

**HB**

**9**

<TARGET><BILL>HB 9</BILL><SUBJECT>HB  
9</SUBJECT><COMM>HL&C30</COMM></TARGET>

# HOUSE COMMITTEE REPORT

7  
Date Referred to Committee: January 18, 2017

FURTHER REFERRALS: Finance

Date of Committee Action: 10 Apr 2017

The LABOR AND COMMERCE Committee considered:

HB 9

**HOUSE BILL NO. 9**

"An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy."

**HB 9-PHARMA BD & EMPLOYEES;DRUG DIST/MANUFAC**

Recommends it be replaced with [ ] HCS or [  ] CS for HB9 (L+C)  
For Senate Bills with new title: [ ] Technical Title [ ] New Title: HCR \_\_\_\_\_ [ ] Same Title [  ] New Title

- [ ] attach amendments
- [ ] add new referral to \_\_\_\_\_ Committee
- [ ] Letter of Intent \_\_\_\_\_ Committee

List of Abbrev for Depts.:  
ADM  
AJS  
CED  
COR  
EED  
DEC  
DFG  
GOV  
DHS  
LWF  
LAW  
LEG  
MVA  
DNR  
DPS  
REV  
DOT  
UA

<b>NEW FISCAL NOTES</b>				
*FN# is assigned by Chief Clerk's Office				
*FN#	List by Dept(s):	Fiscal	Indet.	Zero
1	CEO	✓		

<b>PREVIOUS FISCAL NOTES</b>				
FN#	List by Dept(s):	Fiscal	Indet.	Zero

<u>Signing with recommendations</u>	Printed Last Name	DP	DNP	NR	AM
<i>Colleen Sullivan Leonard</i>	SULLIVAN LEONARD	X		✓	
<i>House Staff</i>	STUTES			✓	
<i>[Signature]</i>	WOOL			✓	
<i>[Signature]</i>	Josephson			X	
<i>Gay Knapp</i>	BRUCH	✓			
	Knapp			X	
Chair: <i>[Signature]</i>	KITO	✓			
Chair:					

# ALASKA STATE LEGISLATURE

*Session:*  
State Capitol  
Juneau, AK 99801-1182  
Phone: (907) 465-3783  
Toll Free: (877) 460-3783



*Interim:*  
12641 Old Glenn Hwy., Ste. 201  
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## REPRESENTATIVE DAN SADDLER

### SPONSOR STATEMENT

#### House Bill 9

*"An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy."*

House Bill 9 strengthens Alaska's prescription drug supply chain, by giving the Board of Pharmacy the authority to license and inspect the facilities of out-of-state wholesale drug distributors and third-party logistics providers shipping pharmaceuticals to Alaska.

Alaska is one of the few remaining states not in compliance with the federal Drug Quality and Security Act of 2013. Passage of HB 9 is critical to making Alaska comply with that Act.

HB 9 closes loopholes in the regulatory system and holds out-of-state wholesale distributors to the same regulations as Alaska wholesalers shipping within the state. The bill creates a new category of pharmacy license for "Out-of-State" Wholesale Drug Distributors.

HB 9 will:

- require any out-of-state wholesale drug distributor or outsourcing facility to obtain a license
- authorize inspection of the facility by a designee of the board
- require a facility to appoint an agent before it advertises its services in Alaska, and before it ships, mails or delivers prescription drugs to a licensee in the state

HB 9 provides the Board of Pharmacy and the State of Alaska with the tools to ensure the safe delivery of controlled, non-counterfeit medications to Alaska. These tools are necessary to combat the increasing production and distribution of counterfeit medications by out-of-state wholesale vendors, and to support efforts to maintain the integrity of the drug supply chain.

To help manage the workload from increasing Federal Drug Administration regulatory and compliance requirements necessary to protect the state-level drug supply chain, the bill also authorizes the Board of Pharmacy to create an "Executive Administrator" position. This position will also help manage current licensees, and serve as a liaison to the legislature, executive branches, and other state pharmacy boards.

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## REPRESENTATIVE DAN SADDLER

### CS for House Bill 9 Version A to Version J (HL&C) Summary of Changes

- **Page 2 Line 29-31 Sec. 1. AS 08.80.030(b)**

Changed Subsection (14) to read - establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business - due to different effective date from Sec. 2

Moved and changed subsection (15) to new Sec. 2

- **Page 2 Line 31 Sec. 2. AS 08.80.030(b)**

Added new Sec. 2 as amended in Sec. 1

- **Page 4 Line 8 Sec. 2. AS 08.80.030(b)**

Added Subsection (15) to read— license and inspect the facilities of wholesale distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159 - due to different effective date from Sec. 1

Amended by adding the words “third-party logistics provider” after wholesale drug distributors,

- **Page 4 Line 17 Sec. 4. AS 08.80.157(k)**  
**Page 4 Lines 22 Sec. 5 AS 08.80.159**  
**Page 5 Lines 3 Sec. 4 AS 08.80.159(b)(2)(c)**

Amended by adding the words “third-party logistics provider” after wholesale drug distributors,

- **Page 5 Lines 12-15 Sec. 6 AS 08.80.270**

Amended by making the executive administrator a principal executive officer and partially exempt under AS 39.25.120, and entitled to Range 23

- **Page 5 Lines 25-29 Sec. 7 AS 08.80.480**

Amended by new paragraph (38) definition of “third-party logistics provider”

- **Page 6 Lines 19 Sec. 8 AS 39.25.120(c)(7)**

Amended by adding new Section and amends to add (Q) Board of Pharmacy

- **Page 6 Lines 20-28**

Amended by adding Sections 9, 10, 11 transition language and effective date clause

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## REPRESENTATIVE DAN SADDLER

### Sectional Analysis CS House Bill 9 / Version J

*"An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy."*

**Section 1: Amends AS 08.80.030(b) by adding a new subsection:**

(14): Establishes qualifications and duties of executive administrator. Executive administrator is delegated authority in order to conduct board business.

**Section 2: Amends AS 08.80.030(b) by adding a new subsection:**

(15): Amends and allows licensing and inspection for out-of-state drug distributors, third-party logistics providers and outsourcing facilities;

**Section 3: Amends AS 08.80.030 by adding a new subsection:**

AS 08.80.030(c): Specifications for facilities, equipment, personnel, and procedures for control of drugs in compliance with the federal Drug Supply Chain Security Act.

**Section 4: Amends AS 08.80.157 by adding a new subsection:**

(k): Applies to wholesale drug distributors, third-party logistics providers, and outsourcing facilities outside the state under AS 08.80.159, regarding licensing.

**Section 5: Amends AS 08.80 by adding a new section:**

**Sec. 08.80.159:** Requires that a wholesale drug distributor, third party logistics provider, or outsourcing facility have a license in Alaska before shipping, mailing, or delivering prescription drugs to a licensee in the state or before advertising in the state, an agent must be appointed in the state, and a designee of the board must authorize inspection of the facility.

An outsourcing facility, in addition, must comply with the federal Drug Quality and Security Act of 2013. The board may require an inspection of facilities located outside of the state, approve a designee to inspect. The board shall adopt regulations to implement this section.

**Section 6: Amends AS 08.80 by adding new section to Article 2:**

**Sec. 08.80.270:** Allows the Board to create an executive administrator position. Defines the role and salary range of the executive administrator.

**Section 7: Amends AS 08.80.480 by adding a new paragraphs:**

**AS 08.80.480(37):** Defines “outsourcing facility”

**AS 08.80.480(38):** Defines “third party logistics provider”

**Section 8: Amends AS 39.25.120(c)(7) by adding**

**(Q)** Board of Pharmacy

**Sections 9, 10, 11:**

Provides transition language and effective date clause

30-LS0131\J  
Bruce  
4/6/17

**CS FOR HOUSE BILL NO. 9( )**  
**IN THE LEGISLATURE OF THE STATE OF ALASKA**  
**THIRTIETH LEGISLATURE - FIRST SESSION**

**BY**

**Offered:**

**Referred:**

**Sponsor(s): REPRESENTATIVE SADDLER**

**A BILL**

**FOR AN ACT ENTITLED**

1 **"An Act relating to the Board of Pharmacy; relating to the licensing of certain entities**  
2 **and inspection of certain facilities located outside the state; relating to drug supply chain**  
3 **security; creating a position of executive administrator for the Board of Pharmacy; and**  
4 **providing for an effective date."**

5 **BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

6 **\* Section 1.** AS 08.80.030(b) is amended to read:

7 (b) In order to fulfill its responsibilities, the board has the powers necessary  
8 for implementation and enforcement of this chapter, including the power to

9 (1) elect a president and secretary from its membership and adopt rules  
10 for the conduct of its business;

11 (2) license by examination or by license transfer the applicants who are  
12 qualified to engage in the practice of pharmacy;

13 (3) assist the department in inspections and investigations for  
14 violations of this chapter, or of any other state or federal statute relating to the practice

1 of pharmacy;

2 (4) adopt regulations to carry out the purposes of this chapter;

3 (5) establish and enforce compliance with professional standards and  
4 rules of conduct for pharmacists engaged in the practice of pharmacy;

5 (6) determine standards for recognition and approval of degree  
6 programs of schools and colleges of pharmacy whose graduates shall be eligible for  
7 licensure in this state, including the specification and enforcement of requirements for  
8 practical training, including internships;

9 (7) establish for pharmacists and pharmacies minimum specifications  
10 for the physical facilities, technical equipment, personnel, and procedures for the  
11 storage, compounding, and dispensing of drugs or related devices, and for the  
12 monitoring of drug therapy;

13 (8) enforce the provisions of this chapter relating to the conduct or  
14 competence of pharmacists practicing in the state, and the suspension, revocation, or  
15 restriction of licenses to engage in the practice of pharmacy;

16 (9) license and regulate the training, qualifications, and employment of  
17 pharmacy interns and pharmacy technicians;

18 (10) issue licenses to persons engaged in the manufacture and  
19 distribution of drugs and related devices;

20 (11) establish and maintain a controlled substance prescription  
21 database as provided in AS 17.30.200;

22 (12) establish standards for the independent administration by a  
23 pharmacist of vaccines and related emergency medications under AS 08.80.168,  
24 including the completion of an immunization training program approved by the board;

25 (13) establish standards for the independent dispensing by a  
26 pharmacist of an opioid overdose drug under AS 17.20.085, including the completion  
27 of an opioid overdose training program approved by the board;

28 **(14) establish the qualifications and duties of the executive**  
29 **administrator and delegate authority to the executive administrator that is**  
30 **necessary to conduct board business.**

31 \* Sec. 2. AS 08.80.030(b), as amended by sec. 1 of this Act, is amended to read:

1 (b) In order to fulfill its responsibilities, the board has the powers necessary  
2 for implementation and enforcement of this chapter, including the power to

3 (1) elect a president and secretary from its membership and adopt rules  
4 for the conduct of its business;

5 (2) license by examination or by license transfer the applicants who are  
6 qualified to engage in the practice of pharmacy;

7 (3) assist the department in inspections and investigations for  
8 violations of this chapter, or of any other state or federal statute relating to the practice  
9 of pharmacy;

10 (4) adopt regulations to carry out the purposes of this chapter;

11 (5) establish and enforce compliance with professional standards and  
12 rules of conduct for pharmacists engaged in the practice of pharmacy;

13 (6) determine standards for recognition and approval of degree  
14 programs of schools and colleges of pharmacy whose graduates shall be eligible for  
15 licensure in this state, including the specification and enforcement of requirements for  
16 practical training, including internships;

17 (7) establish for pharmacists and pharmacies minimum specifications  
18 for the physical facilities, technical equipment, personnel, and procedures for the  
19 storage, compounding, and dispensing of drugs or related devices, and for the  
20 monitoring of drug therapy;

21 (8) enforce the provisions of this chapter relating to the conduct or  
22 competence of pharmacists practicing in the state, and the suspension, revocation, or  
23 restriction of licenses to engage in the practice of pharmacy;

24 (9) license and regulate the training, qualifications, and employment of  
25 pharmacy interns and pharmacy technicians;

26 (10) issue licenses to persons engaged in the manufacture and  
27 distribution of drugs and related devices;

28 (11) establish and maintain a controlled substance prescription  
29 database as provided in AS 17.30.200;

30 (12) establish standards for the independent administration by a  
31 pharmacist of vaccines and related emergency medications under AS 08.80.168,

1 including the completion of an immunization training program approved by the board;

2 (13) establish standards for the independent dispensing by a  
3 pharmacist of an opioid overdose drug under AS 17.20.085, including the completion  
4 of an opioid overdose training program approved by the board;

5 (14) establish the qualifications and duties of the executive  
6 administrator and delegate authority to the executive administrator that is necessary to  
7 conduct board business;

8 **(15) license and inspect the facilities of wholesale drug**  
9 **distributors, third-party logistics providers, and outsourcing facilities located**  
10 **outside the state under AS 08.80.159.**

11 \* **Sec. 3.** AS 08.80.030 is amended by adding a new subsection to read:

12 (c) The minimum specifications for facilities, equipment, personnel, and  
13 procedures for the compounding, storage, and dispensing of drugs established under  
14 (b)(7) of this section must be consistent with the requirements of 21 U.S.C. 201 - 208  
15 (Drug Supply Chain Security Act).

16 \* **Sec. 4.** AS 08.80.157 is amended by adding a new subsection to read:

17 (k) This section applies to wholesale drug distributors, third-party logistics  
18 providers, and outsourcing facilities located outside the state under AS 08.80.159.

19 \* **Sec. 5.** AS 08.80 is amended by adding a new section to read:

20 **Sec. 08.80.159. Licensing and inspection of facilities outside of state.** (a)  
21 Before shipping, mailing, or delivering prescription drugs to a licensee in the state or  
22 advertising in the state, a wholesale drug distributor, third-party logistics provider, or  
23 an outsourcing facility that is located outside the state shall

24 (1) obtain a license under AS 08.80.157;

25 (2) appoint an agent on whom process can be served in the state; and

26 (3) authorize inspection of the facility by a designee of the board under

27 (c) of this section.

28 (b) In addition to the requirements of (a) of this section, an outsourcing facility  
29 shall

30 (1) register as an outsourcing facility with the United States Food and  
31 Drug Administration; and

1 (2) comply with the requirements of 21 U.S.C. 503B (Drug Quality  
2 and Security Act of 2013).

3 (c) Upon application by a wholesale drug distributor, third-party logistics  
4 provider, or an outsourcing facility for a license under this section, the board may

5 (1) require an inspection of the applicant's facility located outside the  
6 state; and

7 (2) approve a designee to conduct the inspection.

8 (d) The board shall adopt regulations necessary to implement this section.

9 \* **Sec. 6.** AS 08.80 is amended by adding a new section to article 2 to read:

10 **Sec. 08.80.270. Executive administrator of the board.** (a) The board shall  
11 employ an executive administrator to carry out the duties established under (b) of this  
12 section. The executive administrator is the principal executive officer of the board.  
13 The executive administrator is in the partially exempt service under AS 39.25.120 and  
14 is entitled to receive a monthly salary equal to a step in Range 23 on the salary  
15 schedule set out in AS 39.27.011(a).

16 (b) The executive administrator shall

17 (1) perform duties associated with the licensing and regulation of  
18 licensees under this chapter as prescribed by the board; and

19 (2) serve as a liaison to the legislative and executive branches of state  
20 government, the media, and other state pharmacy boards.

21 \* **Sec. 7.** AS 08.80.480 is amended by adding new paragraphs to read:

22 (37) "outsourcing facility" means a facility at one geographic location  
23 or address that is engaged in the compounding of sterile drugs for a facility at another  
24 geographic location.

25 (38) "third-party logistics provider" means an entity that provides or  
26 coordinates warehousing or other logistics services for a product in interstate  
27 commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the  
28 product, and that does not take ownership of the product or have responsibility to  
29 direct the sale or disposition of the product.

30 \* **Sec. 8.** AS 39.25.120(c)(7) is amended to read:

31 (7) the principal executive officer of the following boards, councils, or

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commissions:

- (A) Alaska Public Broadcasting Commission;
- (B) Professional Teaching Practices Commission;
- (C) Parole Board;
- (D) Board of Nursing;
- (E) Real Estate Commission;
- (F) Alaska Royalty Oil and Gas Development Advisory Board;
- (G) Alaska State Council on the Arts;
- (H) Alaska Police Standards Council;
- (I) Alaska Commission on Aging;
- (J) Alaska Mental Health Board;
- (K) State Medical Board;
- (L) Governor's Council on Disabilities and Special Education;
- (M) Advisory Board on Alcoholism and Drug Abuse;
- (N) Statewide Suicide Prevention Council;
- (O) State Board of Registration for Architects, Engineers, and  
Land Surveyors;
- (P) Alaska Health Care Commission;
- (Q) Board of Pharmacy;**

\* Sec. 9. The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITION: REGULATIONS. The Department of Commerce, Community, and Economic Development and the Board of Pharmacy may adopt regulations necessary to implement the changes made by this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the relevant provision of this Act implemented by the regulation.

\* Sec. 10. Sections 1, 6, 8, and 9 of this Act take effect immediately under AS 01.10.070(c).

\* Sec. 11. Except as provided in sec. 10 of this Act, this Act takes effect July 1, 2018.

# Fiscal Note

State of Alaska  
2017 Legislative Session

Bill Version: HB 9  
Fiscal Note Number: \_\_\_\_\_  
( ) Publish Date: \_\_\_\_\_

Identifier: HB009-DCCED-CBPL-03-31-17  
Title: PHARMA BD & EMPLOYEES;DRUG  
DIST/MANUFAC  
Sponsor: SADDLER  
Requester: (H) Labor & Commerce

Department: Department of Commerce, Community and  
Economic Development  
Appropriation: Corporations, Business and Professional  
Licensing  
Allocation: Corporations, Business and Professional  
Licensing  
OMB Component Number: 2360

### Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2018	Included in	Out-Year Cost Estimates				
	Appropriation Requested	Governor's FY2018 Request	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
<b>OPERATING EXPENDITURES</b>	<b>FY 2018</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023</b>
Personal Services	136.5		136.5	136.5	136.5	136.5	136.5
Travel	6.0		6.0	6.0	6.0	6.0	6.0
Services	31.7		15.0	15.0	15.0	15.0	15.0
Commodities	10.0						
Capital Outlay							
Grants & Benefits							
Miscellaneous							
<b>Total Operating</b>	<b>184.2</b>	<b>0.0</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>

### Fund Source (Operating Only)

1156 Rcpt Svcs (DGF)	184.2		157.5	157.5	157.5	157.5	157.5
<b>Total</b>	<b>184.2</b>	<b>0.0</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>

### Positions

Full-time	1.0		1.0	1.0	1.0	1.0	1.0
Part-time							
Temporary							

### Change in Revenues

1156 Rcpt Svcs (DGF)	184.2		157.5	157.5	157.5	157.5	157.5
<b>Total</b>	<b>184.2</b>	<b>0.0</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>	<b>157.5</b>

**Estimated SUPPLEMENTAL (FY2017) cost:** 0.0 *(separate supplemental appropriation required)*  
*(discuss reasons and fund source(s) in analysis section)*

**Estimated CAPITAL (FY2018) cost:** 0.0 *(separate capital appropriation required)*  
*(discuss reasons and fund source(s) in analysis section)*

### ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? Yes  
If yes, by what date are the regulations to be adopted, amended or repealed? 07/01/18

### Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By: Janey Hovenden, Director Phone: (907)465-2538  
Division: Corporations, Business and Professional Licensing Date: 03/31/2017 08:00 AM  
Approved By: Catherine Reardon, Director Date: 03/31/17  
Agency: Division of Administrative Services, DCCED

FISCAL NOTE ANALYSIS

STATE OF ALASKA  
2017 LEGISLATIVE SESSION

BILL NO. HB 9

**Analysis**

HB 9 gives authority to the Board of Pharmacy to license and inspect out-of-state wholesale drug distributors and outsourcing facilities. Current statutes allow licensing of in-state wholesale distributors only. Alaska is one of two states that do not currently license out-of-state wholesale distributors.

HB 9 authorizes the board to establish the qualifications and duties of an executive administrator to assist the board in complying with new federal regulations. In November 2013, federal law was enacted under the Drug Supply Chain Security Act (DSCSA) requiring regulations for licensing of wholesale drug distributors within two years after the date of enactment.

This bill will specifically change the Board of Pharmacy licensing program by increasing the number of applications received and processed by division staff. Additional staff will be necessary to implement the additional licensing of out-of-state wholesale distributors and outsourcing facilities.

The board will need to implement new regulations for the licensing and inspection of the facilities, within a time frame of nine to twelve months. The new federal regulations are extensive, requiring research by board staff to ensure regulations meet the Federal requirements.

If the bill passes the following expenses will be incurred:

Personal Services:	\$136.5 (one permanent full time executive administrator, range 23)
Travel:	\$6.0 (executive administrator to attend four board meetings per year)
Services:	\$16.7 (legal costs to amend regulations, printing, and postage in the first year)
	\$15.0 (statewide core services RSAs and allocated costs )
Commodities:	\$10.0 (computer, office furniture, and other one-time needs in first year)

Professional licensing programs within the Division of Corporations, Business and Professional Licensing are funded by Receipt Supported Services, fund source 1156 Rcpt Svcs (DGF). Licensing fees for each occupation are set per AS 08.01.065 so the total amount of revenue collected approximately equals the occupation's actual regulatory costs.



THE STATE  
of **ALASKA**

GOVERNOR BILL WALKER

Department of Commerce, Community,  
and Economic Development

BOARD OF PHARMACY

P.O. Box 110806  
Juneau, AK 99811-0806  
Main: 907.465.2589  
Fax: 907.465.2974

March 6, 2017

The Honorable Dan Saddler  
House of Representatives  
State Capitol Room 513  
Juneau, AK 99801-1182

Re: HB 9

Dear Representative Saddler:

I am writing to express the Board of Pharmacy's strong support for passage of HB 9: An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy.

Passage of this bill will create a more secure drug supply chain by allowing for licensing and inspection of Out-of-State Wholesale Drug Distributors shipping to Alaska. At this time, Alaska is one of the few remaining states that do not license these facilities. Our goal is to eliminate those wholesalers looking for loopholes in the regulatory system by ensuring that these out-of-state applicants are held to the same regulations that Alaska wholesalers shipping from within the state are held to.

This legislation is critical and necessary to bring Alaska in compliance DQSA (Drug Quality Security Act) as required under section 582 of the FD&C Act through the FDA. The new license category will aid in further securing the supply chain and drug distribution system at the state level. Currently, the Board of Pharmacy does not have the authority to regulate Out-of-State Wholesale Drug Distributors, Third Party Logistic Providers, or 503b Outsourcing Facilities.

HB 9 would require that any Out-of-State Wholesale Drug Distributor, Third Party Logistic Provider, or 503b Outsourcing facility follow specific guidelines including obtaining a license, authorizing inspection of the facility by a designee of the board, and appointing an agent before shipping, mailing or delivering prescription drugs to a licensee in the state or advertising in the state.

Additionally, this legislation will allow the Board of Pharmacy to create a new position titled "Executive Administrator" to serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards, as well as implement board statutes and regulations, and aid in managing current licensees. This position must be distinct from the current licensing examiner position due to the impact of increasing FDA regulations and requirements for compliance to protect the drug supply chain at the state level.

The passage of HB 9 is very important to our mission of safeguarding the health and safety of Alaska's citizens.

Sincerely,  
Leif Holm, PharmD  
Chair, Alaska Board of Pharmacy

p.p.  
Donna Bellino  
Licensing Examiner

# BOARD OF PHARMACY

**SB37 & HB9:**

**Why license wholesale drug distributors?**

**Presented by Board Chair Leif Holm, MPH**

**and Vice Chair Richard Holt, MPH**

# Why license out-of-state wholesale drug distributors?

Every U.S. jurisdiction except Alaska, Hawaii, Guam, Utah, and Massachusetts requires nonresident wholesale distributors to obtain licensure.

Without licensure of out-of-state wholesale drug distributors:

- Federal government will take over regulation for Alaska under the Drug Supply Chain Security Act and Drug Quality and Security Acts of 2013
- Drug diverters will exploit this absence of regulation of medication in Alaska
- The longer we wait, the longer we will be facing increased risks to supply chain security and patient safety

# National Call to Action



2012: New England Compounding Center (NECC) acted as an unlicensed manufacturer, creating steroid medication that was mislabeled, unsanitary, or contaminated.

A multi-state outbreak of fungal meningitis occurred as a result. **64 people died of meningitis, and over 800 were sickened.**



**NABP®**

# What Do Counterfeit Drugs Look Like?

*They are hard to detect!*

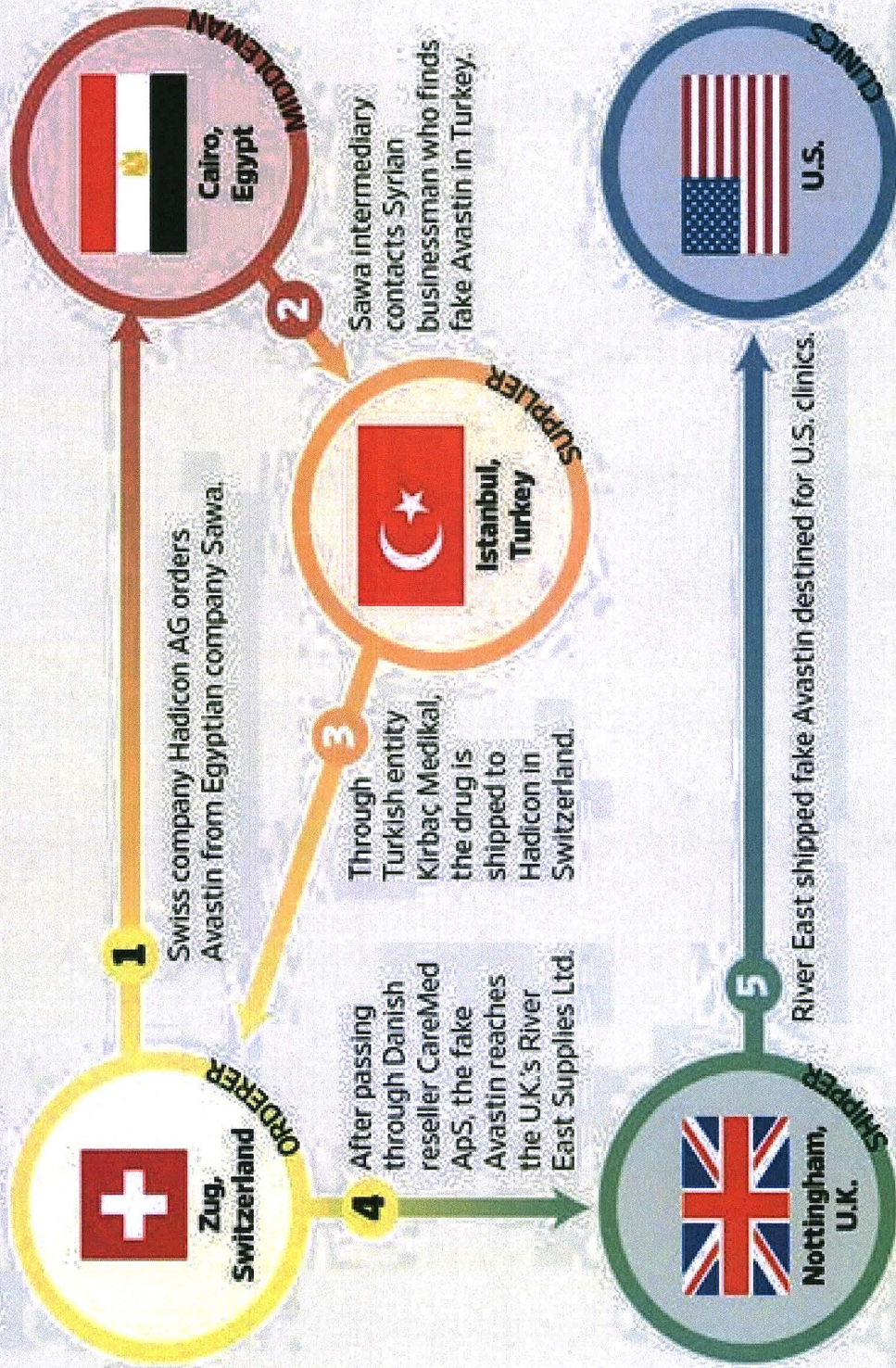


# Trail of Counterfeit Avastin®

(bevacizumab)

## A Murky Path

The convoluted route of the fake Avastin found in February raises questions about oversight of the fragmented global pharmaceutical trade.



Source: WSJ reporting

The Wall Street Journal

**Newsweek – 9/25/15: Chinese law enforcement official  
walks on a mountain of counterfeit drugs**



# ALASKA STATE LEGISLATURE

**Session:**  
State Capitol  
Juneau, AK 99801-1182  
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## REPRESENTATIVE DAN SADDLER

### MEMORANDUM

**DATE:** March 28, 2017  
**TO:** Representative Sam Kito, Chair  
House Labor & Commerce Committee  
**FROM:** Representative Dan Saddler  
**RE:** Hearing Request for HB 9

A handwritten signature in blue ink that reads "Dan Saddler".

I respectfully request a hearing for HB 9, Pharma Board & Employees; Drug Distribution/Manufacturing, in the House Labor & Commerce Committee at your earliest convenience.

Please contact Kim Skipper in my office for additional information at 465-3783.

We will not need any special equipment for the bill hearing.

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## REPRESENTATIVE DAN SADDLER

### Sectional Analysis House Bill 9

*"An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy."*

#### **Section 1: Amends AS 08.80.030(b)**

(14): Amends and allows licensing and inspection for out-of-state drug distributors and outsourcing facilities;  
(15): Establishes qualifications and duties of executive administrator. Executive administrator is delegated authority in order to conduct board business.

#### **Section 2: Amends AS 08.80.030 by adding a new subsection:**

**AS 08.80.030(c):** Specifications for facilities, equipment, personnel, and procedures for control of drugs in compliance with the federal Drug Supply Chain Security Act.

#### **Section 3: Amends AS 08.80.157 by adding a new subsection:**

(k): Applies to wholesale drug distributors and outsourcing facilities outside the state under AS 08.80.159, regarding licensing.

#### **Section 4: Amends AS 08.80 by adding a new section:**

**Sec. 08.80.159:** Requires that a wholesale drug distributor or outsourcing facility have a license in Alaska before shipping, mailing, or delivering prescription drugs to a licensee in the state or before advertising in the state, that an agent must be appointed in the state, and a designee of the board must authorize inspection of the facility.

An outsourcing facility, in addition, must comply with the federal Drug Quality and Security Act of 2013. The board may require an inspection of facilities located outside of the state, approve a designee to inspect. The board shall adopt regulations to implement this section.

#### **Section 5: Amends AS 08.80 by adding new section to Article 2:**

**Sec. 08.80.270:** Allows the Board to create an executive administrator position. Defines the role of the executive administrator.

#### **Section 6: Amends AS 08.80.480 by adding a new paragraph:**

**AS 08.80.480(37):** Defines "outsourcing facility"