

ALASKA STATE LEGISLATURE
HOUSE HEALTH AND SOCIAL SERVICES STANDING COMMITTEE

April 19, 2018

3:04 p.m.

MEMBERS PRESENT

Representative Ivy Spohnholz, Chair
Representative Tiffany Zulkosky, Vice Chair
Representative Sam Kito
Representative Geran Tarr
Representative David Eastman
Representative Jennifer Johnston
Representative Colleen Sullivan-Leonard

MEMBERS ABSENT

Representative Matt Claman (alternate)
Representative Dan Saddler (alternate)

COMMITTEE CALENDAR

SENATE BILL NO. 198

"An Act relating to a study of the effectiveness and cost of providing long-acting reversible contraception to women with substance abuse disorders."

- HEARD & HELD

PREVIOUS COMMITTEE ACTION

BILL: SB 198

SHORT TITLE: UAA LONG-ACTING CONTRACEPTION STUDY

SPONSOR(S): SENATOR(S) KELLY

02/19/18	(S)	READ THE FIRST TIME - REFERRALS
02/19/18	(S)	FIN
03/26/18	(S)	FIN AT 9:00 AM SENATE FINANCE 532
03/26/18	(S)	Heard & Held
03/26/18	(S)	MINUTE(FIN)
04/03/18	(S)	FIN AT 1:30 PM SENATE FINANCE 532
04/03/18	(S)	Moved SB 198 Out of Committee
04/03/18	(S)	MINUTE(FIN)
04/04/18	(S)	FIN RPT 4DP 1NR
04/04/18	(S)	DP: MACKINNON, BISHOP, VON IMHOF, STEVENS
04/04/18	(S)	NR: HOFFMAN

04/09/18 (S) TRANSMITTED TO (H)
04/09/18 (S) VERSION: SB 198
04/11/18 (H) READ THE FIRST TIME - REFERRALS
04/11/18 (H) HSS, FIN
04/17/18 (H) HSS AT 3:00 PM CAPITOL 106
04/17/18 (H) Heard & Held
04/17/18 (H) MINUTE (HSS)
04/19/18 (H) HSS AT 3:00 PM CAPITOL 106

WITNESS REGISTER

HEATHER CARPENTER, Staff
Senator Pete Kelly
Alaska State Legislature
Juneau, Alaska

POSITION STATEMENT: Presented SB 198 on behalf of the bill sponsor, Senator Kelly.

WILLIAM TRAWICK, Advanced Nurse Practitioner
Anchorage, Alaska

POSITION STATEMENT: Testified regarding the NEST/NAS program.

MARILYN PIERCE-BULGER, Owner
FASDx Services, LLC
Anchorage, Alaska

POSITION STATEMENT: Testified during discussion of SB 198.

ROBERT BOECKMANN, PhD
Chair, Institutional Review Board (IRB)
University of Alaska Anchorage
Anchorage, Alaska

POSITION STATEMENT: Testified during discussion on SB 198.

JEANNE GERHARDT-CYRUS
Governor's Council on Disabilities and Special Education
Kiana, Alaska

POSITION STATEMENT: Testified during discussion of SB 198.

ELLEN HODGES, MD
Bethel, Alaska

POSITION STATEMENT: Testified during discussion on SB 198.

GENEVIEVE MINA
Anchorage, Alaska

POSITION STATEMENT: Testified during discussion of SB 198.

BESSE ODOM

Anchorage, Alaska

POSITION STATEMENT: Testified during discussion of SB 198.

ACTION NARRATIVE

[3:04:43 PM](#)

CHAIR IVY SPOHNHOLZ called the House Health and Social Services Standing Committee meeting to order at 3:04 p.m. Representatives Spohnholz, Tarr, Sullivan-Leonard, Johnston, Eastman, Zulkosky, and Kito were present at the call to order.

SB 198-UAA LONG-ACTING CONTRACEPTION STUDY

[3:05:17 PM](#)

CHAIR SPOHNHOLZ announced that the only order of business would be SENATE BILL NO. 198, "An Act relating to a study of the effectiveness and cost of providing long-acting reversible contraception to women with substance abuse disorders."

[3:05:42 PM](#)

HEATHER CARPENTER, Staff, Senator Pete Kelly, Alaska State Legislature, shared some background on how Senator Kelly "got to this point of introducing" the proposed bill. She stated that the proposed bill was part of an ongoing effort to eradicate fetal alcohol spectrum disorder (FASD). She paraphrased from a white paper submitted by the Governor's Council on Disabilities and Special Education [Included in members' packets], which read as follows:

Fetal alcohol spectrum disorders (FASDs) are a range of developmental disabilities caused by consuming alcohol during pregnancy. The most well-known type of FASD is fetal alcohol syndrome (FAS). Alaska has the highest reported prevalence of FAS in the United States. A newly published study found that FASDs may be as common as autism, affecting up to 1 in 20 children.

MS. CARPENTER added that the life-long effects of FAS and FASD could be physical, mental, learning, or behavioral health disabilities. She explained that pre-natal alcohol exposure was dose related, how much alcohol was in the blood stream and when and for how long during the pregnancy. She stated that dependent on when the exposure happened during pregnancy, there

were different impacts on the individual. She further paraphrased from the white paper, which read:

Neonatal abstinence syndrome (NAS) is caused by taking opioids during pregnancy; after birth, babies with NAS may go through drug withdrawal. Over 69% of mothers who had a baby that was diagnosed with NAS had previously given birth to other children.

Infants exposed to opioids and alcohol during pregnancy have an increased risk for pre-term birth, life-long disabilities, and neurodevelopmental delays, with significant emotional, social, and economic costs for individuals, families, and the state.

FASDs and NAS are preventable when women have access to the resources, support, information, and care or treatment they need for their children or themselves.

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MS. CARPENTER reported that Senator Kelly had first introduced legislation addressing FASD in 2014, Senate Concurrent Resolution 13. She highlighted certain whereas clauses included in the resolution:

Whereas, fetal alcohol spectrum disorder permanently alters a child's cognitive abilities;

Whereas, fetal alcohol spectrum disorder has been identified as a pervasive and chronic driver of numerous social challenges throughout the state;

Whereas, the occurrence of fetal alcohol spectrum disorder is preventable;

Whereas, Alaska has the highest documented prevalence of fetal alcohol spectrum disorders in the United States;

Whereas, in 2012, the legislature passed legislation making the existence of fetal alcohol spectrum disorder a mitigating factor for criminal sentencing;

Whereas, misconceptions continue to exist regarding the causal factors and lifelong effects of fetal alcohol spectrum disorder;

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MS. CARPENTER added that a further resolve from this resolution was that the Alaska State Legislature supported programs which would minimize the risk of fetal alcohol exposure. She reported that there had been several efforts to affect the rate of FASD in Alaska, which finally intersected with the four-part FASD prevention model offered by Dr. Nancy Poole, which included: universal messaging strategies promoting FASD prevention; increasing access to pregnancy tests; increasing access to long acting reversible contraception (LARC); and increasing access to substance abuse treatment and support services. She recapped that the proposed bill would allow the University of Alaska Center for Alcohol and Addiction Studies to "evaluate the feasibility and effectiveness of providing long acting reversible contraception to women involved in services such as Alaska Regional's neo-natal abstinence evaluation support treatment (NEST) program." She stated that the population of women served by this program represented one of the highest risk groups in Alaska for unintended pregnancy and pre-natal drug and alcohol exposure. She said that the study would be done in collaboration with hospitals and health care providers in Alaska who treat women with substance abuse disorders. She pointed out that the incidence of children born with neo-natal abstinence syndrome (NAS) in Alaska had increased by more than 500 percent from 2004 - 2015, due in part to the current opioid crisis. Alaska had more than 120 children diagnosed with FASD each year, although, she opined, the true rate could be significantly higher according to recent national prevalence studies. She said that 2,660 children had been diagnosed with FASD in Alaska since 2001. She reported that almost 50 percent of infants with NAS treated at the Alaska Regional Hospital NEST program were immediately placed into the care of the Office of Children's Services (OCS), which, she reminded the committee, was the state law for any infant with drug exposure.

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MS. CARPENTER, in response to Representative Johnston, said that this included both FASD and FAS.

REPRESENTATIVE JOHNSTON shared that an issue for both was a lack of diagnosis in children. She asked if these numbers were for children that had "come through some system where there is some diagnosis."

MS. CARPENTER admitted that this was a part of the challenge, as it was necessary to prove there was some pre-natal alcohol exposure, in order to get diagnosis, adding that diagnosis was a long and lengthy process. She directed attention to letters of support [Included in members' packets] from Karen Perdue and Niesje Steinkruger. She shared some of her personal experiences working with young people who suffered from FASD.

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REPRESENTATIVE SULLIVAN-LEONARD asked about case studies from the Institute of Circumpolar Health with regard to FAS and its prevention and whether this had already been studied.

MS. CARPENTER replied that this study regarding access and the barriers had not specifically been studied. She shared that there was a lot of interest from other states for the results of this study.

REPRESENTATIVE SULLIVAN-LEONARD asked what information had been pulled from these other FAS studies. She asked if it was the desire of the sponsor to work solely through the Alaska Regional Hospital for information from its patients or would there be research for information from rural areas.

MS. CARPENTER replied that the proposed bill was very careful not to name one specific hospital in the legislation. She acknowledged that Alaska Regional Hospital was the first hospital ready to partner because they already had the ongoing NEST program and an ongoing relationship with the university. She expressed hope that other hospitals in Alaska would also be interested in participation.

REPRESENTATIVE SULLIVAN-LEONARD asked about the results of the studies from the pregnancy tests from the various bars.

MS. CARPENTER offered to provide those results to the committee members.

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REPRESENTATIVE ZULKOSKY referenced a program by the [Centers for Disease Control and Prevention] CDC for choices to prevent alcohol exposed pregnancies which used motivational interviewing to increase a woman's motivation and commitment to change. This included two to four counseling sessions, as well as a contraceptive counseling session. She added that this was implemented in various settings including community health centers and family planning clinics. She pointed out that there were also facilitator guides, client workbooks, and counselor manuals all developed by the CDC. She asked if the development of the proposed study had gleaned any best practices from the CDC.

MS. CARPENTER replied that the University [of Alaska] had built on information from that choices study.

REPRESENTATIVE ZULKOSKY reported that the CDC research was being implemented in Baltimore, Denver, New York City, and Los Angeles. She pointed to the proposed fiscal note, and asked why the proposed legislation was not duplicative, hence an unnecessary expense, with this already implemented information and resources.

MS. CARPENTER referenced the personnel costs in the fiscal note, and stated that it was not covering the entire person's salary as that person would continue to work on other projects.

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REPRESENTATIVE ZULKOSKY expressed her understanding that, although it did not cover the full staff expense, there was only \$200,000 of the \$500,000 appropriation left for statistically relevant analysis, whether that be health care, planning, or outreach.

MS. CARPENTER explained that, as this budget was offered in conjunction with the university, she did not have the answers to those questions. She opined that the university would implement other research.

[3:25:47 PM](#)

CHAIR SPOHNHOLZ suggested that a follow up response from the university would be useful.

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REPRESENTATIVE KITO asked about the fiscal note, which identified personal services for more than half the grant and noted that nothing had been allocated for travel. He opined that the vast majority of the money would go to university employees instead of care for the subject of the study. He expressed his concern for adequate medical support, as nothing was mentioned in the fiscal note for medical oversight. He added that the fiscal note description was quite vague. He asked whether there was enough money in the study to "do it right" because if only so much of the money is going to the actual study, a lot of the money is going to personnel. He mentioned that Phase 2 of the program was to implement referral protocols and assemble data collection and network collaboration, and that Phase 3 was to implement data analysis and reporting, data analysis strategy development outcomes, and reporting strategy recommendations. He emphasized that there was nothing mentioned for medical support to the individuals receiving the intervention or for any follow up to those individuals to ensure medical support throughout the time impacted by this intervention. He asked for assurance that the participants would receive adequate medical care.

MS. CARPENTER replied that she would contact the University and request that the fiscal note provide more detail. She explained that part of the money would go for a case manager to ensure that the participants had follow up care and that part of the money would pay for the actual contraception to those participants who did not have medical insurance.

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REPRESENTATIVE EASTMAN asked for the total amount of funding from all the various sources for this project.

MS. CARPENTER replied that the total funding from the fiscal note would be drawn from the general fund, and that currently there were not any matching funds.

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CHAIR SPOHNHOLZ offered her belief that there had also been a federal funding request.

[3:30:12 PM](#)

REPRESENTATIVE EASTMAN asked about the impact to the project if there was not any additional funding.

MS. CARPENTER reported that the entire University budget for the three-year project was \$500,000. She opined that the University would continue to work to get other funding, although they could move forward given this amount.

REPRESENTATIVE EASTMAN asked how the federal funds would be used.

MS. CARPENTER said that she did not know without seeing the application.

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CHAIR SPOHNHOLZ opened invited testimony on SB 198.

[3:32:02 PM](#)

WILLIAM TRAWICK, Advanced Nurse Practitioner, said that he was the author of the NEST program at Alaska Regional Hospital. In response to Chair Spohnholz, he explained that the NEST program was designed to care for substance exposed infants, both the immediate medical care and the detoxification and controlled medical withdrawal. He said that it also involved the care of the families of the infants, with an effort to maintain them or enroll them in substance recovery programs. He reported that this was a diverse population of Alaska residents, and that this population was, on average, 99 percent state Medicaid enrollees. He reported that this diverse population included street level substance users, those in medication assisted drug therapy, and persons who suffered from chronic pain syndromes which required opiate treatment. He said this was a diverse population of both licit and illicit substance using persons.

MR. TRAWICK, in response to Representative Zulkosky, said that the population was very diverse, and it was difficult to draw any specifics from this population. He added that, generally, the patients were Medicaid recipients, were using illicit medications as well as legal drug medication assisted therapy. He stated that frequently there were mothers enrolled in methadone programs, and, after delivery, as the baby would become part of their program, the family would also become part of the program. He explained that a defining characteristic of the NEST program was that it was a family centered, family intensive program.

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REPRESENTATIVE ZULKOSKY asked if there were cases which had been referred statewide in the program, and if so, from where had those referrals originated.

MR. TRAWICK replied that the majority of the patients were from the Anchorage area, although there were also referrals from outside areas. He pointed out that it was expensive and difficult to medically air transport a baby from an outside community to Anchorage. He reported that infants who did require air transport to Anchorage became patients at Providence Alaska Medical Center even though there were not the services of the NEST program.

[3:38:59 PM](#)

REPRESENTATIVE KITO asked about the resources for the NEST program to medically oversee the actions related to the proposed study in regard to the mothers of the children.

MR. TRAWICK reiterated that the primary characteristic of the NEST program was for a family focus and to develop a culture of respect with an absence of shame. He declared that the program goal was to treat babies suffering from withdrawal and to maintain infants in the care of their biological family whenever possible. He emphasized that this was an extremely difficult environment to maintain. He explained that babies who could not be managed effectively with common sense measures such as holding and soothing to decrease stimulation, were moved inside the NEST unit for medically assisted therapies, often including minute doses of morphine, which required very high levels of nursing care. He noted that this was often a ratio of one baby with one nurse, a fundamental requirement for babies suffering from opiate withdrawal. He shared that when possible the biological family was included, under guidance, in this care for the babies, even though this was sometimes too much for the families.

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REPRESENTATIVE KITO asked, as the proposed study included a medical intervention for the mothers, what resources the NEST program had to provide medical oversight and treatment for the mothers receiving the proposed contraception intervention to ensure they were not adversely affected health wise.

MR. TRAWICK explained that an important aspect of the NEST program was that every mother entering Alaska Regional Hospital for delivery underwent a screening process, called the 4 P's Plus, which was a widely validated tool to assess a mother's risk of alcohol and substance use and exposure. He added that this program was now used in hospitals throughout Alaska as it allowed the hospital to know when a woman was at risk for these exposures. He pointed out that the NEST program was well positioned to determine mothers who may be candidates for the LARC, emphasizing that the program was voluntary. He declared that it was vital to maintain this culture of respect.

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REPRESENTATIVE KITO reiterated that, as many of these women did not have regular health care, they had no access to a health care provider. As the proposed legislation was recommending an invasive medical procedure, he asked for assurance that there would be needed medical oversight for the women receiving LARCs.

MR. TRAWICK expressed his agreement that the vast majority of the women in the program did not have a medical provider. He explained that part of the NEST program was to get the women into a "conventional medical relationship." He stated that women were not discharged from the program without follow-up providers, even though it was a small pool of medical professionals who showed an interest in taking care of these mothers.

REPRESENTATIVE KITO asked if there were medical doctors in the NEST program that provided care for the mothers.

MR. TRAWICK replied, "Not in the NEST program."

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REPRESENTATIVE EASTMAN asked if the proposed program would meaningfully contribute to the culture of respect, or was some "fine tuning" still necessary.

MR. TRAWICK expressed his agreement that some "fine tuning" still be necessary as it was a very sensitive issue. He stated that it was a "horrible thought" for any family to think the mother was going to be sterilized. He emphasized that the NEST program was very sensitive to this issue.

[3:49:52 PM](#)

CHAIR SPOHNHOLZ asked how parents were connected with addiction treatment.

MR. TRAWICK explained that there was a licensed clinical social worker who maintained some very close relationships within the provider network.

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CHAIR SPOHNHOLZ asked if there were barriers to getting people into treatment and if there was enough access to addiction treatment in Alaska.

MR. TRAWICK expressed his agreement, stating that there was "no end to the amount of barriers," although he mused that there were some promising developments. He reported that the planning was well underway for the development of a behavioral health program at Alaska Regional Hospital, which would include detoxification beds as well as substance treatment. He said that families had so many reasons to avoid these decisions, and that the NEST focus was to work around these obstructions and visualized threats. He added that a new peer support program had just been instituted which he opined could be a very powerful tool to encourage mothers to proceed in treatment.

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CHAIR SPOHNHOLZ asked if the NEST program had been able to get everyone who was ready into treatment.

MR. TRAWICK said that the biggest issue was almost always for the availability of beds. He reported that very few programs in Alaska would allow a mother to be enrolled in an in-patient program and maintain custody of their child. He noted that the methadone program, although perfectly adequate, was not an inpatient program.

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CHAIR SPOHNHOLZ offered her understanding that the program was primarily designed for families with infants born with an addiction to opiates, whereas the proposed legislation was focused on FASD. She asked how they would identify the patients, and what would be done differently to operationalize this.

MR. TRAWICK replied that the assessment program was well validated for alcohol usage issues. He opined that the efforts for screening, including short interventions and access to further therapies, would be the most valuable tool, adding that all mothers delivering at Alaska Regional Hospital were screened. He expressed his agreement with Chair Spohnholz that this would determine the referrals to the NEST program.

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MARILYN PIERCE-BULGER, Owner, FASDx Services, added that she was also representing the non-profit organization, Alaska Center for FASD. She reported that FASD was more common and prevalent than previously thought, impacting more than 1 in 20 children, whereas autism affected 1 in 68 children and ADHD affected 1 in 110 children. She pointed out that there was not good prevalence data for Alaska, and that individuals who had not been diagnosed were at increased risk for self-medication with alcohol and substances. She reported that data indicated that 80 percent of women using substances were also using alcohol. She noted that individuals diagnosed with FASD were impacting the health, education, social services, and criminal justice systems, and, even more important, their own daily lives and their life trajectories. She emphasized that this was a life long disability which could contribute to chronic pain, immune response conditions, anxiety, and depression. She shared a report from CDC which indicated that the women drinking in pregnancy in 2018 were white, working, college educated women who believed that their low to moderate alcohol doses would not have any impact on their children. She reported that alcohol had more long-term impact than many of the other abused substances. She noted that although many of the women were able to stop the alcohol use, their pregnancies were already impacted. She offered her belief that women using substances wanted something different for themselves and their babies, so that helping them explore the options with LARC and substance abuse treatment offered them more choice and control over their lives. She stated that the proposed bill was a strategy to help women help themselves.

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REPRESENTATIVE ZULKOSKY asked about the reduction for the prevalence of FASD and neo-natal exposure to illicit substances and the need to provide greater support and wrap around services for Alaskans seeking substance abuse treatment and comprehensive contraceptive options for women. She expressed her concern with

the proposed bill as it would seek to treat one part of Alaska's population of women differently than others and would stigmatize one group of Alaska women. She noted that the implication was that women with substance abuse disorders should be prevented from having children. She expressed her difficulty in reconciling how providing effective birth control to a population of women who may be having children who were seen as a cost challenge to the State of Alaska. She deemed this as a fine line into dangerous territory. She expressed her understanding for protecting children but asked how the proposed bill would protect women who were struggling and would not malign them.

MS. PIERCE-BULGER offered her belief that the professionals working with these issues were "incredibly sensitive to all of what you just mentioned." She shared that, in her years of experience working with women living on the edge, that being safe, having a roof overhead, and food on the table was the priority. She noted that these women were also trying to "achieve some level of control over their lives" and wanted to have effective birth control, although some of the women were not able to access it for a variety of reasons. She opined that the proposed bill could make effective contraceptive choices more easily available to vulnerable women in the community. She mused that, as stigma got in the way of all conversations around substance use and FASD, it was necessary to normalizing certain responses in the health care system.

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CHAIR SPOHNHOLZ stated that there was not a great community awareness for the prevalence of FASD and what was needed to provide support. She shared a personal anecdote.

[4:08:27 PM](#)

ROBERT BOECKMANN, Ph.D., Chair, Institutional Review Board (IRB), University of Alaska Anchorage, said that this was sometimes called the ethics committee. He explained the role of the IRB to ensure the respectful and ethical treatment of research participants. He corrected earlier testimony by Senator Kelly which stated that the legislature had the capacity to authorize the conduct of the LARC studies at UAA Center for Addiction Studies, declaring that to be "categorically false." He emphasized that the authorization to conduct the studies had to go through the IRB and that ultimately, it was his decision to authorize the conduct of a study involving human subjects.

He acknowledged that the legislature could authorize the funding but not the conduct of the study. He offered a brief overview of the IRB, its membership, a review of the research protocols, and what the IRB was empowered to do with regard to reaction to those research protocols. He stated that research with human subjects had a fairly long, complicated, and controversial history. He added that concerns about research ethics were not an integral part of research until the Nuremberg Trials, which exposed some horrible atrocities.

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DR. BOECKMANN mentioned the Tuskegee Institute syphilis studies from 1932 - 1972 and those injustices imposed by the U.S. Public Health Service led to the formal adoption of rules and regulations that now guided and ensured respect to research participants. He reported that the conduct of the IRB was guided by federal rules. He explained that the minimum was 5 members while UAA had 11 members, and this had to include a member with scientific expertise, a member with non-scientific expertise, and a member not affiliated with the university, the community representative to bring the community values, needs, and concerns to any discussions. He added that the IRB, under certain circumstances, could be directed to have additional types of representative, specifically from any group to be tested. He pointed out that with any review of a research protocol involving medical intervention, it was necessary to have a medical doctor included in the discussion. He noted that the current membership of the UAA IRB was listed on its website, with the regular open public meetings also posted on the website. He explained that prior to the meetings, the board members reviewed the protocols and prepared notes and comments for deliberation on any concerns. He emphasized that the IRB had the power to disapprove, modify, or stop any studies that were inconsistent with the federal guidelines. He stressed that no human research activity was allowed to be conducted at UAA unless it was rigorously reviewed by the IRB. He highlighted the seven criteria that IRB used for review of a protocol: assess risks and ensure they are minimized for little or no danger to participants; assess that any risks are beneficial to the study results; selection of the research participants is equitable across a wide segment of society; informed consent documented from each participant; adequate provision for monitoring the data security; and, privacy of the data. He added that if and when approval of study was granted, it was necessary for a progress report, which for a high-risk study, was required in 3 months, or at any point necessary to ensure

the safety and well being of the participants. He stated that any modification by the researcher of the protocol had to be presented to the IRB for review.

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REPRESENTATIVE KITO asked how many requests for research involving medical intervention did the IRB review annually.

DR. BOECKMANN replied that they did not see a medically invasive intervention similar to the LARC studies very often, perhaps one or two per year.

REPRESENTATIVE KITO expressed his concern for follow up care and asked about individuals who may leave the study but then have a medical problem post-study. He asked if the IRB would recommend that the intervention be terminated before completion of the study or recommend a protocol for follow up care to every individual who had received the intervention and could have support for removal post-study. He asked for assurance that the individuals would have support while in the study, as well as post-study.

DR. BOECKMANN said that the IRB would require a specific procedure or plan of follow up care and funding for those individuals having the LARC intervention.

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DR. BOECKMANN, in response to Representative Tarr, said that informed consent from each individual in the study would be documented.

REPRESENTATIVE TARR expressed her concern that the actual process would include coercion to participate, as the individual would be in a very vulnerable state during post-delivery and withdrawal. She asked how the plan could be "whole person centered" and suggested that the individual could need an advocate.

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DR. BOECKMANN segued into the informed consent requirement and process. He stated that the IRB reviewed specific procedures and plans, and expressed his understanding that currently this plan did not yet exist. He stated that the federal government required an informed consent process and he listed the seven

requirements for informed consent: the study has been adequately described; a description of an foreseeable risks or discomforts that may be encountered; describe the benefits the subject may receive directly or the benefits extended through study to society; a statement that participation was voluntary and that refusal to participate or discontinue participation at any time would involve no penalty or loss of benefit to which the participant was otherwise entitled; disclosure of any alternative procedures or courses of treatment that may be available; describe the extent to which any confidentiality of record or identifying information would be maintained, and if there were any possibility for a breach of confidentiality; an explanation for more than minimal risks from the research, and any medical treatment available if injury occurs; and, information for who to contact if there are concerns or questions about the research participation. He stated that there are some special requirements for vulnerable populations, including children and adults with diminished capacity, regarding consent.

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REPRESENTATIVE TARR reported that, as her constituency had varying levels of trust for those in positions of authority, there was a concern that individuals would feel they did not have the ability to make their own choice. She stated her need to feel there were enough safeguards in place. She pointed out that reproductive health care and the use of birth control was not always viewed as positive.

DR. BOECKMANN declared that the issue of coercion was very important to the IRB. He offered an example of proposals for research participants from prisons. He pointed out that the issues of choice, coercion, and the power differential between the researcher and the participant was closely examined by the IRB as it differed by population group.

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REPRESENTATIVE KITO expressed his concern that mothers would have an expectation that participation in the study with the LARC, or other contraceptive, might have an impact for whether they would get their child back from OCS custody.

DR. BOECKMANN said that the IRB was very sensitive to the context of the research, recognizing that different groups of people had different needs, concerns, and perceptions. He

acknowledged that a woman may believe that she would gain an advantage, possibly getting her baby back, if she participated. He suggested that this would be a conversation by the IRB, which could require language in the consent form that would indicate that hospital treatment for the baby would not differ as a function of participation in the study.

REPRESENTATIVE KITO said that there were nuances in the proposed bill that could be very complicating.

[4:45:22 PM](#)

REPRESENTATIVE TARR shared a letter to the House Health and Social Services Standing Committee that indicated that the IRB could make mistakes, even though unintentional. She listed some of the concerns for follow up care and removal of the LARC which would be addressed by proposed amendments. She asked about the IRB representation from the people participating in the study.

DR. BOECKMANN acknowledged that IRBs had made mistakes in the past, even as he did his best to ensure that there would not be any mistakes. He directed attention to a letter [Included in members' packets] from Serene Rose O'Hara-Jolley, pointing out that this letter was not clear as to which IRB or which protocol she was referencing, and that he did not recall working with her at the UAA IRB. He relayed that the UAA IRB processed about 600 protocols each year. He spoke about the requirement for representation on the IRB, and, although there was not a requirement for a certain ethnic representation, there was an attempt to have ethnic diversity and a balance of men and women.

[4:51:54 PM](#)

REPRESENTATIVE TARR offered her belief that it was very important to have women, and women of color, as part of this representation to introduce some of their experience. She asked whether there were invitations for feedback or participation, or would the advisory council developing the protocols be diverse.

DR. BOECKMANN said that part of the evaluation was looking at the extent to which the protocol was inclusive and respectful for the community assessed. He pointed out that the actual IRB membership included: a Hispanic woman with advanced health professional credentials, including two master's degrees focused on women and community health, and a Doctorate. He reported that he had been working with this IRB for more than a decade and that "they take the community's concern very seriously."

CHAIR SPOHNHOLZ announced that SB 198 would be held over.

[4:54:47 PM](#)

JEANNE GERHARDT-CYRUS, Governor's Council, shared that she was a parent of multiple children with pre-natal exposure [to alcohol] and that she was Chair of the prevention work group on FASD. She expressed her agreement for the safeguarding of people's rights. She declared support to empower women to plan pregnancies when they were ready and to enable them to give birth to healthy children by virtue of having access to LARC. She pointed out that, although unplanned pregnancies did not mean unwanted pregnancies, it could include unprepared for establishing a healthy environment for the baby. She acknowledged the high rate of women with opioid use disorder who had unplanned pregnancies. She shared her personal experience of children with FASD, all of which was 100 percent preventable. She declared that she was not looking to prevent these children from being born, but just wanted to increase the odds that they would be born healthy by ensuring that women had the access to choose LARC. She encouraged the proposed study.

REPRESENTATIVE TARR reiterated that it is necessary for women to be empowered and to have choices.

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ELLEN HODGES, M.D., advised that she is a physician in rural Alaska that primarily serves Alaska Native residents, and she is testifying on her own behalf. She expressed concern regarding SB 198, the testimony regarding the children affected by drugs and alcohol, and the women who will be affected by this legislation. Dr. Hodges advised that within her practice, she takes care of many women and children and she offers reproductive health. This legislation could return the state to the "shameful days" when forced sterilization and contraceptive coercion was a common occurrence for vulnerable populations, including the Alaska Native and American Indian population. In the 1990s, Norplant was used, which is a long-acting reversible contraceptive (LARC) implant and has since been removed from the market, wherein it was required of some women to obtain its benefits in order to avoid incarceration. Clearly, she said, no one wants children born who have been exposed to drugs and alcohol in utero, but medical professionals already have available the randomized controlled trials that established best practices in order to reduce alcohol use in women who engage in

risky drinking behavior. The Center for Disease Control (CDC) CHOICES program [prevent alcohol-exposed pregnancies] details such best practices and, she advised, there are many other such evidence based programs that have been validated across the nation in many populations. Furthermore, she advised, the American Academy of Pediatrics already established the best treatment for utero abstinence syndrome, and further advised that there are many disciplinary teams across the state able to diagnose and treat fetal alcohol substance disorder (FASD), and follow up with the families. This money, she pointed out, could be better spent on programs such as the CDC CHOICES program that has already been researched and validated, or spend the money on drugs and alcohol treatment programs that are so desperately needed in the rural areas in Alaska, and in her community.

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DR. HODGES further expressed concern about this sort of design and the follow up of the women with long-acting reversible contraceptives implants because this type of contraception cannot be removed by the woman herself, the removal requires an appointment with a health care provider. These implants can remain in place for up to ten years, and she asked: "How will they be followed; who pays for the removal; what if they leave the State of Alaska; who handles complications - for example, an exploratory laparotomy for a woman with a migrated intrauterine device (IUD)." She referred to the evidence that comprehensive wrap around care with motivational interviewing and comprehensive contraceptive counseling reduces risky drinking behavior, and stressed that this legislation does not describe the design in enough detail. The testimonies heard today from the (NEST) program and the IRB from UAA do not alleviate her considerable concerns that these women will either explicitly or implicitly be coerced into using long-acting reversible contraception. Thereby, returning the state to the days of forced sterilization when it was allowed and encouraged, she expressed. Studies have proven that access to birth control counseling and motivational interviewing reduces risky drinking behavior among women who do, and do not, have children. She said that she simply does not believe this study is necessary, and it puts the state at risk of going down in history of using those shameful programs that allow this type of coercion. That history is a dark stain put upon the medical area where she practices, she remarked.

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GENEVIEVE MINA advised that she is a UAA student representing herself, and offered support for the legislation. As a woman with a long-acting reversible contraceptives (LARC), she knows that her IUD is over 99 percent effective and it is far cheaper and convenient than other forms of birth control. She noted that she comes from a privileged background that included comprehensive sexual education at her high school, and knowing under which providers she is covered under her health insurance. Currently, the conventional method of birth control works for her, but it is not working for women with substance abuse issues who statistically have higher rates of unplanned pregnancies. It is her belief, she said, that addressing women's health regarding substance abuse disorders is far more complex and nuanced than simply offering more access to contraceptive care. It is necessary to rethink what access means, and she explained that access is about surpassing financial, institutional, and social barriers. She pointed to the financial barriers and noted that simply because the service can be accessed free of charge does not necessarily mean a woman has the incentive to obtain that service. For example, there are probably legislators who did not obtain the flu shot even though the cost was covered by insurance. As to the institutional barriers, many women may want the service but cannot locate a provider with LARC available at their facility. The conventional method of care in the healthcare system may not work and be accessible for these women. Finally, she stated, as to social barriers, many women have misconceptions about LARC because they have not received proper sexual education, or if they are a user of opioids, they often have a huge distress and fear of the healthcare system and avoid providers all together.

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MS. MINA referred to SB 198, Section 1, subparagraphs (2), (3), and (8), page 2, which read as follows:

(2) evaluate best practices for treating women and children when there is a high risk of neonatal abstinence syndrome or fetal alcohol spectrum disorders;

(3) facilitate the creation of an effective network of hospitals and service;

(8) provide a data-driven framework to establish a comprehensive strategy for using long-acting reversible contraception to reduce the occurrence of

neonatal abstinence syndrome and fetal alcohol spectrum disorders in the state.

MS. MINA related that those subparagraphs support a research project that aims at better strategies for women's health. Additionally, she explained, as was heard today, the concerns about coercion will be acknowledged under the review of the IRB which specified room in the study for education and the economies for the women to choose whether they want to use birth control in the form of a LARC. She described that substance abuse during pregnancy is a complicated and sensitive issue and it does require a nuanced approach in order to improve public health for the most vulnerable in our population, including women and children. She asked that the committee pass SB 198.

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BESSE ODOM advised that she is representing herself, and acknowledged that the intent of the legislation means well. However, she asked that the committee not support this bill in its current form because it does not get to the bottom of the problems for these particular groups of women that it seeks to help. She related that the state should put more resources into programs to help these women in need. She said she would rather see the money allocated to improving the already existing programs and organizations who aid women battling a substance abuse disorder. She described that this bill insinuates that these women should have their rights to have children controlled not by herself, but by those who they do not know and may not even trust. She said that she genuinely believes that the research showing that good educational programs and accessibility to programs wherein women can turn their lives and situations around are being ignored. As a woman, and particularly an African American woman, she described this bill as highly insulting to her because it reminds her of the histories told to her by women such as her grandmother. Many women, living around the time of her grandmother were uneducated and lacked the resources they needed to make a truly informed decision about their reproductive rights and their bodies. Historically, groups of women were targeted and sought out because it was believed their offspring would be less than desirable to the population. This bill is a great reminder that "we should be educating ourselves" regarding the history of reproductive rights and marginalized communities. These women, suffering from substance abuse disorder and women of color, have always been victims of violator reproductive rights and this

bill in its current form opens the door to the rights of vulnerable women being violated. She described that this bill is also insulting because it insinuates that a woman battling substance abuse disorder is not fully capable of having children and turning her own life around with the right support. Clearly, substance abuse disorder is a huge issue in this state as she has three siblings who battle the disorder on a daily basis. Ms. Odem encouraged the committee to read the history books, and to be sympathetic to the groups of women desperately in need of true support systems and great educational programs that address their needs.

CHAIR SPOHNHOLZ left public testimony on SB 198 open.

[SB 198 was held over.]

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ADJOURNMENT

There being no further business before the committee, the House Health and Social Services Standing Committee meeting was adjourned at 5:13 p.m.