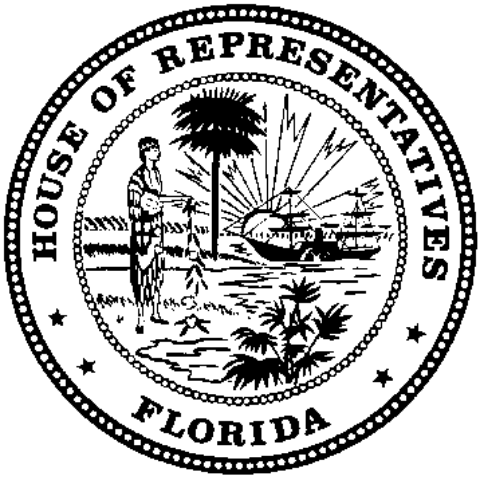

An Evaluation of the Regulatory Scheme of Pedigree Papers

February 13, 2008

Marco Rubio
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I. Executive Summary

One of the most significant developments in the regulation of the wholesale distribution of prescription drugs is the pedigree paper. The pedigree paper emerged in the late 1980s as a tool to inject traceability into the marketplace to protect the integrity of the nation's prescription drug supply.

In Florida, the pedigree paper has changed substantially since it was first created in 1992, most notably in 2003 and in 2006. These changes have been enacted with little time for reflection or analysis. During the same time period, the larger body of law in which the pedigree papers law is contained, the Florida Drug and Cosmetic Act, has been revised and expanded numerous times. The result of these changes is a disorganized body of law that may hinder enforcement and compliance in reaching the ultimate goal of protecting the state's prescription drug supply.

In order to improve the organization of the Florida Drug and Cosmetic Act, the Legislature should consider significantly restructuring the act to combine relevant sections of law together that are now spread over numerous sections of law. In addition, the Legislature should consider rewriting the pedigree papers law, placing it into its own section of law in order to improve organization and clarity.

II. Pedigree Papers

A. Introduction

The prescription drug wholesale distribution market, nationwide, is generally operated by three major companies: AmerisourceBergen Corp., Cardinal Health Inc., and McKesson Corp.[1] Together, these companies hold anywhere from 90 to 95 percent of the prescription drug wholesale distribution market.[2] In addition to these "first tier" wholesale distributors, there are a number of secondary wholesale distributors who may serve a smaller or specialized market, such as distributing directly to individual physician offices.

In Florida, there are approximately 360 in-state and out-of-state prescription drug wholesale distributors (permittees).[3] The number of permittees has declined approximately 75 percent since 2003, illustrating a considerable consolidation over the past several years. This consolidation is due in part to more stringent permit application requirements enacted in 2003 by the Legislature.[4]

The pedigree paper requirement is a key tool used to regulate these prescription drug wholesale distributors. A pedigree paper is generally known as a document that

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[1] *See* http://www.marketwatch.com/news/story/growing-share-big-three-drug/story.aspx?guid=%7B9F3862C1-7E3A-4D82-94B7-A8E4AE5DAE6A%7D (last updated May 30, 2007).
[2] *Id.*
[3] *See* Department of Health, Medical Quality Assurance Annual Report: July 1, 2006 – June 30, 2007.
[4] CS/CS/SB 2312; Chapter 2003-155, L.O.F.

records the distribution of a prescription drug, from initial sale by a manufacturer, to sale by one or more wholesale distributors, to final sale to a person administering or dispensing the prescription drug. The purpose of the pedigree paper is to document prior sales in order to increase the safety of the prescription drug supply chain by preventing the introduction of counterfeited or diverted prescription drugs.

B. Federal Pedigree Papers

At the federal level, the pedigree paper must be distributed by each person engaged in the wholesale distribution of a prescription drug who is not an authorized distributor of record for the prescription drug. [5] This requirement does not preempt state regulation, but serves as a minimum requirement for wholesale distributors. The pedigree paper must identify each prior sale, purchase, or trade of the prescription drug and must be provided for each wholesale distribution, including distributions to authorized distributors of record and retail pharmacies.[6] Under the final regulations promulgated by the United States Food and Drug Administration (FDA), the pedigree paper must include the following information:

- The proprietary and established name of the drug;
- Dosage;
- Container size;
- Number of containers;
- The drug's lot or control number;
- The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
- The date of each previous transaction.[7]

There are two significant exceptions to the federal pedigree paper requirement. The first, noted above, is for authorized distributors of record. The second is for "intracompany transfers", a term which is not defined in federal law.

Shortly before the December 1, 2006, effective date of the final regulations, however, the United States District Court for the Eastern District of New York issued a preliminary injunction enjoining the enforcement a portion of the final regulations.[8] This portion of the final regulations specified the information that is required to be included on the pedigree.[9] At issue is the requirement that the pedigree paper include information about the distribution of the prescription drugs all the way back to the manufacturer. An unauthorized distributor of record would not likely be able to purchase prescription drugs directly from the manufacturer; its primary source would be an ADR (see Figure 1, below). Consequently, as an ADR is exempted from

[5] An "authorized distributor of record" or "ADR" is a wholesale distributor with whom the manufacturer has an ongoing business relationship to distribute the manufacturer's products.
[6] Pub. L. No. 102-353, §4 (1992); 21 U.S.C. §353(e) (2000) (commonly referred to as the Prescription Drug Amendments, or PDA).
[7] 21 C.F.R. §203.50(a) (2007).
[8] *RxUSA Wholesale, Inc. v. Department of Health and Human* Services, 467 F.Supp.2d 285 (E.D.N.Y. 2006).
[9] 21 C.F.R. §203.50(a) (2007).

providing a pedigree paper, and thus exempted from providing such information to the unauthorized distributor of record, the court found that the FDA regulation would "essentially wipe out all the unauthorized distributors" who would not be able to obtain such information.[10] The court also noted that the regulation "may drastically change how prescription drugs are distributed in this country and ultimately affect the cost to the consumer in terms of insurance premiums and prescription drugs."[11] The FDA has appealed the injunction to the Second Circuit Court of Appeals.

As a result of the preliminary injunction, the FDA announced that a pedigree paper must only contain the statutory minimum: the dates of all listed transactions and the names and addresses of all parties involved in those transactions.[12] In addition, the pedigree paper must contain prior transactions back to the last ADR or manufacturer.[13]

The illustration in Figure 1 is a simplified illustration of when a pedigree paper must be supplied under federal law. Notably, a large number of wholesale transactions are not subject to the PDMA pedigree paper requirement.

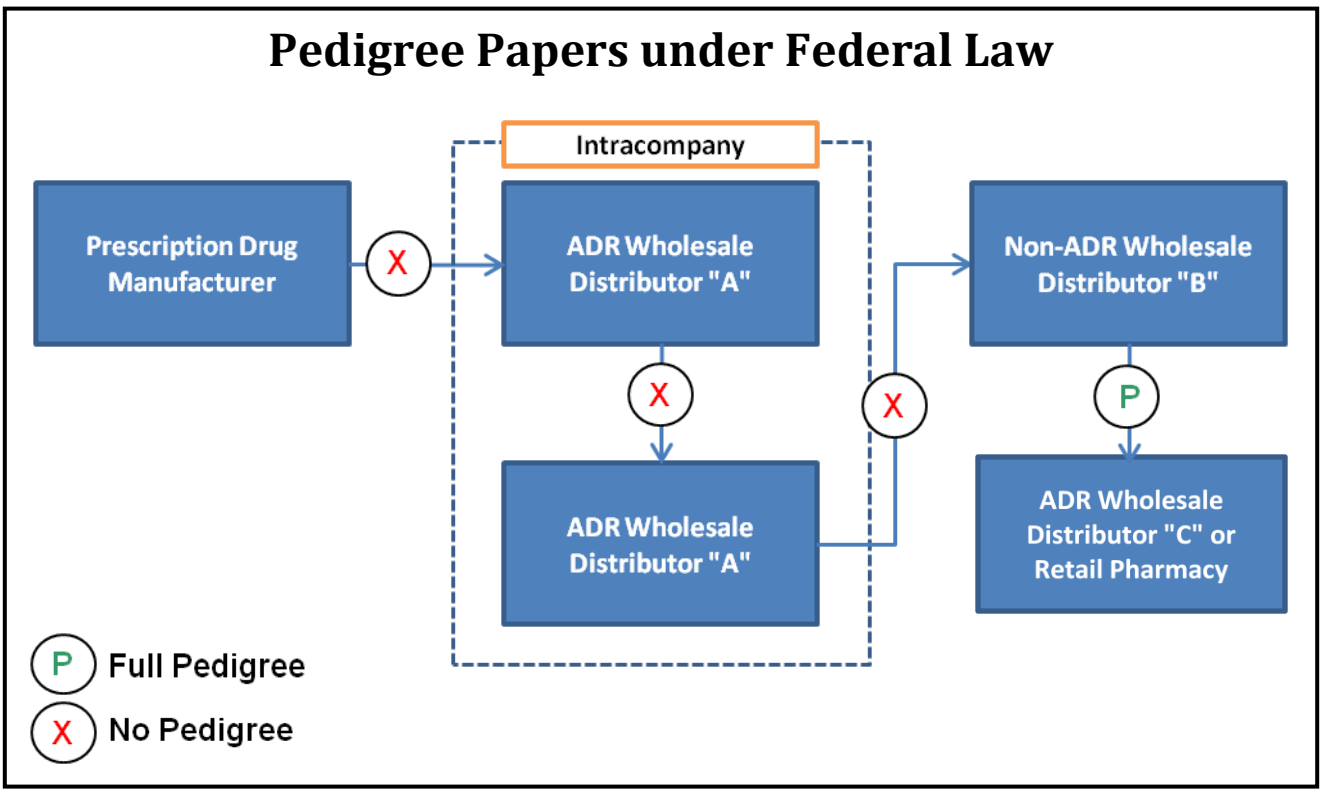

Figure 1

[10] 467 F.Supp.2d at 291.
[11] *Id.*
[12] *See* United States Food and Drug Administration, ADDENDUM to FDA's Guidance for Industry: PDMA Pedigree Requirements – Questions and Answers Related to the Preliminary Injunction ordered 12/5/06 in RXUSA Wholesalers, Inc. v. HHS (2006).
[13] *Id.*

C. Florida Pedigree Papers

In Florida, there are two forms of pedigree papers. The first form is known informally as the "direct purchase" pedigree paper because a wholesale distributor must generally purchase the prescription drug directly from the manufacturer and subsequently directly distribute (with allowance for one intracompany transfer) the prescription drug to an end user or a chain pharmacy warehouse. The second form of pedigree paper must be used for all other wholesale distributions. Figure 2 illustrates the differences between the two forms of pedigree papers.

Full Pedigree	"Direct Purchase" Pedigree
No.	Statement, under oath, that "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."
Name of the prescription drug as it appears on the label.	**Same.**
Quantity, dosage form, and strength of the prescription drug.	**Same.**
Lot numbers of the prescription drug.	*Maintained by the wholesale distributor, made available to the department upon request.*
Name and address of each owner of the prescription drug and his or her signature.	Name and address of the wholesaler and the purchaser of the prescription drug.
Shipping information, including name and address of each person certifying delivery or receipt of the prescription drug.	*Maintained by the wholesale distributor, made available to the department upon request:* The point of origin of the prescription drugs, including intracompany transfers, and the date of the shipment from the manufacturer to the wholesale distributor.
Invoice number, shipping document number, or another number uniquely identifying the transaction.	*Maintained by the wholesale distributor, made available to the department upon request:* Invoice numbers from the manufacturer.
Certification that recipient wholesale distributor has authenticated pedigree papers.	**No.**
The unique serial of the specific unit of prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.	**No.**
Name, address, telephone number and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.	**No.**

Figure 2

Florida law provides several exceptions to the pedigree paper requirement, including:

- The wholesale distribution of compressed medical gas.
- The wholesale distribution of veterinary prescription drugs.
- Drop shipments of prescription drugs by prescription drug manufacturers.
- Certain distributions of prescription drugs by wholesale distributors within an affiliated group.

A "drop shipment" occurs when a wholesale distributor arranges for the direct shipment of a prescription drug from the manufacturer to an end user, such as a hospital, health care practitioner, or pharmacy. The prescription drug manufacturer provides an invoice to the wholesale distributor; the wholesale distributor, in turn, provides an invoice to the end user. At no point in the transaction does the wholesale distributor physically take possession of the prescription drug. Drop shipments are used in a number of situations, such as for prescription drugs with unusual temperature or handling requirements that are not suitable for distribution by a wholesale distributor.

Despite what may appear to be a logical construction of the pedigree paper requirement, the actual text of the statutory law is highly disorganized. For example:

- The circumstances of when a direct purchase pedigree paper may be used (as opposed to a "full" pedigree paper) are contained in the definition of "pedigree paper" in subsection (31) of section 499.003, F.S. This definition also describes the content of the pedigree papers, requires retention of related records, and provides rule authority to the Department of Health.
- The pedigree paper requirement is contained in a sub-paragraph of subsection (6) of section 499.0121, F.S.
- Exceptions to the pedigree paper requirement are contained in subsequent sub-paragraphs and paragraphs of the same section, and are not clearly labeled as exceptions.[14]

In addition, for purposes of the direct-purchase pedigree paper, the law neither defines "intracompany transfer", nor does the law clearly state the number of transfers allowed. This has lead to confusion regarding the circumstances under which the direct-purchase pedigree paper may be used by wholesale distributors.

The illustration in Figure 3 is a simplified illustration of when a pedigree paper must be supplied under Florida law. Unlike federal law and many other states, Florida law subjects a large number of wholesale transactions to the pedigree paper requirement.

[14] *See, e.g.*, s. 499.0121(6)(d)3. (exception for veterinary prescription drugs and compressed medical gasses) and s. 499.0121(6)(f) (exemption for certain wholesale distributions within an affiliated group).

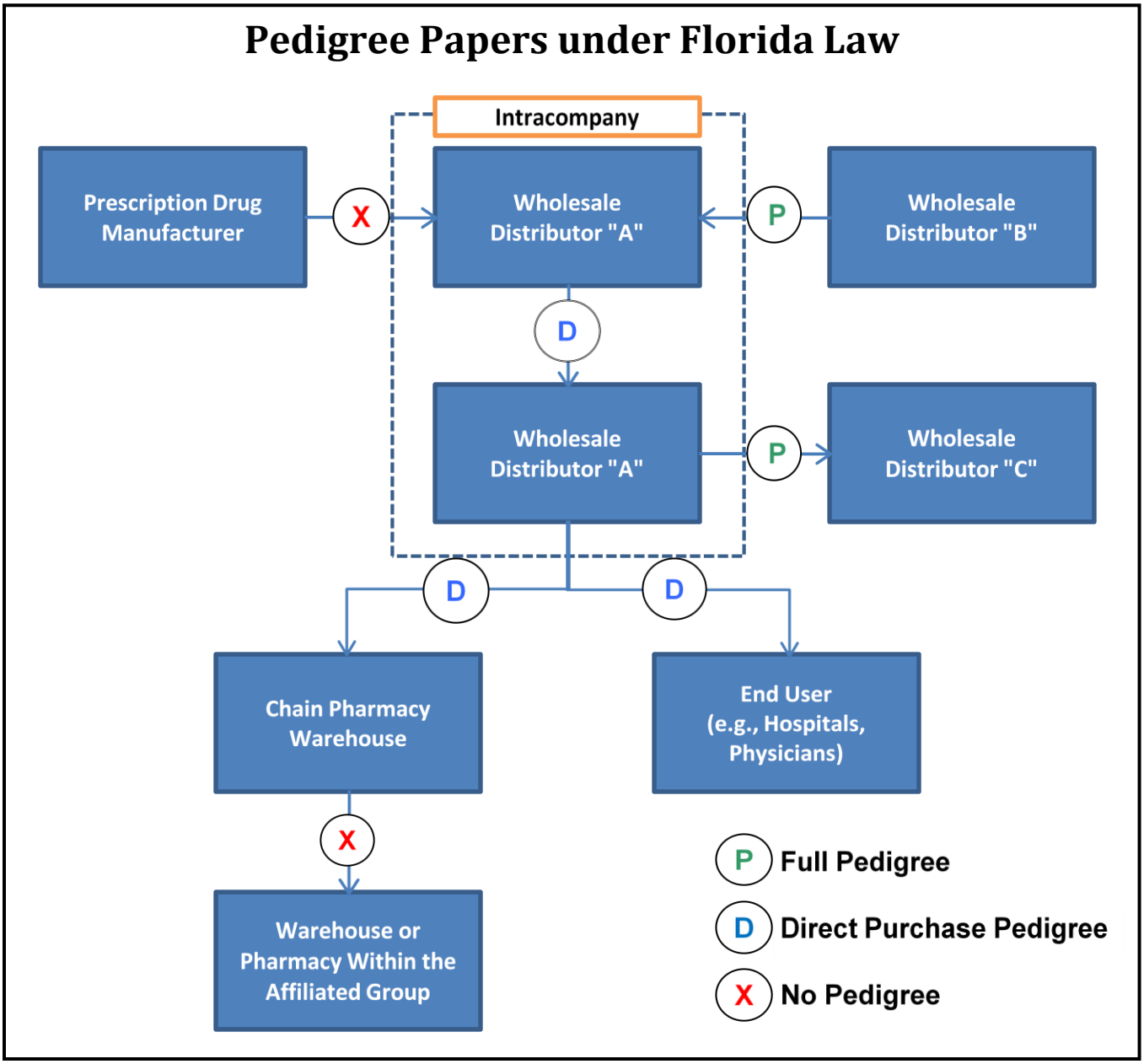

Figure 3

III. Veterinary Prescription Drug Wholesale Distributors

A number of drugs intended solely for animals are required by federal law to be prescribed by a licensed veterinarian.[15] In addition, certain drugs intended for human use are frequently prescribed for animal use, such as the antibiotic amoxicillin.

In Florida, a wholesale distributor who only distributes veterinary prescription drugs must obtain a veterinary prescription drug wholesaler permit. However, prior to 2006,

[15] 21 U.S.C. 353(f) (2005).

if a veterinary prescription drug wholesale distributor wanted to distribute human and animal prescription drugs to veterinarians, the wholesale distributor would have been required to obtain a prescription drug wholesaler permit.[16] The prescription drug wholesaler permit requires a $100,000 security bond and an extensive permit application.

In 2006, the Legislature created a new permit called a "limited prescription drug veterinary wholesaler permit."[17] The new permit authorizes the wholesaler to distribute human and animal prescription drugs to certain persons. However, the wholesaler is limited to distributing human prescription drugs worth no more than 30 percent of the wholesaler's total annual prescription drug sales.[18] Of particular note are two additional requirements:

- The wholesaler must not be permitted, licensed, or otherwise authorized in any state to wholesale human prescription drugs to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans; and
- The wholesaler must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

As no other state has created a license that authorizes a veterinary wholesale distributor to distribute human drugs for animal use, an out-of-state wholesaler cannot both be licensed to engage in wholesale distribution of prescription drugs and not be licensed to engage in the wholesale distribution of prescription drugs to a person who sell, distribute, purchase, trade, or use these drugs on or for humans.

According to the Department of Health, 18 out-of-state wholesale distributors have applied for the limited prescription drug veterinary wholesaler permit. Of these applicants, none have been approved because of the inconsistency noted above.

IV. Organization of Part I of Chapter 499

Part I of chapter 499, F.S., known as the Florida Drug and Cosmetic Act (the act), generally regulates drugs, devices, and cosmetics. Its numerous provisions include:

- Criminal prohibitions against the distribution of contraband and adulterated prescription drugs.
- Regulation of the advertising and labeling of drugs, devices, and cosmetics.
- Establishment of permits for manufacturing and distributing drugs, devices, and cosmetics.

[16] *See* s. 499.012(g), F.S. (2005) (stating that "a veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler or out-of-state prescription drug wholesaler in lieu of the veterinary prescription drug wholesaler permit").
[17] *See* s. 499.012(h), F.S. (2007).
[18] *Id.*

- Regulation of the wholesale distribution of prescription drugs, which includes pedigree papers.
- Regulation of the provision of drug samples.
- Establishment of the Cancer Drug Donation Program.
- Establishment of numerous enforcement avenues for the Department of Health, including seizure and condemnation of drugs, devices, and cosmetics.

The act has been amended numerous times over the course of the past two decades. Recent additions include the 2003 legislation that significantly strengthened the pedigree papers law and the permit application process and the 2006 legislation that created the Cancer Drug Donation Program. As a result of these numerous revisions, the act has become substantially disorganized. In particular:

- The Department of Health's general administrative and enforcement authority is spread over five separate sections of law.[19]
- Criminal prohibitions are spread over six sections of law.[20]
- Permit definitions are spread over five sections of law.[21]
- Generally applicable definitions are spread over five sections of law.[22]
- The terms "legend drug", "prescription drug" and "medicinal drug" are used interchangeably to refer to prescription drugs regulated by the Federal Food, Drug, and Cosmetic Act.[23]
- The terms "wholesaler", "wholesale distributor", and "wholesale drug distributor" are used interchangeably to refer to a person who engages in the wholesale distribution of prescription drugs.[24]

The act also contains a number of incorrect cross-references, one of which, according to the Department of Health, dates back to 1995.[25]

V. Recommendations

Since the enactment of HB 371 and SB 1540 in 2006, a number of issues have been raised by stakeholders relating to the pedigree papers law and the limited prescription drug veterinary wholesaler permit, both of which are contained in the Florida Drug and Cosmetic Act (the act). Many of these issues relate to a lack of clarity and organization. The Legislature should consider undertaking a comprehensive reorganization of the act that addresses pedigree papers, the limited prescription drug veterinary wholesaler permit, and the overall structure of the act.

[19] Sections 499.004, 499.0053, 499.07, 499.071, and 499.081, F.S.
[20] Sections 499.0051, 499.0052, 499.00535, 499.00545, 499.069, and 499.0691, F.S.
[21] Sections 499.012, 499.0122, 499.013, 499.014, and 499.028, F.S.
[22] Sections 499.003, 499.012, 499.0121, 499.029, and 499.0661, F.S.
[23] *See, e.g.,* s. 499.006 (using the terms "legend drug" and "prescription drug"). *See also* s. 499.003(25), F.S. (defining "legend drug", "prescription drug", and "medicinal drug" identically).
[24] *See, e.g.,* ss. 499.012(8)(b), F.S. (using the term "wholesale drug distributor") and 499.0121, F.S. (using the terms "wholesaler" and "wholesale drug distributor").
[25] *See, e.g.,* s. 499.05, F.S. (incorrectly referencing s. 499.006, F.S., instead of s. 499.066, F.S.).

First, regarding the limited prescription drug veterinary wholesaler permit created by SB 1540, the inconsistency in simultaneously requiring a wholesale distributor to possess an out-of-state license to distribute prescription drugs, yet prohibiting the same wholesale distributor from being licensed to distribute human prescription drugs, should be fixed. One solution, recommended in the attached bill draft, would be to amend the law to prohibit a wholesale distributor from distributing human prescription drugs to another person who is authorized to sell, distribute, purchase, trade, or use such drugs on humans. This solution would change the focus of the prohibition from the permit to the activity—i.e., distributing human drugs for ultimate use by humans.

Second, regarding the pedigree papers law, an important first step is a rewrite that focuses on clearly delineating to whom the requirement applies, when it applies, what is required to be contained in the pedigree, and when the requirement does not apply (exceptions). The recommendation in the attached bill draft places the pedigree papers law in its own statutory section and more clearly describes the requirement and its exceptions.

Last, regarding the lack of clarity and organization that pervades most of the act, the recommendation in the attached bill draft represents a significant reorganization. Disparate sections of law are consolidated into single sections of law encompassing criminal prohibitions, enforcement authority, permit requirements, and generally applicable definitions, respectively. Terms used interchangeably, such as “legend drug”, “prescription drug”, and “medicinal drug”, are consolidated to “prescription drug”.

Appendix A: Origin of Pedigree Papers at the Federal Level

At the federal level, the pedigree paper requirement first emerged in the Prescription Drug Marketing Act of 1987[26]— commonly referred to as the PDMA. The act was signed into law on April 22, 1988 by President Reagan. Prior to the passage of the PDMA, in Congress the House of Representatives conducted numerous hearings examining the safety of the nation's prescription drug supply.[27] In particular, the House found that "the integrity of the distribution system is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective or even counterfeit pharmaceuticals."[28] In addition, the House noted that "that most of the drugs that were counterfeits, stolen, expired, or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute that manufacturer's product."[29]

Congress' findings are summarized in the text of the PDMA:

> (1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.
> (2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.
> (3) The existence and operation of a wholesale submarket, commonly known as the 'diversion market', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.
> (4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.
> (5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.
> (6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.
> (7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.
> (8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers.[30]

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[26] Pub. L. No. 100-293 (1988).
[27] *See* H.R. Rep. No. 100-76 (1987).
[28] *Id.* at 6.
[29] *Id.* at 17.
[30] Pub. L. No. 100-293, §2 (1988).

In his signing letter for the PDMA,[31] President Reagan noted that investigations conducted by the Department of Justice into diverted and counterfeited drugs demonstrated that "the principal factor facilitating the illegal activity that this bill is designed to combat is the almost total lack of traceability of drug products in the diversion market."[32]

Among the many provisions of the PDMA was the requirement that each person who is engaged in the wholesale distribution of prescription drugs, who is not an authorized distributor of record for such drugs, must provide to each wholesale distributor, prior to the sale of the drugs, a statement (pedigree paper) identifying each sale of the prescription drug.[33] An authorized distributor of record (ADR) is a distributor with whom the manufacturer has an ongoing business relationship.[34] Subsequent amendments to the PDMA in 1992 clarified that the pedigree paper must identify each prior sale, purchase, or trade of the prescription drug and must be provided for each wholesale distribution, including distributions to ADRs and retail pharmacies.[35] In addition, these amendments also authorized the Secretary of the United States Department of Health and Human Services to specify the format and content of the pedigree paper.[36]

In implementing the PDMA, including the pedigree paper requirement, the Federal Food and Drug Administration (FDA) published proposed regulations in March of 1994[37]; the final regulations were published on December 3, 1999.[38] Subsequent to that time, however, the FDA delayed the pedigree paper requirement over the course of 12 years, based on feedback from the industry and industry trade associations.[39] Concerns were also raised by the Small Business Administration, based on the "severe economic impact" the final regulations would have on thousands of small businesses.[40] Finally, on June 14, 2006, the FDA publicly announced that it would not delay the implementation date of the pedigree paper final regulations beyond the December 1, 2006 effective date.[41]

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[31] *Statement on Signing the Prescription Drug Marketing Act of 1987* (visited December 5, 2007) http://www.reagan.utexas.edu/archives/speeches/1988/042288g.htm.
[32] *Id.*
[33] Pub. L. No. 100-293, §6 (1988).
[34] *Id.*
[35] Pub. L. No. 102-353, §4 (1992); 21 U.S.C. §353(e) (2000) (commonly referred to as the PDA).
[36] *Id.*
[37] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 59 Fed. Reg. 11842 (1994) (to be codified at 21 C.F.R. pts. 203 and 205).
[38] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 64 Fed. Reg. 67720 (1999) (to be codified at 21 C.F.R. pts. 203 and 205).
[39] *See, e.g.*, Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date, 67 Fed. Reg. 6645 (2002).
[40] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date, 66 Fed. Reg. 12850 (2001).
[41] Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Policy Guide; Request for Comment, 71 Fed. Reg. 34249 (2006).

Under the final regulations, the pedigree paper must include:

- The proprietary and established name of the drug;
- Dosage;
- Container size;
- Number of containers;
- The drug's lot or control number;
- The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
- The date of each previous transaction.[42]

Shortly before the December 1, 2006, effective date of the final regulations, however, the United States District Court for the Eastern District of New York issued a preliminary injunction enjoining the enforcement a portion of the final regulations.[43] This portion of the final regulations specified the information that is required to be included on the pedigree.[44] At issue is the requirement that the pedigree paper include information about the distribution of the prescription drugs all the way back to the manufacturer. As an unauthorized distributor of record would not likely be able to purchase prescription drugs directly from the manufacturer, its only source would be an ADR. Consequently, as an ADR is exempted from providing a pedigree, and thus not providing such information to the unauthorized distributor of record, the court found that the FDA regulation would "essentially wipe out all the unauthorized distributors" who would not be able to obtain such information.[45] The court also noted that the regulation "may drastically change how prescription drugs are distributed in this country and ultimately affect the cost to the consumer in terms of insurance premiums and prescription drugs."[46] The FDA has appealed the injunction to the Second Circuit Court of Appeals.

As a result of the preliminary injunction, the FDA announced that a pedigree paper must only contain the statutory minimum: the dates of all listed transactions and the names and addresses of all parties involved in those transactions.[47] In addition, the pedigree paper must contain prior transactions back to the last ADR or manufacturer.[48]

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[42] 21 C.F.R. §203.50(a) (2007).
[43] *RxUSA Wholesale, Inc. v. Department of Health and Human* Services, 467 F.Supp.2d 285 (E.D.N.Y. 2006).
[44] 21 C.F.R. §203.50(a) (2007).
[45] 467 F.Supp.2d at 291.
[46] *Id.*
[47] *See* United States Food and Drug Administration, ADDENDUM to FDA's Guidance for Industry: PDMA Pedigree Requirements – Questions and Answers Related to the Preliminary Injunction ordered 12/5/06 in RXUSA Wholesalers, Inc. v. HHS (2006).
[48] *Id.*

Appendix B: Origin of Pedigree Papers in Florida

In 1992, the Florida Legislature created a pedigree paper requirement to regulate the wholesale distribution of prescription drugs.[49] Administrative rules to implement the requirement were promulgated in 1996.[50] The rules required a non-ADR wholesale distributor engaged in the wholesale distribution of a prescription drug to provide a pedigree paper, prior to the sale of such drug, to a receiving wholesale distributor.[51] The pedigree paper was required to be a written statement identifying:

- The proprietary name or the generic name of the prescription drug;
- The name of the manufacturer or distributor reflected on the label of the product;
- Dosage form and strength;
- Container size;
- Quantity by lot number;
- The name and address of each owner of the prescription drug;
- The name and address of each location from which the prescription drug was shipped, if different from the owner's address; and
- The transaction dates.[52]

However, this requirement was apparently not strictly enforced by the Department of Health until 2001.[53] In November 2001, the Department of Health sent a letter to prescription drug wholesale distributors to clarify the pedigree paper requirements.[54] The letter noted that "the Bureau of Pharmacy Services will be looking more closely at your compliance with the pedigree paper requirements . . . We have already initiated action to revoke prescription drug wholesaler permits or impose administrative penalties in cases where pedigree papers were at issue."[55] Objections by the industry, however, forced the department to create an ad hoc committee to study the issue, which resulted in a new rule that was proposed in March of 2003.[56] The proposed rule required a person who distributes a "specified" prescription drug that it did not manufacture to provide a pedigree paper; the specified prescription drug list included 30 drugs that were frequently counterfeited or diverted.[57]

During the same time period in which the department was struggling to implement and enforce the pedigree paper requirement, Governor Jeb Bush petitioned the Florida Supreme Court to convene a statewide Grand Jury to examine the safety of prescription drugs in the state of Florida.[58] The Grand Jury issued its interim report in

[49] CS/CS/SB 84 (1992); Chapter 92-69, L.O.F.
[50] Rule 10D-45.053, F.A.C. (1996).
[51] CS/CS SB 84 (1992); Chapter 92-69, L.O.F.
[52] *Id.*
[53] *See* First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).
[54] *See* Sandra R. Stovall, Florida Department of Health, Letter to Regulatory Affairs (2001).
[55] First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).
[56] 29 Fla. Admin. Weekly 992 (March 7, 2003).
[57] *Id.*
[58] Petition for Order to Impanel a Statewide Grand Jury, Case No. SC02-2645 (2002).

February, 2003.[59] The Grand Jury noted that the three largest whole distributors obtained approximately 95 percent of their stock directly from the manufacturer.[60] The remaining stock was purchased from the secondary market, where prescription drugs may move "up, down, and sideways through the distribution system[, creating] opportunities for adulterated drugs that have been diverted from other sources to enter the distribution system."[61] It is this secondary market that the Grand Jury, much like Congress, identified as the source of counterfeit or adulterated drugs. The Grand Jury noted that these drugs moved easily throughout the system because federal and state agencies failed to enforce existing law and because wholesale distributors "turn[ed] a blind eye to the corrupt practices of other wholesalers that supply them with some of their pharmaceuticals."[62]

The industry opposition to the pedigree paper at the time was that it would be "prohibitively expensive to segregate . . . stocks of drugs purchased from other wholesalers and stocks of drugs bought directly from the manufacturers."[63] The industry also objected because the pedigree paper would be passed in intracompany transfers, which are "shipments of drugs from one warehouse to another within the same company."[64] Last, the industry objected because "pedigree papers have no real value in deterring or discovering diverted or adulterated drugs . . . [and] can be easily forged."[65] In response to this last objection, the Grand Jury stated the potential for forgery is exactly the reason why the pedigree paper must be verified in order for this "tool" to work.[66]

The Grand Jury concluded that, without a pedigree paper "verified through the chain of transactions, it is impossible for consumers to know with absolute confidence that the drug that they are getting from their doctor or pharmacy has not been diverted or adulterated."[67] The report listed 40 recommendations for the Legislature, the Department of Health, the wholesale distribution industry, and the pharmaceutical manufacturers.[68] These recommendations included specifying additional information that should be reported on the pedigree paper (e.g., lot number); requiring the pedigree paper to be produced in every transaction; and requiring verification of the pedigree paper.[69]

In response to the Grand Jury report, the Florida Legislature amended the pedigree papers laws in 2003 to implement the recommendations of the Grand Jury.[70] Among

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[59] First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] CS/CS/SB 2312; Chapter 2003-155, L.O.F.

other provisions, the bill mandated the provision of a pedigree paper by each person engaged in the wholesale distribution of a prescription drug, implemented over two phases.[71] In addition, more background information was required of wholesale prescription drug permittees and criminal penalties were created for, among other acts, failing to maintain or forging pedigree papers, as well as knowingly selling or purchasing contraband prescription drugs.[72]

The first phase, effective until July 1, 2006, required a wholesale distributor who distributed "specified" drugs, a list of 34 drugs that were likely to be counterfeited or diverted, to provide one of two forms of pedigree paper to a subsequent wholesale distributor, either:

- A statement that the wholesale distributor, or a member of its affiliated group, purchased the prescription drug directly from the manufacturer, or, if the wholesale distributor did not directly purchase the prescription drug,
- A statement under oath identifying:
    - Each previous sale of the specific unit of the prescription drug back to the manufacturer;
    - The lot number of the drug; and
    - The sales invoice number of each previous sale of the drug.[73]

For the wholesale distribution of all other prescription drugs:

- A wholesale distributor who was an ADR for such prescription drugs was not required to provide any documentation for a sale to a subsequent wholesale distributor. The department was required to publish, but not verify, on its website lists of ADRs provided by the manufacturers.
- A wholesale distributor who was not an ADR for such prescription drugs was required to provide a pedigree paper that contained:
    - Each previous sale of the specific unit of the prescription drug back to the last authorized distributor of record;
    - The lot number of the drug; and
    - The sales invoice number.[74]

The second phase, which would have become effective July 1, 2006, superseded the first phase and required each person, other than a manufacturer, involved in the wholesale distribution of a prescription drug to produce a more extensive pedigree paper prior to the distribution of the drug. This pedigree paper was required to be in written or electronic format and include:

- The amount, dosage form, and strength of the prescription drug;
- The lot number;
- The name and address of each owner of the drug and his or her signature;
- Its shipping information, including the name and address of each person certifying delivery or receipt of the drug; and

[71] *See* s. 499.0121(6)(d)-(f), F.S. (2003).
[72] *See* ss. 499.012 (permitting requirements) and 499.0051 (criminal violations), F.S. (2003).
[73] *See* s. 499.0121(6)(e), F.S. (2003).
[74] *See* s. 499.0121(6)(d), F.S. (2003).

- A certification that the recipient wholesaler has authenticated the pedigree paper.

In 2004, the Legislature amended the pedigree paper laws to create an exception from the pedigree paper requirement for transactions within an affiliated group.[75] Specifically, the amendment exempted a warehouse within an affiliated group from providing a "phase one" (but not "phase two") pedigree paper to its affiliated group member warehouse, provided that, if the warehouse received a prescription drug from outside its affiliated group, a pedigree paper must be obtained. The exemption expired on July 1, 2006.

In 2005, the Legislature again amended the pedigree paper laws.[76] These amendments added the following items to the "phase two" pedigree paper:

- The serial number of the individual unit of the prescription drug, if the manufacturer or repackager has uniquely serialized such unit; and
- An invoice number, a shipping document number, or another number uniquely identifying the transaction.

In addition, the amendments made permanent the affiliated group exception to the pedigree paper requirement created in 2004 and expanded the exception in two significant areas:

- Affiliated group warehouses were no longer required to provide a "phase two" pedigree paper as of July 1, 2006; and
- Affiliated group warehouses were no longer required to provide a pedigree paper (phase one or two) to a retail pharmacy.

Finally, in 2006, the Legislature further amended the pedigree paper laws.[77] The new amendments authorized a wholesale distributor to provide an alternative "pedigree paper" in a "normal distribution" or "direct purchase" transaction. In simple terms, a direct purchase transaction occurs where a wholesale distributor purchases the prescription drug directly from the manufacturer and subsequently directly distributes the prescription drug to an end user, such as a hospital, health care practitioner, or pharmacy. The amendments limited the use of the "direct purchase pedigree paper" to the following circumstances:

- The wholesale distributor must provide a sworn statement confirming that it purchased and received the specific unit of the prescription drug directly from the manufacturer;
- The prescription drug was distributed directly, or through an intracompany transfer, to an "end user"; and
- The end user was either a "chain pharmacy warehouse"[78] or a person authorized by law to purchase prescription drugs for the purpose of

[75] CS/CS/CS/CS SB 1372; Chapter 2004-387, L.O.F.
[76] CS/CS SB 874; Chapter 2005-248, L.O.F.
[77] HB 371; Chapter 2006-310.
[78] A "chain pharmacy warehouse" means a physical wholesale distribution center that exists solely to provide drugs to members of its affiliated group through intracompany transfers. These facilities are operated by companies such

administering or dispensing the drug (generally, a hospital, health care practitioner, or pharmacy).[79]

The direct purchase pedigree paper must contain:

- A statement that "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer";
- The manufacturers' national drug code identifier and the name and address of the wholesaler and the purchaser of the prescription drug;
- The name of the prescription drug as it appears on the label; and
- The quantity, dosage form, and strength of the prescription drug.[80]

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot numbers of such drugs; and the invoice numbers from the manufacturer.[81]

All other wholesale distributions of prescription drugs outside of this direct purchase model must be accompanied by a full pedigree paper, as required by law.[82]

In addition to the alternative form of pedigree paper, the amendments of 2006 also created an additional exception for a “drop shipment” transaction. A “drop shipment” occurs when a wholesale distributor arranges for the direct shipment of a prescription drug from the manufacturer to an end user, such as a hospital, practitioner, or pharmacy. The prescription drug manufacturer provides an invoice to the wholesale distributor; the wholesale distributor, in turn, provides an invoice to the end user. At no point in the transaction does the wholesale distributor physically take possession of the prescription drug. Drop shipments are used in a number of situations, such as for prescription drugs with unusual temperature or handling requirements that are not suitable for distribution by a wholesale distributor. Prior to the 2006 amendments, the pedigree paper requirement posed logistical difficulties in executing a drop ship agreement: the wholesale distributor was required to provide a pedigree paper prior to distributing the prescription drug and the end user was required to receive the pedigree prior to receiving the prescription drug. As the wholesale distributor does not control the timing of the shipment from the manufacturer, the end user was required to “quarantine” the prescription drug until a pedigree paper was provided by the wholesale distributor.

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as Wal-Mart, CVS, Walgreens, and Publix, who typically purchase prescription drugs through a first tier wholesale distributor.

[79] *See* s. 499.003(31)(b), F.S. (2007).

[80] *See* s. 499.003(31)(b), F.S. (2007).

[81] *Id.*

[82] *See* s. 499.003(31)(a), F.S. (2007).

The 2006 amendments exempted a drop ship transaction from the pedigree paper laws where:

- The prescription drug is shipped directly from the prescription drug manufacturer to the end user;
- The wholesale distributor does not take physical possession of the prescription drug at any point during the transaction; and
- The end user is a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug (generally, a hospital, health care practitioner, or pharmacy), or a member of an affiliated group, as defined in s. 499.0121(6)(h), F.S. (generally, companies such as Wal-Mart, CVS, Walgreens, and Publix).[83]

Furthermore, the wholesale distributor must provide to the end user, within 14 days of notification of shipment by the manufacturer, a sworn statement that the wholesale distributor purchased the prescription drug directly from the manufacturer and that the manufacturer shipped the prescription drug directly to the end user. The end user must obtain from the manufacturer, within 14 days of the receipt of the prescription drug, a shipping document that contains the following information:

- The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesaler and the purchaser;
- The name of the prescription drug as it appears on the label;
- The quantity, dosage form, and strength of the prescription drug; and
- The date of the shipment from the manufacturer.[84]

Last, the wholesale distributor must maintain and make available to the department, upon request, the lot number of the prescription drug if not contained in the shipping document acquired by the end user. The failure of the wholesale distributor or the end user to acquire or provide this documentation, or forgery of the documentation, will constitute failure to acquire or provide, or forgery of, a pedigree paper—a felony violation.[85]

[83] *See* s. 499.0121(6)(d)5., F.S. (2007).
[84] *Id.*
[85] *See* s. 499.0051, F.S. (2007).

Appendix C: Pedigree Papers in Other States

Several other states have created a pedigree paper requirement. A chart provided by the Healthcare Distribution Management Association summarizes the status of the laws of all 50 states (see Figure 4) as of October 30, 2007.

A discussion of a sample of states with a pedigree paper requirement is provided below.

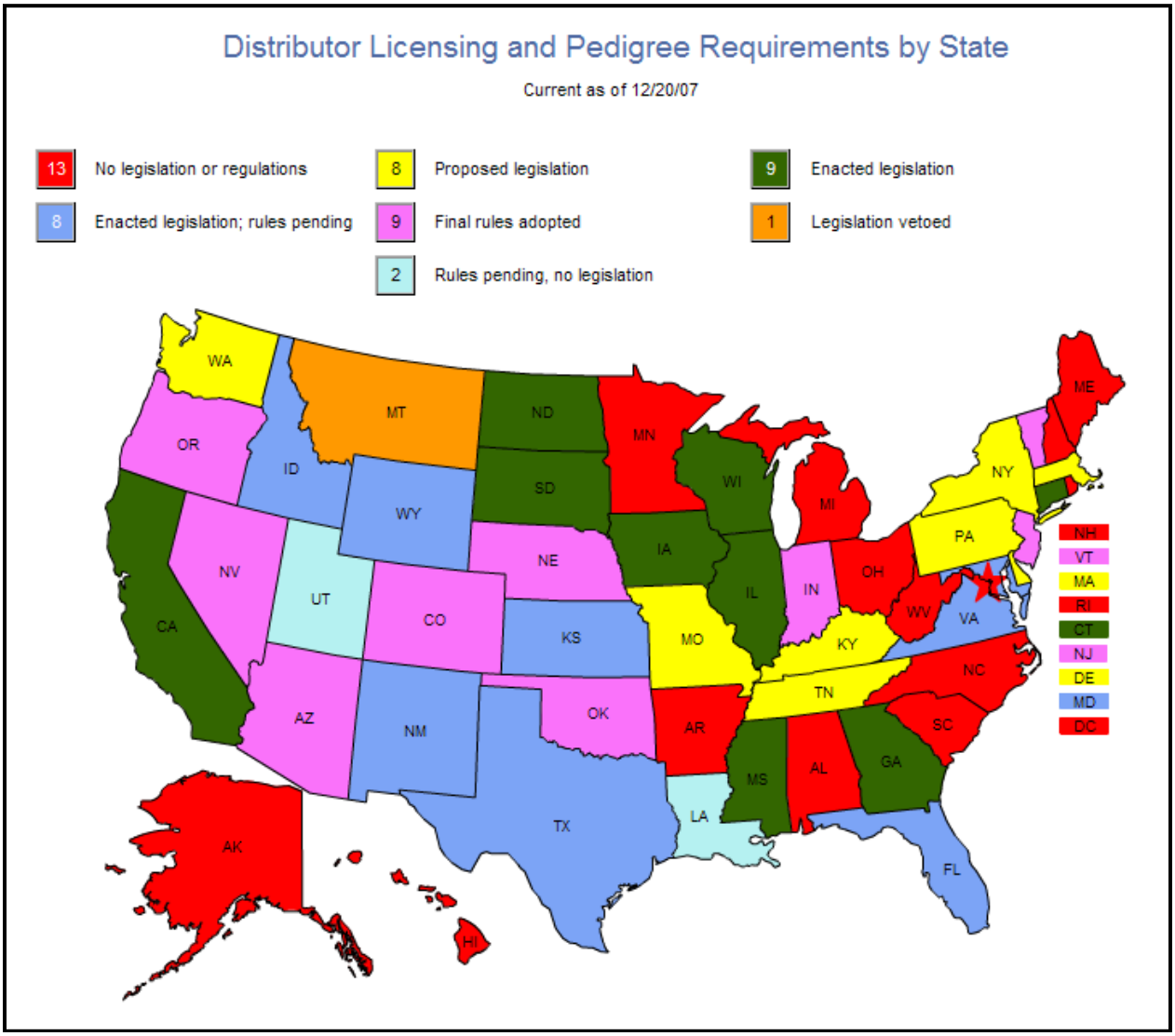

Figure 4

Arizona

In Arizona, a pedigree paper must be provided for prescription drugs that leave the "normal distribution channel."[86] The "normal distribution channel" means the chain of custody that begins with the delivery of the drug by a manufacturer to a wholesale

[86] Ariz. Rev. Stat. §32-1984 (2007).

distributor who then delivers the drug to a pharmacy or a practitioner for final receipt by a patient (end user).[87] A pedigree paper is not required, however, for intracompany transfers (between a division, subsidiary, parent or affiliated or related company under the common ownership of a person).[88]

The items that must be provided in the pedigree paper include:

- The name of the drug and the dosage form and strength;
- The size and number of containers;
- The lot number;
- The name of the manufacturer of finished dosage form;
- Name, address, and phone number of each owner of the drug;
- Name and address of each location from which the product was shipped;
- Transaction dates; and
- Certification that each recipient has authenticated the pedigree paper.[89]

California

In California, as of January 1, 2009 (unless extended by the Board to January 1, 20011) a pedigree is an electronic record of each change of ownership, from the manufacturer, to the wholesale distributor, to the final sale to a pharmacy or other person furnishing, administering, or dispensing the drug.[90] California law is significantly more stringent than any other state in that the pedigree must be originated by the manufacturer, must contain a unique identifier tracking the drug at the smallest container distributed by the manufacturer, and must be furnished for both human and animal prescription drugs. [91]

The items that must be provided in the pedigree paper include:

- The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number and principal address of the source.
- The trade or generic name of the drug.
- The quantity of the dangerous drug and its dosage form and strength.
- The date of the transaction.
- The sales invoice number.
- The container size and number of containers.
- The expiration dates.
- The lot numbers.
- The business name, address, and the federal manufacturer's registration number or a state license number of each owner of the dangerous drug.

[87] *Id.* at §32-1981.
[88] *Id.* at §32-1984.
[89] *Id.*
[90] Cal. Bus. & Prof. Code §4034 (2006).
[91] *Id.*

- The dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.[92]

Indiana

In Indiana, a pedigree paper is a statement or record in a written or an electronic form that either:

- Records each wholesale distribution of a prescription drug from the sale by the manufacturer that leaves the normal distribution chain of custody; or
- Complies with a prescription drug pedigree law or regulation in another state or United States territory that meets the pedigree requirements under this chapter.[93]

Consequently, Indiana does not require a pedigree for distributions within the "normal distribution chain." Indiana law specifically defines which transactions are within the normal distribution chain:

- From a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;
- From a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;
- From a manufacturer to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;
- From a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;
- From a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;
- From a manufacturer to a third party logistics provider, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; or
- As prescribed by rules adopted by the board.[94]

The items that must be provided in the pedigree paper include:

- The name of the drug and its dosage form and strength.
- The size and number of containers.
- The lot or control numbers and expiration dates.
- The name of the manufacturer of the finished drug product.

[92] *Id.*
[93] Ind. Code §25-26-14 (2007).
[94] *Id.*

- The name, address, and telephone number of each entity involved in the chain of custody.
- The name and address of each person certifying delivery or receipt of the legend drug.
- The sales invoice number of other number unique to the shipping document;
- The dates of each transaction, including manufacturer, delivery, and receipt.
- Certification that each recipient has authenticated the pedigree paper back to the manufacturer.
- Certification from the licensed entity that the information contained on the pedigree is true.[95]

Nevada

In Nevada, a wholesale distributor who sells a prescription drug to another wholesale distributor must provide a statement of prior sales (pedigree paper) with the drug.[96] A pedigree paper is not required for the following transactions:

- Transactions between places commonly owned (100%) entities, if the common-owner is a publicly-traded corporation.[97]
- An ADR who purchased directly from the manufacturer and sells directly to an end user.[98]

The statement of prior sales is defined to mean the statement of prior sales required by the federal PDMA:

- The proprietary and established name of the drug;
- Dosage;
- The size and number of containers;
- The drug's lot or control number;
- The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer;
- The date of each previous transaction; and
- Signature of the wholesaler or his designated representative certifying the information is complete and accurate.

If the statement of prior sales indicates that more than 3 prior sales have occurred, including a sale involving an ADR, a person engaged in the wholesale distribution of prescription drugs may not sell the drug to another wholesale distributor.[99]

[95] Ind. Admin. Code tit. 856. r.3 (2007).
[96] Nev. Admin. Code ch. 639, §603 (2007).
[97] *Id.* at §593 (2007).
[98] Nev. Rev. Stat. §639.545 (2007).
[99] *Id.* at §603 (2007).

Texas

In Texas, a pedigree paper must be provided for each prescription drug for human consumption that is not distributed through the normal distribution channel.[100] Texas law specifically defines the "normal distribution chain" as a chain of custody for a prescription drug, either directly or by drop shipment, from the manufacturer of the prescription drug, the manufacturer to the manufacturer's co-licensed product partner, the manufacturer to the manufacturer's third-party logistics provider, or the manufacturer to the manufacturer's exclusive distributor, to:

- A pharmacy to:
  - A patient; or
  - Another designated person authorized by law to dispense or administer the drug to a patient;
- An authorized distributor of record to:
  - A pharmacy to a patient; or
  - Another designated person authorized by law to dispense or administer the drug to a patient;
- An authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy;
- A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or another designated person authorized by law to dispense or administer the drug to a patient;
- A person authorized by law to prescribe a prescription drug that by law may be administered only under the supervision of the prescriber; or
- An authorized distributor of record to one other authorized distributor of record to a licensed practitioner for office use.[101]

The items that must be provided in the pedigree paper include:

- The name of the drug and its dosage form and strength;
- The size and number of containers;
- The lot number;
- The name of the manufacturer of the finished dosage form;
- The name, address, telephone number, and e-mail, if available, of each person who owns or possesses the drug;
- Name and address of each location from which the product shipped;
- Transaction dates; and
- Certification that each recipient of the drug has authenticated the pedigree.[102]

[100] Tex. Code §431.412 (2007).
[101] *Id.* at §431.401.
[102] *Id.* at §431.413.