

HOUSE FINANCE COMMITTEE

April 12, 2018

1:41 p.m.

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CALL TO ORDER

Co-Chair Foster called the House Finance Committee meeting to order at 1:41 p.m.

MEMBERS PRESENT

Representative Neal Foster, Co-Chair
Representative Paul Seaton, Co-Chair
Representative Les Gara, Vice-Chair
Representative Jason Grenn
Representative David Guttenberg
Representative Scott Kawasaki
Representative Dan Ortiz
Representative Lance Pruitt
Representative Steve Thompson
Representative Cathy Tilton
Representative Tammie Wilson

MEMBERS ABSENT

None

ALSO PRESENT

Jane Conway, Staff Senator Cathy Giessel, Sponsor; Tim Lamkin, Staff, Senator Gary Stevens; Allison Kulas, Executive Director, Advisory Board of Alcoholism and Drug Abuse; Kristin Cox, Grant Coordinator, Tobacco Prevention and Control, National Council on Alcoholism Drug Dependence, Juneau; Beverly Wooley, Self, Juneau; Jamie Morgan, American Heart Association, American Stroke Association, Juneau.

PRESENT VIA TELECONFERENCE

Kristin Ryan, Director, Division of Spill Prevention and Response, Department of Environmental Conservation; Sara Chambers, Deputy Director, Division of Corporations, Business and Professional Licensing, Department of Commerce, Community and Economic Development; Richard Holt,

Chair, Alaska State Board of Pharmacy, Anchorage; Leif Holm, Board of Pharmacy, North Pole; Barry Christensen, Alaska Pharmacist Association, Ketchikan; Hilary Martin, Legislative Legal Services, Juneau; Joe Darnell, Manager, Youth Tobacco Enforcement Program, Department of Health and Social Services, Anchorage; Alex McDonald, Self, Fairbanks; Jennifer Chikoyak, Self, Anchorage; Betty MacTavish, Self, Kodiak; Marge Stoneking, American Lung Association, Anchorage; Pamela Howard, Kenai Peninsula Borough School District, Soldotna; Katie Steffens, Self, Anchorage; Joshua Silas, Self, Soldotna.

SUMMARY

CSSB 15 (FIN)

E-CIGS/TOBACCO/NICOTINE & MINORS; SALES

SB 15 was HEARD and HELD in committee for further consideration.

CSSB 37 (FIN)

PHARMACY BD & STAFF; DRUG DISTRIB/MANUFACT

CSSB 37 (FIN) was REPORTED out of committee with a "do pass" recommendation and with a previously published fiscal impact note: FN2 (CED).

CSSB 155 (FIN)

REAL ESTATE APPRAISAL MNGMT. COMPANIES

CSSB 155 (FIN) was SCHEDULED but not HEARD.

SB 158

OIL/HAZARDOUS SUB.: CLEANUP/REIMBURSEMENT

CSSB 158 (FIN) was REPORTED out of committee with a "do pass" recommendation and with a previously published fiscal impact note: FN1 (DEC).

Co-Chair Foster reviewed the meeting agenda.

#sb158

SENATE BILL NO. 158

"An Act relating to oil and hazardous substances and waiver of cost recovery for containment and cleanup of certain releases; and providing for an effective date."

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Co-Chair Foster indicated that bill was previously heard on April 9, 2018.

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KRISTIN RYAN, DIRECTOR, DIVISION OF SPILL PREVENTION AND RESPONSE, DEPARTMENT OF ENVIRONMENTAL CONSERVATION (via teleconference), relayed that the department did not have anything to add on the record for the bill.

Representative Wilson was in support of the bill. She appreciated time to offer amendments but could not find a way to apply the bill retroactively without complications. She would not be offering any amendments to the bill.

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Representative Kawasaki supported moving the bill. He expressed concerns that Section 3 of the bill left the clean-up responsibility up to the state for individuals who could afford to pay the costs. He referred to Page 2, lines 11 through 12 of the bill:

- (3) the person took immediate measures upon discovery of the release to contain the release where possible;

Representative Kawasaki asked about the retroactivity clause. Ms. Ryan responded that he was referring to an existing statute. She explained that upon discovery of a release the property owner was expected to take immediate action to stop the release and minimize the long-term damage from the leak. The bill included a retroactive clause that stated if the homeowner took immediate remedial action the Department of Environmental Conservation (DEC) would not bill them retroactively to the date of the legislation. Representative Kawasaki referred to Section 3 regarding the department's ability to waive the response costs and the use of the word "may." He asked if the department intended to adopt the waiver regulations. Ms. Ryan responded in the affirmative.

Vice-Chair Gara reviewed the zero fiscal note FN1 (DEC), from DEC. He reported that the division expected a loss in cost recovery revenue of approximately \$60.0 annually.

Representative Kawasaki referred to page 2 of the fiscal note analysis that stated:

The Division of Spill Prevention and Response will absorb the cost of promulgating regulations.

Representative Kawasaki referred to previous committee discussion regarding whether agencies should be expected to cover the costs of promulgating regulations and noted DEC's absorption of the expense.

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Representative Wilson cited the analysis on page 2 of the fiscal note that stated regulations would be adopted by FY 2020. She asked whether the division would have to retroactively charge costs. Ms. Ryan relayed that the date was inserted arbitrarily, however the division intended to implement regulations immediately upon passage of the bill.

Co-Chair Seaton MOVED to report CSSB 158 (FIN) out of Committee with individual recommendations and the accompanying fiscal note.

CSSB 158 (FIN) was REPORTED out of committee with a "do pass" recommendation and with a previously published fiscal impact note: FN1 (DEC).

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AT EASE

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RECONVENED

#sb37

CS FOR SENATE BILL NO. 37(FIN)

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

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JANE CONWAY, STAFF SENATOR CATHY GIESSEL, SPONSOR, relayed that SB 37 brought Alaska into compliance with the Drug Quality Security Act (DQSA), which created a new license category for "Out-of-State Wholesale Drug Distributors" established in 2013 to provide oversight to large scale drug compounders. She expounded that currently, the Board of Pharmacy had no authority to regulate out-of-state wholesale drug distributors and the bill provided the authority. The legislation allowed Alaska to act to eliminate wholesalers looking for loopholes in the regulatory system and ensure that out-of-state applicants seeking licensure comply with the same regulations as Alaskan wholesalers. She reported that only one drug wholesaler operated in Alaska; McKesson Drugs Company.

Ms. Conway relayed an incident relating to wholesale drug distributors. She detailed that in 2012, contaminated medications were distributed which resulted in the deaths of people from meningitis. In 2012, a nationwide fungal meningitis outbreak resulted in 751 patients in 20 states being diagnosed and 64 patients in 9 states dying. The outbreak was linked to a compounding facility in Massachusetts. It was found that the employees were producing medications in an unsafe manner in unsanitary conditions and the company allowed the medications to be shipped out anyway. The tragedy highlighted the dangers of unregulated, large scale compounders. She communicated that SB 37 ensured that prescriptions were pure, sanitary and safe. Passage of the bill would create a more secure drug supply chain and ensure that Alaskans were receiving non-counterfeit, unadulterated medications. She delineated that when a pharmacy, doctor, or hospital in Alaska ordered supplies of prescription medications, they may go to the one wholesale distributor in Alaska (McKesson), but they may also order from one of hundreds of others in the Lower 48. The bill required any out-of-state drug distributor or outsourcing facility to follow specific guidelines including: obtaining a license in Alaska, authorizing inspection by a designee of the board, appointing an agent before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state. She pointed out that that last provision identified a responsible party (agent) to serve subpoenas for citing infractions or filing suit in case of problem. She continued that an outsourcing facility must comply with the Drug Quality and Security Act (DQSA) of 2013. She defined that an "outsourcing facility" was a facility in one

geographical location that was engaged in the compounding of sterile drugs for a facility at another geographical location. They were companies that made large batches of compounded drugs that had the highest risk of contamination. The Division of Corporate, Business, and Professional Licensing (DCBPL) estimated that registering and regulating the drug wholesalers equated to approximately 400 new licensees.

Ms. Conway offered that a provision of the bill created an executive administrator position for the Alaska Board of Pharmacy. The board had ever-increasing responsibilities under several healthcare reform bills and opioid response legislation that passed recently. The position would allow the board more capacity to respond more quickly to issues and concerns, manage the licensing of new wholesalers, implement statutes and regulations, and manage the multiple new responsibilities relating to the Prescription Drug Monitoring Program (PDMP). The board currently relied on the division for routine operations assistance. The position would be paid by the fees supplied by the wholesale drug distributor licensees along with current licensee fees and would not impact the general fund.

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Representative Wilson questioned whether Ms. Conway was aware that the Massachusetts facility was inspected but no one performed any follow up. Ms. Conway deferred to a pharmacist online to answer the question. Representative Wilson was aware of the circumstances and relayed that the Massachusetts manufacturer was regulated and fined. She was concerned about the federal mandate requiring the legislation and wondered what repercussions the state would incur if the legislation was not adopted. Ms. Conway was unsure what the federal government would do. She suspected that the message to consumers would be that Alaska did not care about the quality of its medicine. She thought that Alaskan consumers expected the drugs to be manufactured in a regulated facility that maintained quality control. Representative Wilson declared that she did care but explained that her concern focused on requiring the state to perform the inspections. She thought the mandate would result in additional liability for the state. She asked whether her assumption was correct. Ms. Conway responded that it was possible that the state would perform inspections. However, since most other states required

licensure the criteria adopted by other states would likely comply with Alaska's criteria. The inspection could just be a matter of reciprocity with other states licensure that would place an approved wholesaler in another state on an Alaskan list of approved facilities. Representative Wilson asked whether Ms. Conway was aware of any problematic incidents with wholesalers in Alaska. Ms. Conway was not aware of any incidents. She referred to a handout in member's packets titled "The Deadly Counterfeit Drug Trade Thrives in Alaska" (copy on file). She indicated that there were several places in the wholesale drug distribution process where counterfeiting actions could occur. Representative Wilson asked how the bill worked. She asked what provisions in the bill identified where the counterfeiting actions could occur and prevented the activity.

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Ms. Conway responded that bill licensed the entities of the wholesale drug distributors, the outsourcing facilities, and the third-party logistical providers; all would be licensed under the bill. She maintained that the licensing of all entities handling the drugs prevented counterfeit activities. Representative Wilson mentioned that compounding drugs were recently excluded in the state's active employee health plan. She asked whether the legislation would cover compound drugs with passage of the bill. Ms. Conway deferred to the appropriate available testifier to answer the question.

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Representative Kawasaki noted she had mentioned that currently there were 400 out-of-state drug wholesalers engaged in business activities in Alaska. He asked whether his statement was correct. Ms. Conway answered that the 400 number was an estimate. She relayed that Alaskan pharmacists avoided engaging with most of the out-of-state drug wholesalers because they did not know who were reputable. The division had informed her that many out-of-state companies were inquiring whether the state required licensing, some wanting to take advantage of the unlicensed environment. There was a limited number of suppliers that Alaska pharmacists would purchase drugs from and the bill would provide the larger estimated pool of wholesalers.

Representative Kawasaki related a scenario where an out-of-state drug wholesaler did not want to become licensed in Alaska. He asked whether the bill contained transitional language that allowed an Alaskan health care entity to continue to do business with them. Ms. Conway could not imagine a wholesaler not wanting to sell to vendors in Alaska and not obtaining a license. Representative Kawasaki restated his question. Ms. Conway responded that all but 4 other states required licensure so the wholesalers were registered in many other states and was common practice. Representative Kawasaki asked whether the out-of-state drug wholesaler regulations were standardized and similar in every state. Ms. Conway replied that the state of Alaska would apply the current set of regulations it applied to McKesson to the out-of-state drug wholesalers.

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Representative Kawasaki asked why the Board of Pharmacy could not just allow out-of-state drug wholesalers that met the criteria of another state to operate in Alaska and gain an Alaskan license by merely qualifying for licensure in another state. He thought it would save the time and effort required to develop regulation and inspect facilities. Ms. Conway indicated that every state had adopted their own criteria; some maybe more or less stringent. She restated the possibility for reciprocity with states that had the same criteria as Alaska's. She expounded that there was a national certifier called the "Verified Accredited Wholesale Distributor" (VAWD) but was only used by 3 states due to the registration fee costs. However, 23 states accepted the certification.

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Representative Pruitt guessed the transition time would be established through regulation. He cited the two effective dates in the bill, an immediate effective date allowing time to establish regulations and the hiring of an executive director. The second effective date was July 1, 2019 when the law would be implemented. He asked whether the July 1 date offered enough time "to allow the transition to take place."

SARA CHAMBERS, DEPUTY DIRECTOR, DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING, DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT (via

teleconference), thought the time frame was adequate for notifying involved entities and allowing them input in the board's public process for regulation adoption.

Representative Pruitt asked whether the date provided enough time for the public to provide input on the proposed regulations. Ms. Chambers answered in the affirmative.

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Co-Chair Foster OPENED public testimony.

[2:16:32 PM](#)

RICHARD HOLT, CHAIR, ALASKA STATE BOARD OF PHARMACY, ANCHORAGE (via teleconference), testified on behalf of the board in support of the bill. He explained that the legislation provided the board two imperative authorities: to license out-of-state wholesale drug distributors who were shipping pharmaceuticals into the state, and outsourcing facilities and whole sale logistics providers. The other authority allowed the board to hire an executive administrator using the licensing fees. The board determined that the licensure was necessary to fulfill its responsibility to ensure the practice of pharmacy was acting in the best interest of Alaskans. He emphasized that the out-of-state wholesalers shipped anything they wanted to the state because of the lack of oversight from the board. He relayed that the board's licensee examiner received many inquiries from out-of-state wholesalers asking whether the state required a license. He reiterated that the state was unaware of what the wholesalers were shipping into the state. He relayed that recently a registered out-of-state wholesaler turned its license back over to the state and choose to operate as an outsourcing facility to avoid oversight. He commented that the board's workload continued to increase, and the executive director position was necessary to assist the board in carrying out its statutory duties. He urged members to vote "yes" on the bill.

Representative Kawasaki mentioned that the state typically joined interstate compacts for protections and efficiencies. He asked whether "it would be easier to dovetail" off the other 47 states that already required licensure. DR. Holt responded that when the board drafted regulations they examined the provisions other states

adopted. The board would dovetail regulations that were appropriate but would tailor regulations to ensure Alaskan's safety and that they met the state's needs.

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Representative Wilson asked if Dr. Holt felt that the bill would help restore state employee benefits for compounded drugs. Mr. Holt replied that the state currently had regulations for compounding in 12 AAC.52.440 [Alaska Administrative Codes]. He suggested that the issue was an insurance related issue. Representative Wilson conveyed that the employees received notice that the coverage was eliminated due to safety concerns, yet state retirees' compounded drug prescriptions were still covered. She hoped the bill would grant the state more confidence in the safety of compounded drugs. She appreciated all the work accomplished by the board. Dr. Holt affirmed that the bill would provide that state more assurances regarding the safety of compounding drugs.

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LEIF HOLM, BOARD OF PHARMACY, NORTH POLE (via teleconference), wanted to echo Dr. Holt's sentiments on behalf of the board in support of the bill. He offered his testimony from the perspective of an independent pharmacists. He conveyed that ultimately, pharmacists wanted to have confidence that the medications they purchased were safe. He relayed that he restricted his purchasing with primarily one large wholesalers because he could not quickly asses where the small wholesalers' drugs were coming from. Pharmacists were always searching for the lowest prices but revealed that it was potentially dangerous with some of the "unscrupulous characters" that were making substandard drugs, and the situation was serious. He noted that the state currently regulated in-state wholesalers and he did not believe it would take much effort to implement the regulations. He mentioned the likelihood of the board reciprocally accepting other states standards and did not anticipate having to travel to another state to do inspections. He was available for questions.

Representative Kawasaki asked how Dr. Holm currently determined who was a legitimate wholesaler. Dr. Holm voiced that the situation was difficult. He elaborated that he

almost exclusively used the single wholesaler AmerisourceBergen Corporation but at times he had to use another wholesaler and was not able to reliably determine the reputation of another supplier. He wished he could rely on a state website that listed state licensed wholesalers. Representative Kawasaki asked how comfortable he was with using other state regulations and if he agreed that a wholesaler who was reputable for another state was probably a legitimate source for Alaska. Dr. Holm would agree as long as the standards mirrored Alaska's criteria. He deduced that he could go to another state's website to determine whether a wholesaler was licensed and then check the thoroughness of the regulations. He emphasized that he trusted the decisions the board made and would rather consult the state's licensure where he played a role. Representative Kawasaki surmised that the bill provided for an executive administrator at a range 23 attached to the new licensure and wanted to find a less expensive way to accomplish the licensing. He wondered whether there were model regulations from one state that the board approved of, whereby the board could adopt as their own rather than using an executive administrator.

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Dr. Holm asked for a restatement of the concern. Representative Kawasaki wanted to find out whether there was a cheaper way to accomplish the licensure work by board regulation. Dr. Holm answered that the position was covered by the wholesale licensing fees. He noted that the profession was constantly evolving, and it was difficult to keep up with the changes. He countered Representative Kawasaki's notion that the board could do the regulatory work on their own. He remarked on the busy lives of board pharmacists. He shared that he had four jobs with his various pharmacies besides carrying out his board duties, which was very time consuming. He noted that other boards like the medical board and nursing board had an executive administrator. He reported that in person meetings were much more effective than teleconferenced meetings and reported that the board was restricted to two in person meetings per year. He believed that the executive position would act as a liaison, board work would be expedited, and thought it would be easier for the board to stay on top of what other states were doing. He would find it arduous to find the time to analyze many other states regulations. He

acknowledged that he had volunteered for the board, but it did not mean the job did not require significant effort.

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Representative Wilson wondered whether a complaint against an out-of-state wholesaler would force a state investigator to travel to the state to perform an investigation, which was typically a significant cost to the board. She asked whether the investigatory costs would be paid through the wholesale licensure or the profession's general licensure fees. Dr. Holm responded that he did not foresee a scenario that required an Alaskan inspector to travel out of state. He thought that as violations were occurring they would be reported to all states boards. Representative Wilson wondered how the licensure funds would be disbursed in the eventuality of an investigation. Dr. Holm did not know. He supposed that inspection costs would come out of the pharmacy licensure "pot" that included fees from the technicians, pharmacists, and wholesalers.

Representative Wilson spoke about compounding prescriptions. She asked how much revenue Mr. Holm had lost because the state eliminated employee coverage for compounded medications. Dr. Holm answered he lost thousands of dollars in revenues and many patients were unable to obtain their medications due to high costs. Representative Wilson asked if the state would realize it made a mistake due to the safety guarantees embedded in the bill. Dr. Holm stated it depended on whether it was done for safety or financial reasons. He could not speak to exactly what would happen. Representative Wilson thanked Mr. Holm and acknowledged his work.

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Representative Pruitt asked whether the board was comfortable with the licensure fee structure that would facilitate supporting a new executive director position. He asked whether the licensing fees would increase. Dr. Holm responded that the board did not expect an increase in existing licensing fees. The fees collected from the wholesale licenses were expected to fully fund the position. He spoke with wholesalers that supported the licensure and expected to pay licensing fees. Representative Pruitt recounted that there was an expectation the board would not need to increase license

fees to pay for the executive director even though the director would carry out duties other than duties required for the wholesaler licensing. He continued that there was a problem with many boards where the current fee structure could not cover the cost of an investigation. He asked if the board was concerned that when out-of-state investigations did occur the wholesaler licensing fees would increase causing "push back" from the wholesalers.

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Dr. Holm understood Representative Pruitt's point and thought it was hypothetical regarding investigations. He understood the larger investigatory issues pertaining to boards. He noted that the pharmacy board was a well-funded board that had never operated with a negative balance. He opined that the board would deal with the issue if or when it happened. He thought safety was the number one concern with moving forward with the licensure. Representative Pruitt agreed that safety should be the primary concern. He wanted the industry to know that the expectation of the state was the licensure used a "fee for service model" and fees could increase to cover board costs. He asked whether the board was comfortable with the structure. He supported moving the bill forward if the board was in support. Dr. Holm could not speak for everyone and could not speak to how the board would decide on future fee increases but he would support "whatever decision needed to be made by the board to make this happen."

Representative Tilton referred to the fiscal note from DCCED that stated there was no fiscal impact on the public or private sectors in the state as the licensing would impact entities outside of the state [second paragraph on page 2 of the fiscal note]. She was concerned that a potential impact could happen in the future. She wondered whether any latent impact could increase costs to the consumer. Mr. Holm answered that he did not anticipate any fiscal impact on the wholesaler; the fees were minimal for a wholesaler. He deduced that the bill's impact could potentially lower costs by offering more possibilities for the pharmacists to source lower costs drugs.

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BARRY CHRISTENSEN, ALASKA PHARMACIST ASSOCIATION, KETCHIKAN (via teleconference), spoke in support of the legislation

on behalf of the association. He reported that the association attempted to address the issue through legislation for over four years. The membership felt strongly that the pharmacies needed the safety assurance and a trusted source to identify and verify wholesalers. He concurred with the previous statements regarding the inability to validate wholesalers. He added that the national association for the drug wholesale industry reported its support for the bill as currently written. He reiterated that the licensure was the standard practice. He appreciated the work of the board and endorsed the need for the administrative position.

Co-Chair Foster CLOSED public testimony.

Representative Wilson reiterated her question regarding the distribution of investigative costs under the new license. Ms. Conway understood that any investigatory cost was borne by the entity being investigated. She voiced that the sponsors envisioned that investigations would be carried out by contracting out an investigatory work to a qualified provider in the same state the investigation was necessary. She stated if there was a problem in California, they would contract with the proper entity in California. She did not envision "sending people out all across the nation to inspect." Representative Wilson remarked that investigations had been "lopsided" with most of the state's boards increasing licensing fees. She reiterated her question regarding how a costly investigation would affect the boards licensing fees. Ms. Conway deferred to Ms. Chambers for the answer.

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Ms. Chambers answered that the division, which included all 43 of the state's license programs, did not have the statutory authority to recoup investigative costs directly from the entity being investigated. She relayed that penalties and fines imposed were deposited into the general fund. The statutes required that investigatory costs were born by all programs under their licensing board. The division tried to determine whether there were disproportionate investigatory costs per license type. She hypothesized that if investigative costs for out-of-state wholesalers were significantly higher than costs for Alaska pharmacies the division would work with the board to raise the wholesaler licensing fees. She relayed that HB 90 OCC.

(Licensing Fees; Investigation Costs) was introduced to remedy the situation or there might be legislation in the future to address the problem. However, currently the division could not charge any investigative fees or recoup investigative costs; the money was recovered from the licensing program. Representative Wilson understood the issue. However, she wondered how wholesaler license investigatory costs would be split under the pharmacist licensure. Ms. Chambers responded that AS 08.01.065 required that fees were grouped together but allowed the discretion for the board to increase or lower fees according to license type. However, there was not explicit language that separated license type; the statute covered all licenses regulated under a particular board.

Vice-Chair Gara reviewed the one previously published fiscal impact note from the DCCED, FN1 (CED). The bill reflected the cost recovered from board fees in the amount of \$173.3 thousand in FY 2019 and decreased to \$157.5 thousand in the out years.

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Representative Kawasaki MOVED to REPORT CSSB 37(FIN) out of committee with individual recommendations and the accompanying fiscal note.

There being NO OBJECTION, it was so ordered.

CSSB 37(FIN) was REPORTED out of committee with a "do pass" recommendation and with a previously published fiscal impact note: FN2 (CED).

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AT EASE

[3:00:20 PM](#)

RECONVENED

#sb15

CS FOR SENATE BILL NO. 15(FIN)

"An Act relating to possession of an electronic smoking product or a product containing nicotine by a minor and to selling or giving a product containing nicotine or an electronic smoking product to a minor; relating to business license endorsements to sell

cigarettes, cigars, tobacco, products containing tobacco, electronic smoking products, or products containing nicotine; and relating to citations for certain offenses concerning tobacco, products containing nicotine, or electronic smoking products."

3:00:20 PM

TIM LAMKIN, STAFF, SENATOR GARY STEVENS, read a prepared statement:

For anyone not acquainted with E-cigarettes, I have prepared a brief slideshow, to play in the background as I discuss the purpose of this bill. These images will introduce, or remind, you of their common components, sample styles and brands, what are now a multitude of exotic flavorings, and marketing strategies. This bill is about protecting our children from becoming addicted to nicotine. It is about clearly restricting sales to and possession of these products to youth under the age of 19.

The use of electronic cigarettes is an exploding new trend in smoking. It is commonly referred to as "vaping." Public health advocacy, with the help of proven scientific evidence, is winning the war against tobacco. Use of traditional tobacco cigarette and related products is clearly on the decline. Tobacco is a dying industry. The tobacco manufacturers have acknowledged this trend and are responding with a barrage of new fashionable smoking options, in the form of E-Cigarettes and related modular devices designed to appeal to a wide range of consumers.

Currently, according to the US Center for Disease Control, there are in the neighborhood of 4 million middle and high school students using these products nationwide. In Alaska, the numbers show about 15-25 percent of our students have at least been exposed to, if they are not regularly using E-cigarette products. See, there is a loophole.

While it is currently technically illegal to buy or sell nicotine products to minors, it is not illegal to possess E-Cig products. Nor are all of the products supposedly containing nicotine, supposedly. Furthermore, there is currently no provision for law

enforcement or investigators to enforce or issue violations for possession. Nor cite vendors for selling E-products to minors, the penalties are pretty weak right now. And the industry and youth know it.

An informal survey our office commissioned last March, asking Alaska school teachers and administrators about E-Cigarette use in our schools, showed that 78 percent of educators are concerned with a current or foreseeable problem with youth access to and use of E-cigarette products. Meanwhile, the feds, public health advocates, state and local governments, schools and communities are all struggling to catch up and respond to this fast-moving industry.

There are a lot of questions, perhaps the biggest one being, "Are these products safe?" and "should we be tacitly allowing our children to take up this activity?" The latest research available, not funded by big tobacco, shows the health benefits being dubious at best. I would concede that the chemicals used in E-cig products may be safer than smoking tobacco, but we should not be too quick to accept these chemicals as themselves being safe.

The FDA has approved of many of the known chemicals used in E-juice to be safe enough for ingestion, but not as an inhalant, long-term effects are just beginning to be studied. The most common and intuitive approach to addressing a policy on this new era of smoking products is to treat them in the exact same manner as we have structured tobacco policies. And that is what this bill does.

We start with the commercial activity and the vendors selling the products, to include a requirement for a special endorsement on their business license, just like tobacco retailers. This is the only way we can effectively identify who is out there selling these products, and in turn provided state agency authority to monitor sales activity and enforce violations, with stiffer penalties.

Currently, there are several hidden shops out there, selling these products, but by the nature of their business name, would give no indication they are selling E-products.

Examples: Tesoro in the valley, Zooks downtown, Lola's Filipino restaurant and mini grocery store, and the Gas N Go Coffee hut, by Western Auto. Currently the only way to find out that these vendors are selling E-products is by word of mouth, or by driving around and visiting random stores.

In wrap up, and before we get into the nuts and bolts of the bill, I would like to take a moment to address some of the rhetoric you will likely be hearing in opposition to this bill. You will likely hear that we do not need this bill, that the feds already have laws in place restricting youth access and enforce those laws. The fact is the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 requires states to enact and enforce laws restricting youth access to tobacco products. The FDA does have a limited enforcement resources, that are usually contracted out for occasional compliance checks, but penalties consist of little more than a slap on the wrist for vendors. I can go into some detail about federal enforcement if you wish. But, we do need this bill for meaningful monitoring and enforcement purposes.

You may hear that the paperwork for getting the tobacco endorsement is onerous and hurts businesses. Standard business license applications are 4-pages and takes about 10 minutes to complete. You check a box for the endorsement and fill out a 5th page. The cost of a license is \$50 per year and \$100 for and endorsement per location, which were not onerous or damaging to business. This is a very lucrative business.

You may hear that these products are a miracle for smokers trying to quit, which may be true in some cases, most typically for older adults who have smoked for many years. However, that is entirely irrelevant to this bill, as adult smoking habits are not the target here. We are trying to prevent youngsters from taking up the habit in the first place.

You may hear that these are not tobacco products and should be not be associated with tobacco, but they are related. In August 2017, the FDA ruled that for practical and regulatory purposes, these products

should be treated as tobacco products. After all, it mimics traditional smoking: they often look like a cigarette, glow like one, and produce smoke. It's just another kind of smoking. However, they are available in all the flavors and aromas of chocolate chip cookies, apple pie, or cotton candy. You may hear that these products are harmless because they don't always contain Nicotine. That is unproven.

There are currently no requirements to verify or regulate labelling and marketing of this E-juice. A 2016 study in North Dakota found that 51 percent of the samples tested contained higher levels of nicotine than was reported on the labels, sometimes up to 173 percent more than was labelled. Even this little bottle here, which I bought at the Gas N Go for \$1 (no tax), says "Zero Nicotine" but on the side in fine print it reads "may contain trace levels" of nicotine. In that same North Dakota study, 43 percent of E-liquid containers labelled as having no nicotine actually had significant levels of nicotine present. We should be skeptical of nicotine labelling of these products.

You may hear that everyone wants to keep these products out of youths' hands, but it is in their hands, and readily so.

Most vendors are legitimately making that effort. But some are not. If this industry is truly supportive of restricting youth access to E-Cigarette products and nicotine, there should be no opposition to this bill.

In closing, this bill is about closing a loophole. It is about giving our state agencies the tools to monitor and enforce these restrictions. The urgency is growing. Senate Bill 15 would have us approach e-cigarettes with severe caution on behalf of young Alaskans.

Thank you for allowing us to place the issue on the table.

[The presenter played a silent video depicting vape products while making his presentation].

[3:13:19 PM](#)

Representative Kawasaki wondered about the comments that teens introduced to vaping were more likely to develop a habit. He was unsure to what extent that kids would develop an addiction to vaping. He wondered whether scientific evidence existed that proved the statement. Mr. Lamkin indicated there was a "growing body of evidence that vaping was a "gateway activity." He added that nicotine was proven to be addictive and frequently engaging in an activity that delivered nicotine developed into a habit.

Vice-Chair Gara supported the bill. He had a question for Legislative Legal Services. Vice-Chair Gara referred to page 2 of the bill regarding punishment for possession of the product. He asked about the fine and wanted to determine the level of criminality of the fine. He indicated that fines were considered "quasi-criminal." He wondered what the levels of fines and violations were. He wanted to ensure the fine for a 19 year -old in possession of e-cigarettes was a very low-level offense.

HILARY MARTIN, LEGISLATIVE LEGAL SERVICES, JUNEAU (via teleconference), reported that a violation was defined as a non-criminal offense, therefore a fine was only a penalty. She detailed that under AS 12.53.050 a default fine for a violation was \$500. The court ruled that the fine could not be so high that it signified criminality.

[3:17:29 PM](#)

Vice-Chair Gara asked if either a violation or a fine would end up on someone's court record. Ms. Hillary believed violations would show up on someone's record and were posted on Court View. She restated that a fine was only penalty. Vice-Chair Gara asked whether there was anything lower than a violation that would not appear on records. Ms. Martin responded that a violation was the lowest penalty. Vice-Chair Gara asked if the type of violation would be listed in the records. Ms. Martin thought that the violation referenced the statute that was violated.

Mr. Lamkin noted that the provisions in the bill were the existing statute for cigarettes and tobacco. The bill inserted e-cigarettes into existing statute. Vice-Chair Gara understood the bill.

Representative Wilson was having difficulty with non-nicotine products and the potential for a violation. She

asked whether there were products that did not contain nicotine that were included in the bill. Mr. Lamkin answered that it was uncertain whether the products were truly nicotine free. Products that were labeled nicotine free were found to contain nicotine when tested. In addition, current research was discovering the "dubious" effects of other chemicals contained in the e-cigarette "juice." He noted that all juice contained Propylene Glycol, which was an anti-freeze chemical. He believed that our bodies were designed to "just breathe air" and did not believe the products were safe regardless of nicotine contents.

[3:22:49 PM](#)

Representative Wilson asked why the issue was not left up to parental choice. Mr. Lamkin maintained that the question applied to any number of issues related to parental involvement. He informed committee members that a provision in the bill allowed parents to "make the accommodation" if the Food and Drug Administration (FDA) approved the products for smoking cessation, which it had not. Representative Wilson asked if the product was approved as a cessation product by the FDA, it would not fall under the bill and under such circumstances could a parent provide the product to their children. Mr. Lamkin answered in the affirmative and added that the products had to be used only as a cessation product for the child.

[3:24:26 PM](#)

Representative Grenn asked how many states had "closed the loophole." Mr. Lamkin responded that approximately 20 states had adopted the regulations. Representative Grenn asked who regulated e-cigarette liquid. Mr. Lamkin answered that the FDA was just beginning to regulate the industry. Representative Grenn asked whether the hope was that a detailed ingredient list would be published. Mr. Lamkin answered in the affirmative. He heard antidotes that generic 55-gallon drums of juice could be purchased from China and an individual could concoct their own potion at home. Representative Grenn referred to Page 2, Section 2. He wanted to better understand the section that allowed a child under 19 to obtain an e-cigarette as a cessation device from a pharmacist without a prescription. Mr. Lamkin reiterated the answer he gave to Representative Wilson. He restated that the product had to be approved by the FDA as

a cessation device, was marketed as a cessation device, and was either prescribed by a health care professional, or by the Department of Health and Social Services (DHSS), or provided by the parents or a pharmacist. Representative Grenn asked whether e-cigarettes were an FDA approved cessation device. Mr. Lamkin asserted that in no way the products were approved as a cessation device by the FDA.

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Representative Tilton asked whether someone under the age of 19 who was in possession of e-cigarettes was a violation and the highest charge one would receive. Mr. Lamkin stressed that the real target of the bill were the vendors and the bill was not about giving teenagers tickets. Representative Tilton relayed a story from personal experience. She asked if he had seen the devices that dispensed vitamins in a type of vaping device. Mr. Lamkin answered in the negative. He suggested that manufacturers would find creative ways to market the devices. Representative Tilton confirmed that the devices were available with vitamins.

[3:32:08 PM](#)

Representative Kawasaki ascertained that currently a business that did not sell tobacco products could sell e-cigarettes. Mr. Lamkin responded that the bill provided endorsements that enabled vendors to sell only e-cigarettes or only tobacco products or both. Representative Kawasaki surmised that a business could obtain an e-cigarette endorsement and not sell any products containing nicotine and would be licensed separately than a vaping shop that would sell both. Mr. Lamkin replied that "nicotine products" was the "distinction" in the bill. He delineated that all the vaping "hardware" was considered a nicotine product. Representative Kawasaki asked whether businesses that were currently selling the vaping equipment and juices that did not contain nicotine and no other tobacco products would need an endorsement to continue selling vaping products under the bill. Mr. Lamkin clarified that the bill offered 2 separate endorsements; one was for tobacco products and the other was for e-cigarettes and its components; pens and juice regardless of whether the juice contained nicotine.

[3:35:20 PM](#)

Representative Kawasaki asked whether underage youth could legally purchase a bong in a vape shop. Mr. Lamkin believed bongs were associated with the consumption of marijuana and was not the subject of SB 15. Representative Kawasaki asked whether a youth could purchase a tobacco pipe. Mr. Lamkin replied that pipes were treated like tobacco products and purchases were restricted to individuals under 19 years of age and reiterated that it was similar to purchasing vaping hardware which would be restricted to youth under 19 years old.

Representative Guttenberg reiterated similar questions as the previous inquiry regarding the vaping hardware. Mr. Lamkin restated that the all the products associated with vaping was covered under the bill and restricted from purchase for youth under the age of 19. Representative Guttenberg assumed the devices were preloaded. Mr. Lamkin responded that not all devices were pre-loaded; the components were modular. Therefore, the hardware was regulated.

[3:38:47 PM](#)

Co-Chair Seaton OPENED public testimony.

[3:38:59 PM](#)

ALLISON KULAS, EXECUTIVE DIRECTOR, ADVISORY BOARD OF ALCOHOLISM AND DRUG ABUSE, related that in her previous job she worked as a Tobacco Regulatory Science Fellow with the National Academy of Medicine placed in the Food and Drug Administration Center for Tobacco Products. She was not speaking on behalf of the FDA but used the knowledge gained to "protect Alaska's children." She believed that SB 15 was "an important step to prevent youth from tobacco products." Research had proven that nicotine was highly addictive, harmful to teenager's brain development and exposure to nicotine left them more susceptible to nicotine and other substance additions. Nicotine also reduced impulse control and was attributed to mood disorders and deficits in attention and cognition. Nicotine in any form was unsafe for use, yet e-cigarettes were the most commonly used tobacco products. A newly released report discovered that e-cigarettes increased the risk of using combustible cigarettes. She commented that SB 15 was consistent with the current laws that restricted tobacco products. Preventing illegal sales to minors protected the nations

youth from the harmful effects of nicotine. Alaska had a proven track record of effective enforcement of businesses with a tobacco endorsement. The bill clarified the business rules and restrictions on the sale of tobacco products by including e-cigarettes in the existing statutes and further protected Alaska's youth. She urged member to vote in favor of the bill.

Representative Grenn asked whether evidence existed that tobacco companies were manufacturing e-cigarette products. Ms. Kulas responded that the FDA did not know all the manufacturers of the products. She indicated that some existing tobacco companies were marketing the products along with small businesses. Representative Grenn asked if the marketing of e-cigarette were targeted at youth. Ms. Kulas answered in the affirmative and expounded that the e-cigarette advertising was like cigarette advertising. The FDA had spent ample funding to develop marketing campaigns for youth to counter the advertising exposure. She reported that in October 2017 the FDA developed a digital campaign aimed at e-cigarette youth prevention.

[3:43:51 PM](#)

Representative Guttenberg wondered whether there were any other products that people ingested without any safety standards because it appeared that e-cigarettes were totally unregulated. He wondered whether any existing standards applied to e-cigarettes and confirmed what was in the products. Ms. Kulas answered that the FDA did not know what ingredients were in the products. The FDA was currently accepting applications that included the liquid product ingredient list and FDA's toxicologists were attempting to identify what was in the product and if the ingredients were safe. She noted that some ingredients when ingested were designated by the FDA as Generally Recognized As Safe (GRAS) but it was unknown if they were harmful when inhaled.

[3:45:32 PM](#)

KRISTIN COX, GRANT COORDINATOR, TOBACCO PREVENTION AND CONTROL, NATIONAL COUNCIL ON ALCOHOLISM DRUG DEPENDENCE, JUNEAU, supported SB 15. She shared some statistical information. She indicated that flavors attracted children and 81 percent of youth tobacco users chose a flavored product as their first product and 25 percent believed that

flavored tobacco products were safer. However, they were unsafe because they initiated youth into cigarette smoking and nicotine addiction. Three recently published studies in medical journals determined that youth that used e-cigarettes were 4 to 7 times more likely to become tobacco smokers. She added that the effect was "unilateral" meaning cigarette smoking was not associated with increased vaping. She concluded that restricting youth access to e-cigarettes would reduce youth smoking and adult addiction rates.

[3:47:23 PM](#)

BEVERLY WOOLEY, SELF, JUNEAU, was retired but previously served as the Director of the Division of Public Health with the state and the municipality. She related that in the 1990's the state knew that large numbers of retailers were selling tobacco products to children due to lack of accountability. The state instituted enforcement and the number of incidents decreased to 5 percent. She emphasized that SB 15 would establish the same laws that regulated the tobacco industry for e-cigarettes and close the loophole and provide enforcement. She underscored that edibles that were considered healthy were much different when turned into an aerosol or combusted and inhaled into the lungs. She noted a state-wide study where researchers went to some of the "vape" shops and found they were more likely (36 percent of shops) to sell e-cigarettes to children while established retailers only sold the product 5 percent of the time to children. She believed in protecting children. She urged members to move the bill out of committee.

[3:50:06 PM](#)

JAMIE MORGAN, AMERICAN HEART ASSOCIATION, AMERICAN STROKE ASSOCIATION, JUNEAU, spoke in support of SB 15 for the associations and urged members to move the bill from committee. She reiterated that e-cigarettes were harmful and unregulated. She reported that in the 2016 surgeon general report on e-cigarette use showed that e-cigarette use in children increased the likelihood of cigarette use. She related that the associations supported including e-cigarettes in laws that restricted access to children.

[3:51:39 PM](#)

JOE DARNELL, MANAGER, YOUTH TOBACCO ENFORCEMENT PROGRAM, DEPARTMENT OF HEALTH AND SOCIAL SERVICES, ANCHORAGE (via

teleconference), related that he was the Chief Investigator for Tobacco Enforcement for the state. He spoke in support of the bill. He cited the states statewide vape shop study and reported that in 2016 he encountered a 26 percent sell rate for vaping products versus 5.4 percent for tobacco products; in Anchorage the sell rate was 50 percent. He added that in 2017 the statewide sell rate jumped to 35 percent. He supported the bill and asked for member's support.

[3:53:40 PM](#)

ALEX MCDONALD, SELF, FAIRBANKS (via teleconference), testified against the bill. He shared that he owned the vape shop Ice Fog Vapor. He declared that he heard much misinformation in the prior testimony. He stated that federal law required him to age verify customers for any vape equipment. He countered that since the previous fall FDA instituted registering and labeling requirements. He emphasized that federal regulations were the norm that considered vape products tobacco products. He noted that compliance checks were carried out for the federal government through a contracted vendor. He opined that "new rules" were not necessary but better enforcement of the existing rules were. He related that the American Cancer Society recommended that long time smokers switch to a less harmful product such as vapor products. He mentioned that the FDA was engaged in studies related to the safety of e-cigarettes. He concluded that everything in the bill was covered under federal tobacco law.

Representative Grenn asked whether he knew all the ingredients in the juice. Mr. McDonald answered in the affirmative and maintained that propylene glycol acted as a carrier and was found in asthma inhalers and oxygen tanks and had been used for a long time. He added that vegetable glycerin and food flavorings had also "been around for a long time." Some vape juice did not contain nicotine. He claimed that propylene glycol was added to hospital H Vac systems to keep airborne infections down. Representative Grenn asked why the label read that the product may contain nicotine. Mr. McDonald responded that the labeling was an FDA requirement. Representative Grenn asked why the nicotine labeling would be necessary. Mr. McDonald answered that there was a very low chance of cross contamination.

[3:59:53 PM](#)

Representative Wilson mentioned the age requirement of 19 for purchasing vape products and asked whether she was correct. Mr. McDonald answered in the affirmative.

Representative Kawasaki asked if the bill was more restrictive than federal law. Mr. McDonald thought the bill seemed redundant to federal law, although federal law did not require licensing. He thought SB 15 provided a duplicate service since the federal law required full enforcement authority and compliance checks. He surmised that the legislation was more of a licensing law than one designed to protect children. He purported that the prevalent source for youth tobacco products was "social"; supplied by older friends or family. Representative Kawasaki suggested that the state survey showed that many vape shops were not in compliance with federal laws. He asked for comment. Mr. McDonald felt that it did not make sense to make new laws when the current laws were not enforced.

Vice-Chair Gara had been told numerous times that until federal laws were implemented the heating element in e-cigarettes could contain asbestos and other toxic materials. Mr. McDonald replied in the negative. He explained that the heating elements used Kanthal A-1, a resistance heating wire found in toaster ovens and hair dryers and the wicking material was organic cotton. He did not know where it was even possible to purchase asbestos.

[4:03:38 PM](#)

JENNIFER CHIKOYAK, SELF, ANCHORAGE (via teleconference), spoke in support of the bill. She spoke from the perspective of a parent and shared that she tried to "guide her son into making good choices" and she valued the assistance that tobacco and alcohol laws supplied. She "appreciated the state stepping in and regulating" e-cigarettes like other tobacco products. She favored the state's penalties for tobacco sales to minors and wanted to close the loophole for e-cigarettes.

[4:04:59 PM](#)

BETTY MACTAVISH, SELF, KODIAK (via teleconference), spoke in favor of the bill. She shared that she was a retired school teacher and was currently a substitute teacher. She stated that e-cigarette use among youth was increasing and

characterized e-cigarettes as an "addictive tool" for the tobacco industry rather than a "quit" tool. She observed that youth who would not use conventional tobacco products were attracted to vaping, and she characterized vaping as "the new cool thing to do." She noted that toxic aerosols and chemicals were "hidden" in flavored vape juiced. She supported protecting the state's youth through passage of the bill.

[4:07:12 PM](#)

MARGE STONEKING, AMERICAN LUNG ASSOCIATION, ANCHORAGE (via teleconference), spoke in support of the bill. She relayed that almost all e-cigarette contained nicotine and chemicals and toxins that were unsafe to inhale. The FDA delayed review of ingredients and any potential harmful effects of e-cigarettes until 2022 leaving unregulated products. She thought members were aware of the harmful effects of nicotine on youth's brain development and functioning and the increase in teen use. She reported that the FDA had performed some product testing but there were thousands of ingredients that varied from product to product. The testing had discovered that "ultra-fine" particles were inhaled deep into the lungs like diacetyl, which was a flavorant linked to lung disease, volatile organic compounds, and heavy metals. She argued that whether the product contained nicotine or not there were inherent risks in the use of the products. The bill would hold vendors accountable. She felt that the bill would also assist in changing the public perception that the products were safe.

[4:10:41 PM](#)

PAMELA HOWARD, KENAI PENINSULA BOROUGH SCHOOL DISTRICT, SOLDOTNA (via teleconference), spoke in support of SB 15. She had been a school nurse for over 30 years and taught students about the harmful effects of vaping. She reported that in her school district principles saw a significant increase in students use of vaping products. The bill addressed students carrying devices. She believed that the students carrying the devices showed intent to use the device and possession should be prohibited. She had not seen vitamin e-cigarette products. She spoke of the importance of educating students on the health risks of using the products.

[4:13:37 PM](#)

KATIE STEFFENS, SELF, ANCHORAGE (via teleconference), spoke in support of the bill. She related that e-cigarette use contributed to harmful brain development and addiction in youth. She spoke about the other aerosol ingredients that were smaller in particulate composition and the associated risks of inhaling those particulates. She reported that the Philip Morris tobacco company was promoting a "smoke free future" by supporting the use of vape products. She felt that vaping would become a future trend making the bill timelier. She urged for passage of the bill.

[4:15:32 PM](#)

JOSHUA SILAS, SELF, SOLDOTNA (via teleconference), spoke in opposition SB 15. He worked at Mapes Vapes vape shop. He agreed that the bill was redundant and was a waste of time and state government resources. He purported that the FDA had addressed regulating vaping products and carried out enforcement. Alaskan vape shops were compliant with the federal regulations. His shop was committed to offering a healthy alternative to smoking and helped 554 adults quit smoking in the last 26 months. He wondered what the cost of enforcement was to the state. He believed that "there was no reason" to move forward with the bill.

[4:18:16 PM](#)

Co-Chair Foster CLOSED public testimony on SB 15.

[4:18:49 PM](#)

Co-Chair Foster asked whether Mr. Darnell had heard the testimony of Mr. McDonald regarding the redundancy of the Alaska law and if he had any comments.

Mr. Darnell reported that he heard criticism that the state did the requirement check study but did not carry out enforcement. He noted that the state did not currently have enforcement authority. He reported that the study was performed as a baseline to determine what was necessary when enforcement became law. He declared that he did not know of any FDA compliance checks that had been conducted in vape shops. He had only heard of them being carried out in convenience stores. He informed committee members that the fiscal note would be zero and the compliance checks

could be done without any additional costs to the state. He had had numerous complaints from parents about where their children had been able to obtain vape products. He knew of vape shops that operated legally but others knowingly broke the law. He relayed anecdotal evidence that when he went into a tobacco only shop that was not smoke free and was subjected to tobacco smoke he had some nasal discomfort and his clothes smelled but when he went into a vape shop for 15 or 20 minutes and people were vaping it left him with a burning sensation in his chest.

Co-Chair Foster indicated that amendments were due by tomorrow at 5:00 pm.

SB 15 was HEARD and HELD in committee for further consideration.

Co-Chair Foster indicated that SB 155 would be moved to tomorrow morning's meeting at 9:00 am.

#

ADJOURNMENT

[4:23:58 PM](#)

The meeting was adjourned at 4:24 p.m.