COMMONWEALTH OF VIRGINIA:

DEPARTMENT OF HEALTH PROFESSIONS

6603 West Broad Street, 5th Floor

Richmond, Virginia 23230

Public Hearing

RE: Before the Board of Pharmacy

Transcript to the comments received at the public hearing when held on Tuesday, June 12, 2007, at 11:30 a.m.

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SPEAKERS:

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MR. JOHN BECKNER: Good morning, I now call for this public hearing to receive comments on the proposed amendment to the regulations governing the wholesale distributors, manufacturers, and warehousers for the establishment of a pedigree system. Copies of the proposed amendments are available at the table in the back of the room. At this time, I'm going to call on persons who have signed up to comment. As I call your name, please come forward and tell us your name and where you're from.

MS. KERR: My name is Anne Leigh Kerr and I'm with the law firm of Troutman Sanders. We really have one comment on the pedigree regulations. With me here today is Clemet CyPra and he is with PhRMA. We have one comment concerning the pedigree system. If you look at Section 18VAC110-50-180 – Authentication of a pedigree, page 4. We have had a company bring to our attention an issue they have with Section A. If read, in my opinion, somewhat widely, Section A could require a manufacturer to have to provide information in 1, 2, 3, and 4, which comes below "A". We have a manufacturer who has specific questions from PhRMA asking if they would have to provide information dealing with the receipt or shipment of their drug to the wholesaler #1. The example of manufacturer to wholesaler #1 and the wholesaler #2 to the end user, CVS – use that as an example. They can verify the transaction of manufacturer to wholesaler #1 but would not have any information on the transfer of the medication from wholesaler #1 to wholesaler #2. Reading this very widely, there was some concern that there would be some requirement made and that the manufacturer would have to know all of the

pages of where the medication goes. So it was brought to our attention by a representative representing PhRMA, and I want to bring it to your attention that there was some concern, sort of when we were dabbing around whether or not there was any way to restrict this. We thought that if you included language in Section A, something along the lines of only for those applicable transactions conducted by that manufacturer or wholesale distributor. It might tighten it up, at least in the minds of this particular company, to say that a company would provide any information to wholesaler #2 or whoever down the line to authenticate the pedigree. They could provide anything that they knew but would not be required to research or authenticate something that happened with their medication after it went past the first transaction which they would have no information on. Does that make sense?

MS. RUSSELL: Would you repeat how that would affect--

MS. KERR: --If you would insert in 110-50-180 "A", and after the words timely manner in line 3, it would read: provide requested information in a timely manner only for those applicable transactions conducted by that manufacturer or wholesale distributor.

MS. RUSSELL: Only for those applicable transactions for that--

MS. KERR: --Conducted by that manufacturer or wholesale distributor. We were working on this late last night so I apologize I don't have anything in writing for you to make it easier.

MS. RUSSELL: Let me reiterate that Number A would read, "Any manufacturer or wholesale distributor listed on the

pedigree shall provide requested information in a timely manner, only to those applicable transactions conducted by that manufacturer or wholesale distributor, to include the following."

MS. KERR. Correct. I think the likelihood of a wholesaler #2, wholesaler #3, or someone asking the manufacturer to verify some transaction is probably not going to happen, but I'm a lawyer and it does sort of lead that to the possibility. I don't know why they would, but they could and the company doesn't want to get into the problem of not being able to provide the requested information.

MR. BECKNER: Does any Board member want to comment on that edition?

MS. EDWARDS: Would it be sufficient instead of adding that on "A", maybe under #1 when you say that dates of receipt or shipment of the drug as well as the name, address, and other contact information of the entity from whom they received the drug or to whom they shipped the drug? Are you trying to eliminate from where they received it, one step before and one step after?

MR. CYPRA: I think the idea was you'd only be able to report information about what you had knowledge of. There is a genuine concern expressed that the manufacturer I was representing would have to know what happened in all the stages of that and be required to report on something about which we had no ability to report and then the drug not being able to be held up and sent back to DEA, along those lines. I think up in "A" it makes it broader and more specific to the transaction that we're looking to getting a clarification on. You probably theoretically could

do it with #1, but I'm not a lawyer. But the lawyers who do come up with language such as this, recommended "A".

MR. BECKNER: Thank you. Any other comments?

MS. KERR: That's all I have, except to say, Thank you for working through this, two, three, a long time. Thank you."

MR. BECKNER: Thank you. Is there anyone else signed up to comment? Is there anyone not signed up that wants to comment? Thanks. I'll remind everyone that written comments must be received through August 10, 2007, and should be directed to Scotty, Executive Director of the Board of Pharmacy. The Board will consider all comments prior to the adoption of final regulations at its meeting on September 12, 2007. We thank you for taking the time to participate. This concludes our public hearing.

PROCEEDINGS CONCLUDED.

COMMONWEALTH OF VIRGINIA,

CITY OF RICHMOND, to wit:

I, Medford W. Howard, hereby certify that I was the court reporter at the Board of Pharmacy public hearing held in Richmond, Virginia, on June 12, 2007, at the time of the hearing herein.

I further certify that the foregoing transcript is true and accurate as set down, to the best of my ability.

Given under my hand this 15th day of June, 2007.