

NorthAmerican - PCA

NorthAmerican-Pharmotherapeutic Consultants Association

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October 28, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 2003N-0361

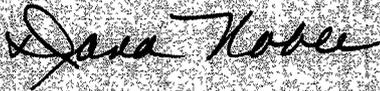
Dear Sir/Madam:

The enclosed attachment is North American-Pharmotherapeutic Consultants Associations (NorthAmerican-PCA) response to the request for comments to the "FDA's Counterfeit Drug Task Force Interim Report" dated October 2003. Our recommends apply directly to the Options for Improving Prescription Drug Security and Secure Business Practices.

Our comments focus on assuring consumer quality of mailorder prescription drugs. The comments of NorthAmerican-PCA are those of physicians and pharmacists from the United States, Mexico and Canada. NorthAmerican-PCA is based in the United States and has no interest in pharmaceutical manufacturing or retail drug sales.

I am available to answer any questions you may have. Do not hesitate to contact me at your convenience.

Sincerely,



Dana Noble, RN, MBA
Executive Director

attachment

2003N-0361

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Preface

NorthAmerican-Pharmotherapeutic Consultants Association (NorthAmerican-PCA) appreciates and supports the efforts of the FDA in assuring the quality of prescription drug supply to American consumers.

We believe that in the current global market a standardized set of quality measures to evaluate pharmacy functions and operations can assure a safe product for consumers. Other health care arenas, such as, hospitals have established precedent for this methodology of measuring against a standard set of rigorous measures.

We highly recommend that an independent (non-industry) body based in the United States use a set of quality standards to measure and accredit internet and mailorder pharmacies in the United States and in pharmacies located other foreign trade nations.

Recommendations

NorthAmerican-Pharmotherapeutic Consultants Association (NorthAmerican-PCA) recommends that the following core measures be use to accredit mailorder and internet pharmacies:

Quality Assurance

Standard 1: There are mechanisms in place to assure the quality of pharmaceutical dispensing and distribution.

Standard inclusions:

- Drug tracking mechanisms including point of origin
- Professional licensure requirements
- Provider and consumer access to a licensed pharmacist
- Requirement for staff competency review
- Evidence of peer review
- Evidence of performance improvement activity
- Evaluation of dispensing errors and follow-up process
- Corporate attestation to drug origin

Pharmacy Management

Standard 2: The Pharmacy is organized and functions to assure drug integrity and safety.

Standard inclusions:

- Clinical oversight pharmacy operations
- Event reporting process
- Security and safety of drug handling
- Infection control processes
- Drug storage and handling
- Recall processes
- Staff access to current references
- Evidence of staff oversight
- Evidence of staff training
- Operational policies and procedures
- Quality Control procedures
- Human Resource management

Consumer Safety

Standard 3: Consumers are assured safety in the dispensing of pharmaceuticals.

Standard Inclusions:

- Requirement for clinical assessment
- Drug container labeling and shipping
- Follow-up to assessment findings
- Clear and factual marketing materials
- Licensed professional oversight of all dispensing
- Order filling as written
- Therapeutic review

Customer Satisfaction

Standard 4: Performance quality is determined by consumer satisfaction.

Standard Inclusions:

- Requirements for customer feedback mechanism
- Requirement for customer complaint process
- Customer and provider satisfaction process
- Measurement of follow-up turn around time

Health Information Technology

Standard 5: Privacy and Protection of Consumer Health Information. Standard encompasses Healthcare Information Portability and Accountability (HIPAA) and Personal Health Information Act (PHIA)), as applicable.

Standard Inclusions:

- Health information security measures
- Data back up systems
- Privacy policies
- Record maintenance and destruction
- Process for staff confidentiality statements

Website Content

Standard 6: Website provides consumers pharmacy access

Standard Inclusions:

- Website disclosure of state licensure
- Provision of consumer access to a licensed professional
- Disclosure of pharmacy location

Shipping and Handling

Standard 7: Shipping and Handling process is disclosed to consumers and provides ease of access

Standard Inclusions:

- Full disclosure of all shipping fees
- Measures of shipping turn around time
- Safety of drug packaging

Customer Call Center

Standard 8: Customer Call Centers assure consumer access and timely response

Standard Inclusions:

- Call center access is toll free
- Evidence of staff evaluation and training
- Supervision of call center operations
- Response turn-around time

Accreditation process includes: document review, personnel records review, staff interviews, and pharmacy and customer call-center site inspection.

NorthAmerican-PCA Board of Directors

Juan Angeles, B.S. : Director

Juan Angeles is the General Director for CAFET in Mexico City, Mexico. With a Bachelors of Science Degree in Industrial Pharmacy and post graduate studies in applied statistics, he has been a director of research and development in various pharmaceutical industry settings and has a number of patents approved in the United States and worldwide. He has also been a professor of pharmaceutical technology and participated in a various committees to develop and revise education programs in industrial pharmacy. Mr. Angeles is a member of and has served as an officer in the Mexican Pharmaceutical Association and National Association of Pharmacists. His professional interests include dissolution testing and bioequivalence studies, generic drug products, and international and Mexican pharmaceutical legislation. Mr. Angeles serves as an expert for commissions authorized by the Ministry of Health in Mexico.

John Dzurka, B.S.P. : Vice President

John Dzurka is the Vice President of Bourke's Drug Stores Limited, the parent company of Medi Plus, in Ontario, Canada. A retail pharmacist for over 20 years, he graduated from the University of Saskatchewan. He is active in Canadian Pharmaceutical Association, Ontario's Pharmacist's Association and Thunder Bay Pharmacist's Association. His professional interests include promotion and coordination of health care events for the public and professional communities, and pharmotherapeutic assessment and management of elderly patients and patients with diabetes. Mr. Dzurka is also the Vice President of Category Management Systems, a pharmacy plan-a-gram service, which is an inventory control system to meet consumer demand and reduce waste.

Dana Noble, R.N., M.B.A. : Executive Director

Dana Noble is the Executive Director of NorthAmerican-Pharmotherapeutic Consultants Association and a principal in HealthInova, a healthcare consulting firm. With over 20 years experience in clinical care and healthcare administration, she has held both executive and middle management positions and has developed expertise in operations, program development, performance improvement and care management. She has created integrated clinical services and care management programs within acute care, home care, sub acute care and long term care settings, and facilitated processes between providers and managed care entities. Her professional interests include access to safe affordable prescription drugs, expansion of the role of physicians and clinicians in health care public policy, and quality improvement. She has a bachelor's degree from Russell Sage College and a master in business administration from Western New England College.

Doug Penner, B.P.S. : Director

Doug Penner is the President of Alentex Health (Canada), headquartered in Winnipeg, Manitoba. He has degrees in psychology and pharmacy, and is currently completing his Doctor of Pharmacy at the University of Minnesota. His professional career has spanned community, hospital, and industrial pharmacy environments with specialization in palliative care, oncology, and regulatory affairs. His involvement on various professional and government committees as well as his continuing role at the front-line of patient care has enabled him to identify and satisfy the numerous needs of persons involved in the health care arena. As president of Alentex Health, he actively promotes patient health and the primary care role pharmacy can deliver. Alentex specializes in more complicated therapies associated with more challenging pharmaceutical care areas. Institutional drug delivery, innovative medicinal compounding, drug infusion services, pharmaceutical research and clinical trials, and nuclear medicine allow Alentex to provide the highest quality of product and services to those patients who require the greatest of care.

Eric Seyferth, M.D. : Secretary/ Treasurer

Dr. Eric Seyferth has a busy solo internal medicine practice in Bennington, Vermont. He is Chairman of the Board of Directors of United Health Alliance, a physician hospital organization (PHO) and Chairman of the Department of Medicine of Southwestern Vermont Medical Center. Dr. Seyferth originated the idea of systematizing and disseminating a practical method for accessing prescription drugs from Canada for United States patients who were having difficulty affording the skyrocketing cost of prescription drugs. This inspired creation of the MedicineAssist, a program to support personal re-importation of prescription drugs from Canada. Dr. Seyferth remains committed to ensuring access to safe, high quality affordable prescription pharmaceuticals for all North Americans. Dr. Seyferth is a graduate of Albany Medical College in Albany, New York.

Peter Shumlin : Chairperson

Senator Peter Shumlin served in the Vermont Legislature for 13 years (1990-2002). From 1990-92, he represented Windham in the House of Representatives. In 1993, he was elected to the Vermont Senate and served there for 10 years. His Senate colleagues elected him Minority Leader after his first term. Mr. Shumlin was the youngest Senator serving at that time. After leading a successful effort to regain the majority while serving as minority leader, he was unanimously elected President pro tem of the Senate in 1997, a position that he held for 6 years. In the Senate he served on numerous committees including the Appropriations Committee and chaired the Senate Rules Committee and The Finance Committee. During his tenure as President of the Senate, Mr. Shumlin worked closely with Gov. Howard Dean to pass landmark legislation that led the country in education funding, fair prescription drug prices, mental health parity, civil

rights and consumer protection. He was instrumental in the creation of the Legislative Association on Prescription Drug Prices which brings legislative leaders together to develop strategies to aid in the reduction of pharmaceutical costs. He served as Chair of the Legislative Association on Prescription Drug Prices for 3 years. His professional interests include access to and affordability of high quality prescription drugs. He remains active in Vermont and national politics. Together with his brother, he directs Putney Student Travel, an educational summer program for high school age students. Mr. Shumlin earned a bachelor in arts degree from Wesleyan University, Middletown, Connecticut.

Fermin Valenzuela, M.D. : Director

Fermin Valenzuela, M.D. is a medical physician in Mexico who has completed a second doctorate in physiology and a post doctorate fellowship in physiology. He has extensive experience in research at the National Institute of Cardiology. For over 20 years, he was a professor in pharmacology, cardiology and physiology in Mexican Schools of Medicine. As a researcher and professor, Dr. Valenzuela has been recognized with a number of awards including Dr. Ignacio Chavez Award for research, Funsalud Alfonso Robinson Bours Award for Medical Education and the Martin de la Cruz Award by the Counsel for General Health. He is a member of and has served as an officer in various professional association including the Mexican Society of Cardiology, the Mexican Association of Pharmacology, and the National Academy of Medicine. Dr. Valenzuela's professional interests include pharmotherapeutic guidelines, bioequivalence of generic medications, and pharmacological regulations in Mexico, as well as research interest in cardiovascular clinical studies and basic pharmacology. He has served on numerous liaison committees with the pharmaceutical industry, the National Academy of Health, and the Mexican government and is sought after as consultant on pharmacology in Mexico.

Arthur Zoloth, PharmD. : Director

Arthur Zoloth, PharmD. is the Vice President of Professional Affairs for Northwest Pharmacy Services, a national pharmacy benefit management company, located in Puyallup, Washington. With over 30 years experience in the pharmacy industry, he has held staff and pharmacy leadership positions in various hospitals and served in executive positions in pharmacy benefit management companies. He has been active in professional associations serving on the Board of Directors and as Chairperson on the Legislative Committee on the Washington State Pharmacy Association and served on the Washington State Board of Pharmacy. Dr. Zoloth holds a faculty appointment as a Clinical Professor of Pharmacy at the University of Washington. His professional interests include balancing quality care and cost-effective utilization of drugs. As an advocate of quality pharmacy care, he has provided testimony to the Washington State legislature and the US Congress. Dr. Zoloth has a doctorate in pharmacy from the University of California.