VIRGINIA BOARD OF PHARMACY
MINUTES OF AD-HOC PEDIGREE COMMITTEE

October 31, 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 9AM.

PRESIDING: John Beckner, Board Vice-Chairman

COMMITTEE MEMBERS PRESENT: Michael J. Ayotte

COMMITTEE MEMBERS ABSENT: Bobby Ison

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General

DISCUSSION: The committee continued discussion of the draft regulation from the last meeting. (Attachment 1)

There was further discussion concerning whether the Board could exempt "normal" distribution channels from the regulation. Cardinal Health had submitted comments for consideration, most related to exempting authorized distributors of record. Mr. Casway again advised that the statute is not ambiguous and does not allow for this. The Board did take one suggestion to define "single source drug". There was some discussion as to whether the Board would seek legislation to amend the statute to allow this. Ms. Yeatts advised that the Board would not be able to seek such legislation until the 2007 session.

Mr. Beckner stated that the committee would allow public comment throughout the meeting. Representatives from Pfizer, PhRMA, HDMA, VACDS, and UPS were present for the meeting and participated in the discussion. Anne Leigh Kerr, representing PhRMA indicated that legislation may be sought to correct some of the problems and give the Board authority to carve out certain channels of distribution from the pedigree requirement and to add products to the susceptible products without going through the full rulemaking process. If such legislation is sought, the committee agreed to review and offer technical assistance in drafting a

legislative proposal, but made it clear that such assistance could not be construed as a position of support for the proposal by either the Board of Pharmacy or the Department of Health Professions.

The committee continued work on the draft and made a number of amendments (Attachment 2). However, in light of the possibility of legislation, the committee decided that a draft proposed regulation would not be presented to the full board for adoption at its December 1, 2005 meeting. The Chair asked those persons present if there was any objection to delaying the completion of the draft until after the General Assembly session. Everyone present was in agreement that this should be delayed. There were no requests to go forward at the December meeting.

NEXT MEETING DATE The Chair did not set the date for the next meeting, electing to wait for further direction as to whether legislation will be introduced.

ADJOURN: With all business concluded, the meeting adjourned at 11:15AM

Elizabeth Scott Russell
Executive Director

John O. Beckner, Vice Chairman

Date

WORKING DRAFT FROM 9/19/2005 MEETING
Part IV. Pedigree requirements

18VAC110-50-160. Susceptible products.

A. A pedigree shall be required for all dosage forms, strengths and container sizes for the following list of drug products susceptible to adulteration, diversion or counterfeiting:

1. Combivir (lamivudine/zidovudine)
2. Crixivan (indinavir)
3. Diflucan (fluconazole)
4. Epivir (lamivudine)
5. Epogen (epoetin alfa)
6. Gamimune (globulin, immune)
7. Gammagard (globulin, immune)
8. Immune globulin
9. Lamisil (terbinafine)
10. Lipitor (atorvastatin)
11. Lupron (leuprolide)
12. Neupogen (filgrastim)
13. Nutropin AQ (somatropin, E-coli derived)
14. Panglobulin (globulin, immune)
15. Procrit (epoetin alfa)
16. Retrovir (zidovudine)
17. Risperdal (risperidone)
18. Rocephin (ceftriaxone)
19. Serostim (somatropin, mannalian derived)
20. Sustiva (efavirenz)
21. Trizivir (abacavir/lamivudine/zidovudine)
22. Venoglobulin (globulin, immune)
23. Viagra (sildenafil)
24. Videx (didanosine)
25. Viracept (nelfinavir)
26. Viramune (nevirapine)
27. Zerit (stavudine)
28. Ziagen (abacavir)
29. Zocor (simvastatin)
30. Zofran (ondansetron)
31. Zoladex (goserelin)
32. Zyprexa (olanzapine)

B. The board may place a drug on the list of susceptible products under its authority to adopt emergency regulations pursuant to § 2.2-4011 of the Administrative Process Act, if it has seized or issued a stop sale notice of a prescription drug or if it has received notice electronically or in writing from the FDA, a manufacturer, a wholesale distributor a state or federal law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs that a drug has been

adulterated, counterfeited or diverted from the legal channels of distribution; and the prescription drug satisfies one of the following criteria:

1. A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or missing;

2. The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer solely because of concerns about counterfeiting or diversion;

3. The board is aware of five or more instances in which pedigrees or similar documentation were not passed on other than because of unintentional oversight or have been passed on to or by a wholesale distributor and were fraudulent;

4. The prescription drug is used extensively for serious and/or life-threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

5. The prescription drug is a single source injectable drug;

6. The prescription drug is commonly prescribed and available for normal use in dosages or strengths that have substantial wholesale cost or appears among the IMS top 50 single source revenue-generating prescription drugs; or

7. The prescription drug is in limited supply due to a national shortage that has a duration of not less than nine months.

C. The board may add a drug to the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if the drug is added to the National Association of Boards of Pharmacy Susceptible Product List, or if any three of the above-listed seven criteria exist and the board determines that the drug is susceptible to adulteration, diversion from the legal channels of distribution, or counterfeiting.

D. The board may delete a drug from the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if the drug is deleted from the National Association of Boards of Pharmacy Susceptible Product List, or if the board otherwise determines that a drug should be deleted from the list as specified in paragraph E of this section.

E. Not less than annually, the board shall evaluate whether each prescription drug included on the list of susceptible drugs should remain on the list. In determining whether a prescription drug should remain on the list, the board shall consider the following:

1. The availability of generic forms of the drug;

2. Pricing of the drug that may impact diversion or counterfeiting potential since it was placed on the list; and

3. Whether the conditions contributing to the placement of the list continue to exist.

18VAC110-50-170. Requirement for a pedigree.

A. Pursuant to § 54.1-3307of the Code of Virginia, a pedigree shall be recorded for distribution of any drug listed in 18VAC110-50-160, starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, whether an authorized distributor of record or not, until final sale to a pharmacy or other authorized person administering or dispensing the susceptible drug.

B. The requirement for a pedigree shall be effective beginning (one year from the effective date of a final regulation).

C. All wholesale distributors shall provide a pedigree for those susceptible drug products sold or returned to another wholesale distributor before the transaction is made to such wholesale distributor.

D. The failure to obtain, authenticate or pass on a pedigree, when required by this chapter, may subject a licensee to disciplinary action by the board.

18VAC110-50-180. Authentication of a pedigree.

A. Wholesale distributors shall, at least quarterly, conduct authentications of pedigrees of at least 90% of sale units of distributions of drugs on the list of susceptible drug products that were purchased from another wholesale distributor.

B. Wholesale distributors that have engaged in the distribution of a drug, for which a purchasing wholesale distribution is conducting an authentication, shall provide requested information in a timely manner, to include the following:

1. Date of purchase;

2. Lot number or control number;

3. Sales invoice number; and

4. Contact information, including name, address, telephone number, and email address (if available) for the wholesale distributor that sold or purchased the drug, for which the distribution is being authenticated.

C. If a wholesale distributor that is attempting to authenticate the distribution of a drug back to a manufacturer is unable to authenticate each distribution, the wholesale distributor shall quarantine the drug and report to the board and the FDA within three business days after completing the attempted authentication.

D. If the authentication is satisfactorily completed, the wholesale distributor shall maintain records of the authentication for three years and shall produce them to the board upon request.

18VAC110-50-190. Content of a pedigree.

The pedigree shall minimally include the following information on a prescription drug on the susceptible list:

1. The trade and generic
name of the drug;

2. The dosage form and strength, the container size, number of containers, and lot number;

3. The name of the manufacturer of the finished drug product;

4. The business name, address, telephone number and email address, if available, of each entity involved in the chain of the drug's custody.

5. The sales invoice number or other unique shipping document number that identifies the transaction;

6. The dates of the transactions to include the shipping date when the seller ships the product and the receiving date when the purchaser receives the product.

7. The name and address of each person certifying delivery or receipt of the drug;

*8. A certification that each recipient has authenticated the pedigree; and

*9. A certification from the licensed entity that the information contained therein is true and accurate.

18VAC110-50-200. Recordkeeping.

Wholesale distributors shall establish and maintain inventories and records of all transactions relating to the receipt and distribution or other disposition of drugs included on the list of susceptible drugs for a period of not less than three years.

*** did not complete work on this section, and may need further revision.**

WORKING DRAFT AFTER CHANGES FROM 10/31/2005 MEETING
Part IV. Pedigree requirements

18VAC110-50-160. Definitions

"Single source drug" means a prescription drug that is produced under an original new drug application (NDA) approved by FDA for which there are no generic alternatives.

18VAC110-50-170. Susceptible products.

A. A pedigree shall be required for all dosage forms, strengths and container sizes for the following list of drug products susceptible to adulteration, diversion or counterfeiting:

1. Combivir (lamivudine/zidovudine)
2. Crixivan (indinavir)
3. Diflucan (fluconazole)
4. Epivir (lamivudine)
5. Epogen (epoetin alfa)
6. Gamimune (globulin, immune)
7. Gammagard (globulin, immune)
8. Immune globulin
9. Lamisil (terbinafine)
10. Lipitor (atorvastatin)
11. Lupron (leuprolide)
12. Neupogen (filgrastim)
13. Nutropin AQ (somatropin, E-coli derived)
14. Panglobulin (globulin, immune)
15. Procrit (epoetin alfa)
16. Retrovir (zidovudine)
17. Risperdal (risperidone)
18. Rocephin (ceftriaxone)
19. Serostim (somatropin, mannalian derived)
20. Sustiva (efavirenz)
21. Trizivir (abacavir/lamivudine/zidovudine)
22. Venoglobulin (globulin, immune)
23. Viagra (sildenafil)
24. Videx (didanosine)
25. Viracept (nelfinavir)
26. Viramune (nevirapine)
27. Zerit (stavudine)
28. Ziagen (abacavir)
29. Zocor (simvastatin)
30. Zofran (ondansetron)
31. Zoladex (goserelin)
32. Zyprexa (olanzapine)

B. The board may place a drug on the list of susceptible products under its authority to adopt emergency regulations pursuant to § 2.2-4011 of the Administrative Process Act, if it has seized or tagged a prescription drug pursuant to §54.1-3459 or if it has received notice electronically or in writing from the FDA, a manufacturer, a wholesale distributor a state or federal law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs that a drug has been adulterated, counterfeited or diverted from the legal channels of distribution; and the prescription drug satisfies one of the following criteria:

1. A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or missing;

2. The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer solely because of concerns about counterfeiting or diversion;

3. The board is aware of five or more instances in which pedigrees or similar documentation were not passed on other than because of unintentional oversight or have been passed on to or by a wholesale distributor and were fraudulent;

4. The prescription drug is used extensively for serious and/or life-threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

5. The prescription drug is a single source injectable drug;

6. The prescription drug is commonly prescribed and available for normal use in dosages or strengths that have substantial wholesale cost or appears among the IMS top 50 single source revenue-generating prescription drugs; or

7. The prescription drug is in limited supply due to a national shortage that has a duration of not less than nine months.

C. The board may add a drug to the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if the drug is added to the National Association of Boards of Pharmacy Susceptible Product List, or if any three of the above-listed seven criteria exist and the board determines that the drug is susceptible to adulteration, diversion from the legal channels of distribution, or counterfeiting.

D. The board may delete a drug from the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if the drug is deleted from the National Association of Boards of Pharmacy Susceptible Product List, or if the board otherwise determines that a drug should be deleted from the list as specified in paragraph E of this section.

E. Not less than annually, the board shall evaluate whether each prescription drug included on the list of susceptible drugs should remain on the list. In determining whether a prescription drug should remain on the list, the board shall consider the following:

1. The availability of generic forms of the drug;

2. Pricing of the drug that may impact diversion or counterfeiting potential since it was placed on the list; and

3. Whether the conditions contributing to the placement of the list continue to exist.

18VAC110-50-180. Requirement for a pedigree.

A. Pursuant to § 54.1-3307of the Code of Virginia, a pedigree shall be recorded for distribution of any drug listed in 18VAC110-50-170, starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor until final sale to a pharmacy or other authorized person administering or dispensing the susceptible drug.

B. All wholesale distributors shall provide an authenticated pedigree for those susceptible drug products sold or returned to another wholesale distributor before or at the time such product is shipped to such wholesale distributor.

C. The pedigree shall minimally include the following information on a prescription drug on the susceptible list:

1. The trade or generic name of the drug;

2. The dosage form and strength, the container size, number of containers, and lot or batch number;

3. The name of the manufacturer of the finished drug product;

4. Each transaction in which the drug is shipped or received by a manufacturer or wholesale distributor showing the following:

a. The business name and address of each entity involved in the chain of the drug's physical custody;

b. Telephone number and other contact information needed to authenticate the pedigree.

c. Sales invoice numbers or other unique shipping document numbers that identify each transaction;

d. The dates of the transactions to include shipping dates when a seller ships the product and the receiving dates when a purchaser receives the product; and

e. A statement of certification that the information contained in the pedigree is true and accurate and the name and signature of the individual certifying the authenticity of the pedigree at the time of shipment of the drug.

D. The requirement for a pedigree shall be effective beginning (one year from the effective date of a final regulation).

E. The failure to obtain, authenticate or pass on a pedigree, when required by this chapter, may subject a licensee to disciplinary action by the board.

18VAC110-50-190. Authentication of a pedigree.

A. Upon request of a wholesale distributor who is attempting to authenticate a pedigree for a drug listed in 18VAC110-50-170, any manufacturer or wholesale distributor listed on the pedigree shall provide requested information in a timely manner, to include the following:

1. Dates of receipt or shipment of the drug as well as the name, address, and other contact information of those entities from whom they received the drug or to whom they shipped the drug;

2. Lot number or batch number;

3. Sales invoice number or other unique shipping document numbers that identify each transaction; and

4. Person's name who is providing the requested information.

B. The wholesale distributor shall record the above information and maintain the information in accordance with 18VAC110-20-200.

C. If a wholesale distributor that is attempting to authenticate the distribution of a drug back to a manufacturer is unable to authenticate each distribution, the wholesale distributor shall quarantine the drug and report to the board and the FDA within three business days after completing the attempted authentication.

18VAC110-50-200. Recordkeeping.

A. Wholesale distributors shall establish and maintain inventories and records of all transactions relating to the receipt and distribution or other disposition of drugs included in 18VAC110-50-170, to include records of authentication of pedigrees, for a period of not less than three years.

B. All records shall be made available to the Board or its authorized agent upon request. If records are not kept on premises at the address of record, they shall be made available within 48 hours of such request.