

ALASKA STATE LEGISLATURE

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North to the Future

Senator Cathy Giessel
Senate District N

Responses to questions during SB 201 hearing SFIN 4-9-16

- 1. Would SB 201 apply to regulation of international wholesalers? (sub question..... do our AK licensees do business with wholesalers in Mexico or Canada or similar?) But even so, we can't regulate a business in another country could we?**

Alaskan pharmacies do not do business with wholesalers in Mexico or Canada since they presumably don't sell US FDA approved drugs and as such the FDA does not allow import of said drugs.

Q1. We are only able to order from US based wholesalers and Pharmaceutical companies. We have never tried to order outside those parameters because we, as Pharmacists, cannot guarantee that the medication will conform to USP (United States Pharmacopeia) and FDA standards for potency and efficacy for our patients. No the Alaska Board of Pharmacy has not authority in another country and limited in other states.

There is an exemption in the importation laws/regs for a doctor to obtain or use a medication on a patient by their, the patient's, request for any medication worldwide. So if I've got cancer and I've read about some tree bark concoction from Tibet that I would like to try and my doctor is willing to work with me on using it then it can be imported for me and me only. This may only apply to commercially available medications from other countries that I am not sure of. Now of course there is no way to know if the product will work but that is between me, the patient, and my doctor. As far as ordering a medication that is commercially available here in the US then my understanding is that is not allowed just because you can get it cheaper in Tijuana Mex.

2. Are internet sales regulated? Sub question - would AK licensees purchase off the internet? Are they even allowed to do that?

Alaskan Pharmacies may purchase off the internet from Wholesalers licensed in the United States and purchase FDA approved drugs. Alaskan pharmacies may not purchase and then dispense drugs from wholesalers (presumably out of the country) that are NOT FDA approved.

For example, FDA has uncovered numerous instances of medical practitioners deliberately obtaining unapproved drugs, some which have been counterfeits directly from foreign sources for administering to patients.

These laws would not prevent situations where consumers purchase drugs from rogue Internet websites or where a pharmacy purchases product from outside the legitimate supply chain and dispenses directly to a patient.

I think what the above says is that there will continue to be "roque" internet wholesalers that are selling non-fda approved drugs. These entities would presumably not register with the State of Alaska. It would seem to me that it would be the intent of the bill to stop these illegal entities if they are operating in the United States.

Q2. No. We can probably find cheaper medications off the internet but again since we have no idea where these medications are coming from, country and or manufacturing facility, I don't know any Pharmacist that would do that. Again, without assurance of any compliance with USP or FDA standards we would never order from them.

Internet Sales—

1. “While the new authorities under DQSA and FDASIA help address some of the risks posed by counterfeit drugs, they will not prevent all types of illegal diversion or distribution schemes that FDA has discovered in recent years. For example, FDA has uncovered numerous instances of medical practitioners deliberately obtaining unapproved drugs—some which have been counterfeits—directly from foreign

sources for administering to patients. These laws would not prevent situations where consumers purchase drugs from rogue Internet websites or where a pharmacy purchases product from outside the legitimate supply chain and dispenses directly to a patient.”

- a. <http://www.fda.gov/NewsEvents/Testimony/ucm387449.htm> (under “Remaining Challenges” section in the article)

Now to respond to the problem of internet “pharmacies” the National Association of Boards of Pharmacy (NABP), of which every state Pharmacy Board is a member, has been working with ICANN (Internet Corporation for Assigned Names and Numbers) to obtain exclusive rights to the dot pharmacy internet protocol identifier. They obtained those rights about a year ago and for me to have the HarryRace.pharmacy domain name I’m in the process of applying to them for the rights to use that website. If I obtain that website then anyone in the world that goes to that site will know that I am a licensed pharmacy and I will only dispense genuine USP/FDA quality medications. So these sites will start to show up on the WWW shortly. I don’t know if anyone has passed all the inspections from NABP to have been issued a domain yet but when it happens I know it will be a big media splash.

International wholesalers—

1. Bulk drugs manufactured in a foreign establishment must be registered under section 501(i) of the FD&C (Food, Drug, and Cosmetic Act). They must be accompanied by a valid certificate of analysis.

As for bulk powders/drugs. We are strictly prohibited by the FDA to import these types of materials.....Thank you PHARMA. As a compounding pharmacist and working with Prescription Compounding Centers of America (PCCA) for 30 years I’ve come to understand the issues that they as importers of bulk powders have to deal with. The paperwork that is required by the FDA to import these chemicals is very onerous and getting worse by the year. Something a mom/pop shop like ours would never be able to comply with. That is why we have PCCA as our trusted wholesaler of these products, because for one thing I’ve toured the plant and I’ve seen the pallets with the drums and bags of chemicals/medications in the warehouse. I’ve seen how they handle the whole process from the product landing on their docks to the finished bottled packages that I would obtain in my pharmacy. They would then, of course, have to comply with this statute. Knowing them that will not be an issue.