LA

Martin Surgical Supply Co.
Houston, TX

MBI, Inc
Las Vegas, NV

McKendree Wholesale
Murray, KY

Med Chem Inc.
Fountain Inn, SC

Med-Search Pharmaceutical
Fort Lauderdale, FL

MedSource Direct
Woods Cross, UT

Med X Pharmaceutical, Inc.
Stanton, CA

Med-Search Pharmaceutical
Davie, FL

Medical Supplies of America, LLC
Alcoa, TN

Medical Wholesale, Inc.
San Antonio, TX

Merit Pharmaceutical
Los Angeles, CA

Midland Medical Supply Co.
Lincoln, NE

Midwest Med Specialties, Inc.
Loogootee, IN

MyMedSource
Anaheim, CA

NuCare Pharmaceuticals, Inc
Orange, CA

Ocean Medical Supply
Ronkonkoma, NY

PD-Rx Pharmaceuticals, Inc.
Oklahoma City, OK

Pharma Rx Health, Inc.
Totowa, NJ

Physician Supply Company, Limited
Pasadena, TX

Pocket Nurse
Ambridge, PA

Precision Healthcare, Inc.
Nashville, TN

Preferred Pharmaceuticals, Inc
Anaheim, CA

Premium Health Services, Inc
Columbia, MD

Priority Pharmaceuticals, Inc.
San Diego, CA

QK Healthcare
Ronkonkoma, NY

Quality Care Products, LLC
Temperance, MI

R Medical Supply, Inc.
Hillsborough, NC

R. Weinstein Pharmaceuticals & Medical Products
Honolulu, HI

Rally, Inc.
Houston, TX

Richmark Medical Supply, Inc
West Chicago, IL

River City Rx
Cincinnati, OH

SavMart Pharmaceutical Services, Inc.
San Diego, CA

STAT Pharmaceuticals
Santee, CA

Southern Safety Sales, Inc.
Austin, TX

Summit Medical Supplies, Inc

Sun Surgical
Gainesville, FL

Superior Medical Supply, Inc.
Superior, CO

TW Medical Veterinary Supply
Lago Vista, TX

United Medical Supply
Greensboro, NC

University Specialty Drugs
San Diego, CA

U.S. Medical Distribution Systems, Inc.
Jessup, MD

Valley Apothecary Wholesale
Salem, VA

Vet Brands International, Inc.
Miramar, FL

Wilmington Hospital Supply Co. Inc
Wilmington, NC