March 30, 2005

ATTORNEY GENERAL OPINION NO. **2005-11**

The Honorable Doug Mays
Speaker of the House, 54th District
1920 S.W. Damon Court
Topeka, Kansas 66611

Re:

Public Health--Regulation of Pharmacists--Practice of Pharmacy; Legality of State of Kansas' Involvement in I-SaveRx Program That Directs American Consumers to Pharmacies in Canada and Other Countries

Synopsis:

The State of Kansas' promotion of the importation of pharmaceutical products from Canada or other foreign jurisdictions through the I-SaveRx program does not violate laws within the Kansas Pharmacy Act. Further, it does not appear that the State of Kansas' participation in that program violates any statute within the Kansas Food, Drug and Cosmetic Act, although the ultimate determination lies with the Secretary of Health and Environment who has jurisdiction over that Act.

In the absence of any case law that addresses a state's liability for the type of involvement such as the State of Kansas' in the I-SaveRx program, we are unable to say with any degree of certainty whether Kansas' involvement in that program would create any liability exposure for the State of Kansas or its employees.

Because a physician's participation in the I-SaveRx program is limited to a review and verification of a patient's medications and health information, we do not believe that these actions would result in civil liability against the physician. A physician who operates within the parameters of the I-SaveRx program would not be subject to discipline by the Board of Healing Arts.

Because the State of Kansas would not be considered a "supplier" for purposes of the Kansas Consumer Protection Act, the State's involvement in that program does not create express or implied warranty issues under the Kansas Consumer Protection Act.

The Federal Food, Drug and Cosmetic Act (FFDCA) prohibits the importation and reimportation of prescription drugs into the United States if such drugs are unapproved by the Food and Drug Administration (FDA), are labeled incorrectly, or are dispensed without a valid prescription. Additionally, the FFDCA prohibits the "causing" of such

violations. Whether a court would find that the State of Kansas' involvement in the I-SaveRx program would amount to a responsible share in furtherance of acts prohibited under the Federal Food Drug and Cosmetic Act, thus causing violation of prohibited acts, is difficult, if not impossible, to predict. However, based on FDA statements and the limited case law, we believe that Kansas' involvement, as described herein, comes perilously close to causing violations of the FFDCA.

The FDA is the only agency charged with the responsibility of enforcing the FFDCA. Thus, the decision whether to seek an injunction to enjoin the State of Kansas from participating in the I-SaveRx program lies solely with the FDA. To date, we are aware of no enforcement action on the part of the FDA to enjoin or penalize states or other governmental entities from participating in the way the State of Kansas is participating; however, there are a number of letters warning governmental entities of the FDA's concerns in this regard. Cited herein: K.S.A. 2004 Supp. 50-624; K.S.A. 50-623; 50-627; 50-635; 50-639; 65-656; 65-657; 65-658; 65-659; K.S.A. 2004 Supp. 65-1626; K.S.A. 65-1627; 65-1631; 65-1634; 65-1636; 65-1643; 65-1657; 21 U.S.C. §§ 201.15; 301; 314.50; 331; 352; 353; 355; 362; 363; 381.

* * *

Dear Speaker Mays:

As Speaker of the Kansas House of Representatives, you have asked a number of questions that relate to the State of Kansas' involvement in the I-SaveRx program that directs American consumers to pharmacies in Canada and other countries for the purchase of prescription drugs. We address each of your questions after a brief summary of the facts as we understand them to exist at the time of this writing.

Kansas' Involvement in I-SaveRx

Upon accessing the website http://www.accesskansas.org/healthykansasrx/index.shtml, a "Home" webpage titled "Welcome to the Healthy Kansas Prescription Drug Resource Center" is found. This webpage includes the seal of the State of Kansas as well as the identifier "Kathleen Sebelius, Governor, State of Kansas." This site contains links to the following: Rx Resources, Drug Safety, Generic Drugs, Reduce Your Drug Costs and I-SaveRx. By clicking the last link under this website, the following preliminary information from Governor Sebelius about the "I-SaveRx: Safe and Affordable Prescription Drugs" is found:

> "Kansas has partnered with the states of Illinois, Wisconsin and Missouri in the *I-SaveRx*(1) program to provide Kansans access to medication from Canada, the United Kingdom and Ireland at a lower cost."

The webpage offers a brief discussion regarding possible savings on the cost of prescription drugs through the I-SaveRx program, as well as by the purchase of generic drugs in this country, and the value of talking with one's physician and pharmacist prior to ordering medication from another country, and then provides the following information:

> "Pharmacies that participate in the I-SaveRx program have all been physically inspected by Illinois investigators to ensure that they comply with U.S. and Illinois safety standards. These pharmacies are not licensed or inspected by the Kansas Board of Pharmacy. For the I-SaveRx program, these pharmacies can only dispense drugs that have been manufactured and approved for use in their countries."

This webpage additionally contains the following disclaimer:

> "The State of Kansas accepts no legal liability or responsibility for the health decisions made by consumers based upon the information provided in this Web site."

Following a reminder of risks associated with purchasing medications via the internet or mail order, the webpage gives the following "Legal Information":

> "The United States Food and Drug Administration (FDA) maintains that reimportation into the United States of prescription drugs that were originally produced in the United States is in violation of the United States Food, Drug and Cosmetic Act; and
>
> "Importing medications made in other countries is in violation of the Food, Drug and Cosmetic Act if the medicine is not approved by the FDA or does not meet all of the FDA approval requirements.
>
> "While the FDA has stated reimportation and importation is illegal, they have allowed individual consumers to purchase prescription drugs through Canada for personal use."

By clicking the "I-SaveRx" link located in the preliminary paragraph, the actual "I-SaveRx: Safe and Affordable Prescription Drugs" (http://www.i-saverx.net/) page is accessed. This website, sponsored by Illinois Governor Ron Blagojevich, contains the following pages: About I-SaveRx; How I-SaveRx Works; Find Your Medication; How to Enroll; Frequently Asked Questions; Newsroom; Contact Us; En Espanol; and Home. The "About I-SaveRx" webpage states, "With I-SaveRx, for the first time, you can take advantage of lower prescription drug prices offered in Canada, Ireland and the United Kingdom, without taking a trip across the border." It further asserts program safety and convenience measures.

The "How I-SaveRx Works" webpage provides a telephone number to enroll as well as a link to download enrollment forms, and then directions to take the following steps:

> "After you complete the form, review the Medical History Form with your doctor for verification of your medications and health information.
>
> "Send your forms and prescriptions directly to I-SaveRx. For health and safety reasons, only prescriptions for refills will be accepted. You may also mail your original prescriptions and Enrollment Form to I-SaveRx.[(2)]
>
> "I-SaveRx will call you to confirm your order for accuracy.
>
> "I-SaveRx will review your forms, prescriptions and health profile, and

conduct safety checks for drug interaction and appropriateness.

"I-SaveRx will send your prescription to a licensed physician for further review.

"I-SaveRx network pharmacists perform additional safety checks in compliance with local laws before dispensing your medication. I-SaveRx inspects and approves all pharmacies participating in the program.

"You should expect to receive your medication approximately 20 days after your Enrollment Form is processed.

"An I-SaveRx representative will contact you 30 days before your next refill is due to update your health and medication profile and help you stay current with your prescriptions."

Federal Food, Drug and Cosmetic Act

You first ask whether it is a violation of federal law for the *State of Kansas* to promote the importation of pharmaceutical products from Canada or other foreign jurisdictions.(3) To answer this question, we have reviewed the Federal Food, Drug and Cosmetic Act(4) (FFDCA), administered by the United States Food and Drug Administration (FDA), and FDA correspondence relating to this Act.(5)

The FDA expressed its position concerning the actual importation of drugs in a letter to a California Deputy Attorney General:

"First, virtually all drugs imported to the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 363), or dispensed without a valid prescription (21 U.S.C. §353(b)(1). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. § 331(a), and/or (d).

"FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 U.S.C. § 314.50. Generally, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. §355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 362 or 362(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).

"Second, with respect to 'American goods returned,' it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and

> sent abroad. (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in a violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).
>
> . . . .
>
> "Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ('The following acts and the causing thereof are hereby prohibited . . . ."). Thus, neither the public nor private entities mentioned in Mr. Lilyquist's letter can avoid jurisdiction under the FFDCA by merely 'facilitating' the sale of Canadian drugs to California citizens through a third-party internet service."[(6)]

We note that the FDA has authority to seek an injunction in the federal district courts to restrain most violations of 21 U.S.C. § 331.

The last paragraph of the above-quoted letter brings us to the heart of the matter. While the State of Kansas' involvement in the I-SaveRx program may not directly constitute acts prohibited by 21 U.S.C. § 331, the issue is whether such involvement *causes* the violation of prohibited acts.[(7)] As seen from the factual presentation, Kansas' involvement could be described as "promoting," "facilitating," "brokering," "informing about," "providing access to" "endorsing," "referring," "supporting," "recommending," or "encouraging" the purchase of imported drugs through the I-SaveRx program.

We have located only one case that addressed the meaning of the word "causing" as used in 21 U.S.C. § 331. In *United States v. Rx Depot, Inc.*,[(8)] the United States brought an action to enjoin two companies involved in procuring prescription drugs from Canada for American patients alleging violation of the FFDCA. The federal district court held that the injunction was warranted to prevent continued facilitation of illegal prescription drug importation. While this case involved corporations that directly assisted individuals in procuring prescription drugs from Canada, as opposed to Kansas' indirect assistance, the court addressed the meaning of "causing" under 21 U.S.C. § 331:

> "Defendants advertise and handle orders for Canadian pharmacies and are remunerated for their efforts. Their actions encouraging and facilitating the illegal importation of drugs amount to a responsible share in the furtherance of these transactions prohibited by the FDCA. Thus, their actions constitute the requisite 'causing' under 21 U.S.C. § 331. *See United States v. Dotterweich*, 320 U.S. 277, 284, 64 S.Ct. 134, 88 L.Ed.2d 48 (1943) (holding liable under FDCA those who have a 'responsible share in the furtherance of the transaction which the statute outlaws"); *United States v. Brittain*, 931 F.2d 1413, 1419 (10th Cir. 1991) (applying the same rationale to the Clean Water Act.)."

A key factor on which the Court focused in its analysis appears to be "remuneration" by this commercial operation, a factor that is not present in the State of Kansas' participation

in the I-Save Rx program. The State of Kansas receives no direct benefit from the program. The corporations' actions of advertising, handling orders and receiving payment for a commercial operation were found by the Depot RX Court to amount to encouraging and facilitating in a manner that equaled a responsible share in furtherance of prohibited acts. Whether a court would find that the State of Kansas' involvement in the I-SaveRx program would likewise amount to a responsible share in furtherance of acts prohibited under 21 U.S.C. § 331 is difficult, if not impossible, to predict. However, based on the statements made by the FDA and the court's decision in *Rx Depot, Inc.*, we believe that at best Kansas' involvement comes perilously close to causing violations of the FFDCA and at worst does cause such violations.

Finally, we echo the sentiment of the Maryland Attorney General's Office in a letter to a Maryland legislator:

> "Since the FDA is the agency charged with enforcement of the federal laws governing prescription drugs, their interpretation of the statutes is entitled to significant weight. Indeed, a letter from me concluding that the FDA misinterprets its own law would be of little use in the event that the FDA were to decide to bring an enforcement action against the State or one of its political subdivisions for facilitating the importation of prescription drugs."(9)

As noted, the FDA is the only agency charged with the responsibility of enforcing the FFDCA. Thus, the decision whether to seek an injunction to enjoin the State of Kansas from participating in the I-SaveRx program lies solely with the FDA. To date, we are aware of no enforcement action on the part of the FDA to enjoin or penalize states or other governmental entities from participating in the way the State of Kansas is participating; however, there are a number of letters warning governmental entities of the FDA's concerns in this regard.

Kansas Pharmacy Act and
Kansas Food Drug and Cosmetic Act

As with your first question, your second question asks whether the *State of Kansas* violates the Kansas Pharmacy Act(10) in promoting the importation of pharmaceutical products from Canada or other foreign jurisdictions through the I-SaveRx program.(11)

We reviewed statutes within the Kansas Pharmacy Act with an eye toward whether any violation by the State of Kansas would be possible, given the level of the State's involvement in the I-SaveRx program. In particular, we considered the following statutes and reached the following conclusions:

- K.S.A. 65-1627 establishes grounds for which the Board of Pharmacy may take disciplinary action against a licensed pharmacist, permitted retail dealer, registered wholesaler or registered pharmacy. Thus, this statute does not provide any basis for consideration of whether the State of Kansas' involvement in the I-SaveRx program is unlawful.
- K.S.A. 65-1631(a) makes it "unlawful for any person to practice as a pharmacist in this state unless such person is licensed by the board as a pharmacist." In our opinion, the level of the State of Kansas' involvement in the I-SaveRx program does not amount to practicing as a pharmacist and thus this statute does not provide any basis for consideration of whether the State of Kansas' involvement in

the I-SaveRx program is unlawful.

- K.S.A. 65-1634 establishes that "every person holding a license, registration or permit who engages in the sale of drugs, medicines, chemicals and poisons" is responsible for the quality of those substances except when sold in the original package. Violation is a class A misdemeanor. On its face this statute is applicable only to Board of Pharmacy licensees, permittees and registrants.
- K.S.A. 65-1634 also makes it a class A misdemeanor for "any person" to intentionally adulterate or mislabel any drugs, medicines, chemicals or poisons or knowingly cause any of those substances to be adulterated, mislabeled or exposed for sale. Although "person" includes "government, governmental subdivision or agency,"[(12)] it does not appear that the State of Kansas, through promotion of the I-SaveRx program, would be involved in the intentional adulteration or mislabeling of these substances or the causing of such adulteration or mislabeling.
- K.S.A. 65-1636 limits the sale and distribution of drugs to licensed pharmacists or persons acting under their immediate personal direction and supervision and in registered pharmacies. However, as we understand it, the State of Kansas' promotion of the I-SaveRx program does not reach the level of the sale or distribution of drugs. Thus, the State of Kansas does not run afoul of this statute by promoting the I-SaveRx program.
- K.S.A. 65-1643(a) makes it unlawful "for any person to operate, maintain, open or establish any pharmacy within this state without first having obtained a registration from the board." By merely promoting the I-SaveRx program, the State of Kansas' is not operating, maintaining, opening or establishing a pharmacy in Kansas, and thus is not in violation of this statute.
- K.S.A. 65-1643(f) makes it unlawful, with some exceptions, for any person to operate "a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board." Again, by merely promoting the I-SaveRx program, the State of Kansas' is not operating a store or place or business that sells, offers for sale or distributes drugs to the public, and thus is not in violation of this statute.
- K.S.A. 65-1657 prohibits nonresident pharmacies from shipping, mailing or delivering prescription drugs to a Kansas resident unless registered as a nonresident pharmacy. However, by its participating in the I-SaveRx program, the State of Kansas is not acting as a nonresident pharmacy.

We also reviewed statutes within the Kansas Food, Drug and Cosmetic Act[(13)] which falls within the jurisdiction of the Secretary of Health and Environment. In particular, we considered the unlawful acts set forth in K.S.A. 65-657. That statute prohibits specified acts *and the causing* of such acts. The prohibited acts pertain primarily to adulteration and misbranding or mislabeling of drugs, as well as food and cosmetics. The primary sections we considered were section (a) that prohibits the manufacture, sale, delivery, holding or offering for sale any drug that is adulterated or misbranded, and section (b) that prohibits the actual adulteration or misbranding of any drug. Violation could result in an injunction[(14)] and/or conviction of a misdemeanor.[(15)] It does not appear that mere involvement of the State of Kansas in the I-SaveRx program *causes* the adulteration or misbranding of drugs or the sale or distribution of such drugs. However, as noted, the ultimate determination concerning whether the State's involvement violates the Kansas Food, Drug and Cosmetic Act lies with the Secretary of Health and Environment.

In relation to your second question, we conclude that the State of Kansas' promotion of the importation of pharmaceutical products from Canada or other foreign jurisdictions through the I-SaveRx program does not violate laws within the Kansas Pharmacy Act. Further, we are unable to conclude as a matter of fact or law that the State of Kansas' participation in that program violates any statute within the Kansas Food, Drug and Cosmetic Act.

Liability of the State of Kansas

Your third question is whether, despite a disclaimer on the Kansas website, action by the State of Kansas promoting the purchase of pharmaceutical products from foreign jurisdictions creates any liability exposure for the State of Kansas or its employees under the Kansas Tort Claims Act.

As indicated, the Kansas website provides the following disclaimer of liability:

> "The State of Kansas accepts no legal liability or responsibility for the health decisions made by consumers based upon the information provided in this Web site."

Varying degrees of concern that have been raised in a number of memorandums of law, letters and reports regarding this issue:

- "If a state government were to begin facilitating drug orders despite the FDA safety prohibitions, the state - and therefore the taxpayer - would almost certainly be liable for any health problem caused or claimed by anyone who had received an off batch of medication like the 99 percent of shipments in September. While the FDA has not directly addressed questions of tort liability, its response to the questions from California's Deputy Attorney General suggests 'we question whether the state would be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law.' As a liable party with fairly deep pockets, the state of New Hampshire (and the taxpayers who fund it) would seem a fairly likely target for any potential lawsuits. Therefore potential costs need to include liability insurance and the legal costs associated with some lawsuits."(16)
- "The potential tort liability that a state could face for providing or facilitating the provision of Canadian drugs to patients who are subsequently harmed by the drugs is illustrated by examining the law in two particular states - Massachusetts and Illinois. States, of course, have not previously engaged in these types of activities, and thus there is not case law that addresses the precise circumstances that would be presented by a state drug import plan. Nevertheless, as discussed in the following sections, clear potential causes of action could lie where patients are harmed from a foreign-sourced drug. Such harm could occur, for example, where the potency of the imported drug is not the same as that of the FDA-approved drug for which it is intended to substitute, resulting in an over- or under-dose, or where the import causes side effects or dangerous interactions that would not be expected with the FDA-approved version.

  "States that provide Canadian drugs directly to patients or that facilitate the provision of these drugs, through a state-sponsored pharmacy benefit plan or by other means, thus face real risks of liability, including under the tort theories of negligence, strict liability/breach of implied warranty of merchantability, failure to

warn, and fraud or misrepresentation."(17)

- "Liability is another critical issue that the report(18) fails adequately to address. It is inconceivable to FDA scientists that there will not be some injuries arising from the sale of unapproved drugs to your employees or citizens. . . . Moreover, we query whether the state would be potentially liable in tort if a drug that the state purchased and sold in violation of Federal law injured an Illinois citizen."(19)
- "Some analysts and state officials are also concerned about state liability for brokering arrangements with Canadian suppliers and encouraging cross-border trade. The question of who is liable if imported drugs harm individual consumers remains unanswered. . . .

  "According to some legal experts, states, cities and counties that support prescription drug importation run substantial financial risks of being embroiled in litigation and may be liable for damages. . . .

  "The absence of a legal precedent makes it difficult to evaluate the potential legal and financial liability for states that broker imported medications. Because determining liability is a very fact-specific inquiry, HHS has been reluctant to give an advisory opinion on the issue.
- "Most state Web sites that link consumers to Canadian pharmacies include explicit disclaimers. . . . Although such waivers may partially insulate governments from legal liability, they make consumer recourse difficult in cases of defective medication."(20)
- "Notwithstanding disclaimers to the contrary, Governor Sebelius' weblink importation plan could potentially trigger state liability as the facilitator of illegal federal and state activity. While difficult to predict, this could create a cause of action under the Kansas Tort Claims Act - the claim being that the state at least acted negligently when creating the weblink, thereby compromising its governmental immunity while engaging in more of a 'proprietary' rather than 'governmental' function that disregarded the potential harm arising from state residents purchasing illegal, unsafe drugs."(21)
- "Without writing my own treatise on tort law, I think that it is safe to conclude that there are possible State or local programs, and possible fact situations, under which the State or a political subdivision could find itself liable for injuries caused by use of imported prescription drugs. This risk would obviously be higher if the State itself engaged in importation, and lower at lesser levels of participation. However, the State has the authority to statutorily immunize itself or its political subdivisions against suits brought on this basis if it decides to establish a program or to allow its political subdivisions to do so. . . ."(22)
- "Several states and municipalities have begun programs to buy, or to encourage their citizens to buy, pharmaceuticals from Canada. For example, Governor Doyle of Wisconsin provided testimony to the Task Force outlining the program created by Wisconsin to facilitate the importation of prescription drugs from Canada by creating a state-sponsored website linking Wisconsin residents to specific Canadian sellers. . . .

  "States as a general matter are immune from liability for acts they take as sovereigns. All states, however, waive their sovereign immunity under some circumstances, with the precise outlines of those waivers varying from state to

state. Depending on the terms of a given state's waiver, it may expose itself to civil liability by participating in a drug importation scheme. In Wisconsin, and in every other state and municipality that has set up programs to encourage drug importation from Canada, the state has included a very detailed disclaimer of all liability associated with harm that may result from the drugs ordered. In those cases in which sovereign immunity is found to have been waived, the effectiveness of the use of disclaimers in preventing state liability is unclear. The Uniform Commercial Code (U.C.C.) permits courts to disregard such disclaimers under fairly discretionary standards with respect to private parties. Courts have in some cases ignored tort liability waivers, citing the need for protection of unsophisticated parties. Even if courts were to enforce these clauses in cases involving state importation programs, the result would most likely not be a reduction in total liability but simply a shift in liability from the state to private parties involved in the transaction."(23)

- State and local governments view the importation of foreign drugs as a quick fix to budgetary problems and an easy way to please their constituents with cheaper medications. It does not appear that governments have fully considered the potential liability costs of distributing or facilitating the distribution of drugs to its citizens. Due to the characteristics of this activity as a businesslike function for which injuries may result from the day-to-day challenges in ensuring that the drugs are safe and unadulterated, the state's actions may result in forfeiting its immunity and finding itself subject to lawsuits and subsequent liability.(24)

As seen, these various memorandums of law, letters and reports raise issues of fairly mild concern to great alarm, largely depending on the position being argued. Because Kansas' as well as other states' involvement with websites that provide information that enable persons to purchase medications from Canada is fairly new, no case law has developed addressing the issue of a state's potential liability. Additionally, legal liability is very fact specific. Obviously, the higher the degree of actual involvement, the greater the liability potential.(25) Thus, we are unable to say with any degree of certainty whether Kansas' involvement in the I-SaveRx program would create any liability exposure for the State of Kansas or its employees.

Liability of Prescribing Physician

Your fourth question is whether the State's involvement in the I-SaveRX program creates legal issues or potential liability exposure for prescribing physicians.

Based on the I-SaveRx website, a Kansas physician's role would be limited to a review and verification of the patient's medications and health information. From that point on, actions to use the I-SaveRx program are taken solely by the patient. While liability may lie within the realm of all-things-are-possible, it is nevertheless difficult to imagine this scenario actually resulting in civil liability of the prescribing physician.

In relation to possible discipline against a physician's license, on October 21, 2003, the Kansas Board of Healing Arts issued a letter opinion that reached the following conclusion:

> "In our opinion, if a physician actively participates in the process of purchasing prescription drugs from an unregistered pharmacy, that physician might be found to have violated the healing arts act. Merely writing a

> prescription order that the physician suspects might be presented to a foreign pharmacy, or discussing the advantages or disadvantages of Canadian drugs with a patient would not likely constitute a violation."

The Board of Healing Arts is charged with the responsibility of implementing and enforcing the Healing Arts Act. Thus, it appears that a physician who operated within the parameters of the I-SaveRx program would not be subject to discipline by that Board.

Kansas Consumer Protection Act

Finally, you ask whether the State's involvement in the I-SaveRx program creates express or implied warranty issues under the Kansas Consumer Protection Act,(26) which might result in the State being a defendant to actions under this Act.

The purpose of the Kansas Consumer Protection Act includes protecting "consumers from *suppliers* who commit deceptive and unconscionable practices."(27) With some specified exceptions, "unconscionable practices" cover a *supplier* who excludes, modifies or otherwise attempts to limit either the implied warranties of merchantability and fitness for a particular purpose or any remedy provided by law for a breach of those warranties.(28)

However, the Act defines "supplier" as:

> "A manufacturer, distributor, dealer, seller, lessor, assignor, or other person who, in the ordinary course of business, solicits, engages in or enforces consumer transactions whether or not dealing directly with the consumer."(29)

Based on the information provided on the State of Kansas' website and weblink to I-SaveRx, the State would not be considered a "supplier" for purposes of the Act and thus not covered by the Act's consumer protection provisions.

Additionally, the Act explicitly is made not applicable to:

> "[A] publisher, broadcaster, printer or other person engaged in the dissemination of information or the reproduction of printed or pictorial matter so far as the information or matter has been disseminated or reproduced on behalf of others without actual knowledge that it violated the Kansas consumer protection act."(30)

The Comment explains that this section exempts disseminators of information unless they commit a violation of the Act on behalf of others with actual knowledge that they are violating the act or unless they commit a violation on their own behalf.

In answer to your fifth question, in our opinion the State of Kansas' involvement in the I-SaveRx program does not create express or implied warranty issues under the Kansas Consumer Protection Act. Thus it is highly doubtful that the State's involvement would result in the State being a defendant to actions under the Act.

Sincerely,

Phill Kline

Attorney General of Kansas

Camille Nohe
Assistant Attorney General

PK:JLM:CN:jm

FOOTNOTES

Click footnote number to return to corresponding location in the text.

1. Emphasis indicates a link to a separate website.

2. The address provided is I-Save Rx, P.O. Box 21086 c/o CanaRx Services Inc., Tecumseh, Ontario, Canada N8N 4S1.

3. Consequently, this opinion does not address whether persons who purchase medications through the I-SaveRx program may violate the Federal Food, Drug and Cosmetic Act, nor does it address whether participating Canadian, Irish or United Kingdom pharmacies may violate the Act.

4. 21 U.S.C. § 301 *et seq.*

5. *See* http://www.fda.gov/importeddrugs/.

6. Letter dated August 25, 2003, to Mr. Gregory Gonot, Deputy Attorney General, State of California from William K. Hubbard, Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration (available at http://www.fda.gov/opacom/gonot.html).

7. *See also* letter dated November 6, 2003, to G. Anthony Howard, President, CanaRx Services, Inc., from David J. Horowitz, Director, Office of Compliance, FDA.

8. 290 F.Supp. 1238 (N.D.Okla. 2003)

9. Letter dated January 28, 2004 to The Honorable Kunar P. Barve from Kathryn M. Rowe, Assistant Attorney General, State of Maryland.

10. K.S.A. 65-1626 *et seq.*

11. Again, this opinion does not address whether persons who purchase medications through the I-SaveRx program may violate the Kansas Pharmacy Act, nor does it address whether participating Canadian, Irish or United Kingdom pharmacies may violate the Act.

12. K.S.A. 2004 Supp. 65-1626(r).

13. K.S.A. 65-656 *et seq*.

14. K.S.A. 65-658.

15. K.S.A. 65-659.

16. "Should the State Government Import Prescription Drugs," January 28, 2004 report from The Josiah Bartlett Center for Public Policy, written by Charles Arlinghaus. (The Center is a non-profit, non-partisan, independent think tank focused on state and local public policy issues that affect the quality of life for New Hampshire's citizens.)

17. "Liability of States Importing Prescription Drugs from Canada," October 3, 2003 memorandum of law by Michael S. Labson and Miriam J. Guggenheim, Covington & Burling Law Firm, Washington, D.C.

18. Prepared by Special Advocates for Prescription Drugs present to Illinois Governor Blagojevich.

19. November 6, 2003 letter to Special Advocates for Prescription Drugs from William K. Hubbard, Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration.

20. "Prescription Drug Importation," June 2004 report of The Council of State Governments.

21. December 8, 2004 memorandum of law by Anthony Wisniewski prepared for the Pharmaceutical Research and Manufacturers of America.

22. Letter dated January 28, 2004 to The Honorable Kunar P. Barve from Kathryn M. Rowe, Assistant Attorney General, State of Maryland.

23. HHS [Health and Human Services] Task Force on Drug Importation, December 2004.

24. Undated Memorandum of Law titled "States that Import or Facilitate the Importation of Foreign Pharmaceuticals Risk Lawsuits," by Shook, Hardy & Bacon, LLP, Washington, D.C.

25. *Mitzner v. State*, 257 Kan. 258 (1995) (state generally not responsible for negligent acts of its independent contractors).

26. K.S.A. 50-623 *et seq.*

27. K.S.A. 50-623(b).

28. K.S.A. 50-627(b)(7); K.S.A. 50-639.

29. K.S.A. 2004 Supp. 50-624(i).

30. K.S.A. 50-635.

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