FINAL/APPROVED (9-19-05)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD-HOC PEDIGREE COMMITTEE

August 18, 2005
Fifth Floor
Conference Room 1

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the ad hoc committee appointed by the Board of Pharmacy to draft regulations to implement a pedigree system was called to order at 1PM.

PRESIDING: John Beckner, Board Vice-Chairman

COMMITTEE MEMBERS PRESENT: Bobby Ison
Michael J. Ayotte

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst

DISCUSSION

Ms. Russell reviewed the 2005 legislation requiring that the Board establish a pedigree system. Ms. Yeatts provided an overview of the regulation promulgation process and told the committee that with the various review processes and public comment periods, the earliest the Board could expect to have regulations in place will be sometime in 2007. The charge to this committee would be to have draft regulations ready for Board review and adoption at its December 1, 2005 meeting.

The committee reviewed NABP model regulations related to pedigrees and also Florida requirements, and two written comments received from HDMA and from Cardinal Health. The public was informed that the committee would like to hear verbal comments today and have an informal discussion, and that written comments in response to the NOIRA could be submitted until close of business, August 24, 2005.

Mr. Beckner called for public comment. Timmy Nelson, representing UPS spoke on the issue of third party logistics providers, who are contract warehousers for manufacturers, take possession of drugs from a manufacturer, store them, and arrange for shipments as directed by the manufacturer, but never take title to the drugs. All decisions about shipping and billing are handled by the manufacturer. These entities are licensed in some states as wholesale distributors and in most states as non-resident wholesale distributors, but because they are an agent of the manufacturer with no independent authority to distribute, they do not want to have to be listed on the pedigree, as they consider that the drugs they store still rest with the manufacturer.

Todd Kaufman, representing Genentech, a pharmaceutical manufacturer, stated that typically pedigree systems exempted the manufacturer from having to initiate a pedigree, and also exempted authorized distributors of record (ADR). He requested that Virginia follow this systems approach, starting the pedigree with the last ADR who sells to a non-ADR. He stated that Florida, when it loses its ADR exemption in June 2006 will begin with the first wholesale distributor who has to call the manufacturer for verification. He stated that Texas has a different approach where a pedigree is not required for distributions from manufacture to wholesale distributor to retail outlet, but is required only for drugs that move outside of the usual distribution chain into the secondary wholesale market.

Liz Gallenagh representing HDMA stated that HDMA is advocating for exemption from pedigree for drugs that flow from the manufacturer to one ADR, to a second ADR or chain drug warehouse, then to retail outlet. Allowing for this second intermediary step will allow for legitimate movement due to shortages or the way in which chain warehouses operate routinely.

There was general discussion as to what requirements were for a company to be an ADR. Anne Leigh Kerr and Tara Ryan representing PhRMA stated that they would try to get some information on what manufacturers require and forward this to the Board office. It was generally agreed by the public participants that there is not a need for a pedigree at this time provided a drug flows through known channels from manufacturer through a primary wholesale distributor and/or chain drug warehouse to a retail outlet. The committee agreed, for drafting purposes, that if the Board has the authority to exempt certain distribution practices from the pedigree requirement, it should not just use the ADR term, but should establish the criteria for defining those entities or transactions that would be exempt.

There was also general discussion and agreement that true "track and trace" technology of the unit of sale, such as RFID will track a drug from the manufacturer through the system completely once the technology is widely available and standardized, but that this may not be for years, some estimates 2010 and beyond, and until that time, the Board will have to have a pedigree system in place, but that it shouldn't unduly burden legitimate entities.

Brenda Kelly, representing SupplyScape, a company offering software to manage an electronic pedigree advised the committee

not to confuse an electronic pedigree which is an electronic document with track and trace technology, something different.

There was next discussion on the Board's charge to limit the pedigree to certain schedules of drugs or drugs more susceptible to counterfeiting. The committee reviewed HDMA's suggested criteria, as well as the NABP model criteria and Florida's current criteria, and determined that it would draft its own criteria using those as guidelines, but would begin with the list already developed by NABP, and establish a process whereby the Board would review the list annually for additions or deletions, and would also have a process whereby drugs could be added on an emergency basis, and whereby persons could petition the Board for addition or deletion of drugs. Also there would be time for implementation for any drug added to the list to ensure that the drugs already in the distribution channels would not need pedigrees. It was recommended that the Board post any addition/deletion on its website, but that it also provide written notice to wholesale distributors.

The committee determined that the draft regulations could be subdivided into several categories as follows for consideration:
1. List of susceptible products, criteria for list, addition/removal
2. Who has to make the pedigree, where it starts, exemptions of certain entities or transactions
3. Elements of a pedigree
4. Recordkeeping requirements
5. Implementation date

It was discussed that data elements should be standardized to facilitate companies operating in more than one state. It was noted that in the Cardinal written comment, approximately 12 data elements were listed which would be a starting point for drafting. Liz Gallenagh stated that she would send any additional information on data elements not covered in the Cardinal comment to the Board office.

There was also some general discussion about setting minimum requirements for electronic pedigrees to ensure security of a database, that Florida was looking at some detailed regulations related to the electronic pedigree. It was discussed that much of Florida's proposed requirements was taken from the new DEA requirements for electronic Schedule II ordering which was a one to one ordering process and different from a pedigree system. It was suggested that the Board may want to write regulations flexibly enough that industry could drive the standards for

electronic pedigrees. It was also suggested that the Board put in regulation that it will accept another state's pedigree provided the requirements are substantially the same.

NEXT MEETING DATE The next meeting was set for September 19, 2005 from 9AM until noon.

ADJOURN: With all business concluded, the meeting adjourned at 3:45PM

Elizabeth Scott Russell
Executive Director

John O. Beckner, Vice Chairman

Date