MINUTES OF THE
SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES

Eighty-second Session
May 16, 2023

The Senate Committee on Health and Human Services was called to order by Chair Fabian Doñate at 3:32 p.m. on Tuesday, May 16, 2023, in Room 2134 of the Legislative Building, Carson City, Nevada. The meeting was videoconferenced to Room 4412 of the Grant Sawyer State Office Building, 555 East Washington Avenue, Las Vegas, Nevada. Exhibit A is the Agenda. Exhibit B is the Attendance Roster. All exhibits are available and on file in the Research Library of the Legislative Counsel Bureau.

COMMITTEE MEMBERS PRESENT:

Senator Fabian Doñate, Chair
Senator Rochelle T. Nguyen, Vice Chair
Senator Roberta Lange
Senator Robin L. Titus
Senator Jeff Stone

GUEST LEGISLATORS PRESENT:

Senator Marilyn Dondero Loop, Senatorial District No. 8
Senator James Ohrenschall, Senatorial District No. 21
Assemblywoman Michelle Gorelow, Assembly District No. 35
Assemblywoman Heidi Kasama, Assembly District No. 2

STAFF MEMBERS PRESENT:

Jennifer Ruedy, Policy Analyst
Eric Robbins, Counsel
Mary Ashley, Committee Secretary

OTHERS PRESENT:

Kelsey Lamph
Shelbie Swartz, Battle Born Progress
Juanita Cooper
Briana Escamilla, Planned Parenthood Votes Nevada
Edith Duarte, Novartis Services, Inc.

Caitlin Gatchalian, American Heart Association
Katie Ryan, Dignity Health-St. Rose Dominican
P.J. Belanger
Matthew Wilkie
Naomi Lopez, Vice President for Healthcare Policy, Goldwater Institute
Hideto Peter Kasama
Lisa Santwer, Comprehensive Cancer Centers of Nevada
Helen O'Hanlan
Annette Whittemore, Whittemore Peterson Institute
Joshua Smith
Janet Campbell
Jason Greninger
Wiz Rouzard, Deputy Director, Americans for Prosperity

CHAIR DOÑATE:
We will open today's meeting with Assembly Bill (A.B.) 169.

ASSEMBLY BILL 169 (1st Reprint): Revises provisions governing the labeling of feminine hygiene products. (BDR 51-617)

ASSEMBLYWOMAN MICHELLE GORELOW (Assembly District No. 35):
It is my pleasure to present A.B. 169. This bill is concerning the labeling of feminine hygiene products. With me today is Kelsey Lamph, a University of Nevada, Las Vegas (UNLV), law student who brought this issue to my attention. Assembly Bill 169 requires each package or box containing feminine hygiene products for sale or distribution in Nevada to bear a label containing a plain and conspicuous list of all ingredients in a feminine hygiene product.

KELSEY LAMPH:
As previously mentioned, I am a law student at UNLV's William S. Boyd School of Law. I originally began this project as an assignment in one of my law school classes. As I did more research, I discovered the vast potential dangers of using certain feminine products. For example, in January 2023, Thinx period underwear, which is specifically marketed as being safe and better for menstruators, settled a lawsuit for fraud and deceptive business practices. The lawsuit followed from a third party testing the underwear and discovering the presence of per- and polyfluoroalkyl substances (PFAS) in the products. The PFAS are man-made forever chemicals that have a negative health effect on people. I humbly urge this Committee to support A.B. 169.

I am a childhood leukemia survivor. My mother is a thyroid cancer survivor, and my great grandmother was a breast cancer survivor. So, I understand how illness can disrupt and devastate lives. It can strike for no good reason. Some of the products that menstruators use regularly while bleeding have the potential to cause short-term and long-term health issues like ulcers, rash, endocrine disruption, reproductive toxicity and cancer. The presence of certain ingredients in feminine products can cause issues in the female reproductive area that may not be caused when they come in contact with skin or are ingested. The products come in contact with this reproductive tissue made up of mucous membrane. Unlike something you swallow, substances that come in contact with these organs do not go through the body's typical elimination and metabolic processes. Instead, the chemicals are absorbed by the mucosa and from there can pass almost directly into the bloodstream.

The Food and Drug Administration (FDA) categorizes menstrual products as medical devices. This means the products do not have to be labeled with its ingredients. Any recommendations the FDA makes about chemical levels are simply recommendations and do not have to be followed. The purpose of this policy is to provide information transparency. It will allow menstruators to make informed decisions about what they put in their bodies.

The added transparency is our hope toward an increased demand for products with natural ingredients. So far, only California and New York have passed this legislation. Assembly Bill 169 presents a wonderful and important way for Nevada to show that it supports female reproductive health and transparent consumer choice.

ASSEMBLYWOMAN GORELOW:
You should have a copy of Proposed Amendment 3644 (Exhibit C). We have worked diligently with the Center for Baby and Adult Hygiene Products, which represents many of the manufacturers of these products. We collaborated with this organization to ensure we include items they want. It has asked us to not only model our language after California so it is uniform but to make our legislation as submitted.

In section 1.5, subsection 1, the typographical error of the word "does" needs to be changed to "dose." Although I will defer to Legal Counsel, in section 2.3, we must separate out the "combination of substances is confidential business

information." We cannot have a definition and rules in the definition. We need to separate those out. Is that correct?

ERIC ROBBINS (Counsel):
The issue is in section 3, subsection 2, subparagraph (b) of the bill. The organization Assemblywoman Gorelow referred to earlier wanted the last sentence to be "If the ingredient is confidential business information, the ingredient may be identified by its common name." The Center wanted it separated out into its own subsection, so it was abundantly clear. We did not have any problem with this change.

ASSEMBLYWOMAN GORELOW:
Another change to section 3, subsection 2, paragraph (b) is to the amendment from, "If the ingredient does not have a standardized nomenclature, the ingredient may be identified" to a "shall be identified." This change was the request of Procter & Gamble.

CHAIR DOÑATE:
To clarify, there are two amendments. One is Proposed Amendment 3644, and the other amendment (Exhibit D) is adding cosponsors.

SENATOR NGUYEN:
If you are making amendments, I would love to be a cosponsor.

ASSEMBLYWOMAN GORELOW:
We would love to add your name as a cosponsor.

SENATOR STONE:
Thank you for presenting this bill and for coming into my office to discuss it. Are you targeting any products with specific ingredients with this bill? Are you aware of any rejections that cannot go into California because it has a certain particular ingredient?

ASSEMBLYWOMAN GORELOW:
I do not think it is about specific ingredients. Some women may be allergic to certain products, and the information will inform them the product contains something that may irritate them.

SENATOR STONE:
Who defines whether a chemical additive, a fragrance or excipient is considered to be a dangerous carcinogen? What source do we rely on to provide us that information?

ASSEMBLYWOMAN GORELOW:
That is an excellent question, and I will rely on Legal Counsel to respond. This is something we questioned. We could not include the California list because that is not the way Nevada writes laws. Our State has a list, but it is slightly different. California has more chemicals on its list than Nevada.

MR. ROBBINS:
The operative provisions of the bill are in section 3 that states how the ingredients will be listed. It would have to have all of the ingredients on the label. The term fragrance ingredient added in section 2.1, subsection 1 of the amendment, Exhibit C, indicates it is present in certain concentrations on a designated list. Section 1.5 defines designated list and references the entities that will identify ingredients which may be carcinogenic. The responsible parties are federal and State agencies.

Section 1.3, subsection 2, paragraph (b) of Exhibit C states a fragrance allergen is a European Union regulation as it existed on January 20, 2023. The European Union would not have authority to adopt requirements binding our State forever. It is just stating Nevada is adopting this regulation as it exists now. Those are the sources for determining which ingredients would be considered dangerous or allergenic.

SENATOR STONE:
Is it fair to say these are reputable federal government agencies that have studied these products and determined the safety and efficacy of these ingredients?

MR. ROBBINS:
I believe so, except one is a State agency. In addition, there is a reference to a European regulation regarding allergens. In summary, all are reputable governmental sources.

SENATOR STONE:
We discussed that a big company, like Procter & Gamble, would not want to create a unique label for each state. As I recall, we would not require unique labeling in Nevada, and it would conform with California's labeling. Is that correct?

ASSEMBLYWOMAN GORELOW:
That is correct. We worked diligently to make sure this legislation is similar and would not create a burden on the companies. As of today, the companies are agreeable with our work.

SENATOR STONE:
I am sure the industry appreciates your work.

SENATOR TITUS:
I have a question for Legal Counsel. In the bill, section 1.3 refers to the European Union Cosmetics Regulation. Does Nevada have any other laws that refer to Europe or other countries that we would emulate?

MR. ROBBINS:
I am unaware of any but, as I stated, this is not delegating permanent rulemaking authority to the European Union. It is just stating that Nevada adopted its standard as it currently exists. Although I am not aware of any other references to standards of a foreign government, on occasion we do refer to things like nonprofit organizations. It is not unprecedented to adopt by referencing a standard prescribed by a non-Nevada governmental entity.

SENATOR TITUS:
My follow-up question can be answered by whomever is appropriate. Section 1.5, subsection 6 refers to a specific federal code. I bring this up because it can change. We should have language allowing State law to remain current with a federal act. I am not in favor of citing things like this in our laws because of external changes. In the past, I have seen wording like current standards or have a caveat to allow our law to remain current. Am I missing the allowance to remain current?

MR. ROBBINS:
That language is not included because when there is a reference to a federal law, it is assumed it will update with federal publications. This does not apply to

the European Union regulation. We would be delegating authority to an entity not part of the Nevada government that has no accountability to Nevada voters.

SHELBIE SWARTZ (Battle Born Progress):
We are in strong support of A.B. 169. Passage of this bill will allow people who use feminine hygiene products or menstrual products to make smart decisions about the items they are placing in and/or around their bodies. We hope that you will support this bill today.

JUANITA COOPER:
I support A.B. 169. It should be mandatory that products for women who are menstruating and other products like that should have that … (unintelligible statement) … donated or free.

BRIANA ESCAMILLA (Planned Parenthood Votes Nevada):
We support A.B. 169. People who utilize menstrual products deserve to know what they are exposing their bodies to. It will allow them to make informed decisions about the products they are choosing. We urge your support.

CHAIR DOÑATE:
I have three documents (Exhibit E) in support of A.B. 169. We will close the hearing on A.B. 169 and open the hearing on Senate Concurrent Resolution (S.C.R.) 5.

SENATE CONCURRENT RESOLUTION 5: Urges the expansion of comprehensive cardiovascular screening programs and directs the Joint Interim Standing Committee on Health and Human Services to conduct a study concerning such programs. (BDR R-1025)

EDITH DUARTE (Novartis Services, Inc.):
I am here to present S.C.R. 5. Novartis is an innovative medicine company that supports efforts to improve the quality of life of Nevadans and health outcomes for all residents. The U.S. Centers for Disease Control and Prevention states that Nevada healthcare professionals have diagnosed 8 percent of adults in the State with symptoms of arteriosclerotic cardiovascular disease. The symptoms include angina, stroke, heart attack and coronary heart disease. However, many Nevadans have yet to be diagnosed, particularly in the underserved communities.

The resolution urges State agencies to expand comprehensive cardiovascular screening programs to allow earlier identification of patients at risk for cardiovascular events. Secondly, it urges State agencies to explore ways to collaborate with federal agencies and national organizations to establish or expand comprehensive cardiovascular screening programs. It continues with a request to evaluate State cardiovascular health programs to accelerate improvements in care rendered to patients with cardiovascular events. Finally, the State should develop policies to reduce the number of Americans who die from cardiovascular disease.

The Joint Interim Standing Committee on Health and Human Services study is committed to working with the American Heart Association (AHA).

CAITLIN GATCHALIAN (American Heart Association):
We would like to thank Senator Lange for sponsoring this bill and making cardiovascular disease a priority for the State. May is American Stroke Awareness Month. The AHA is happy to present and support S.C.R. 5 because cardiovascular disease is the No. 1 killer worldwide, in the U.S. and in Nevada. These screenings will help save lives.

Screenings are important for patients to provide a picture of their cardiovascular risk. By prioritizing cardiovascular screenings, patients will know what undiagnosed medical conditions they may be experiencing and not realizing it. An important aspect of lowering the risk of cardiovascular disease, also called coronary artery disease, is managing health behaviors and risk factors. However, a screening test is needed to know which risk factors a person has.

Ensuring Nevadans can access screening will help them identify issues and seek preventative care. Nevada can also take steps to improve the quality of care in our State. The AHA supports a program called “Get With The Guidelines” (GWTG). Under this program, people work to improve healthcare outcomes and quality of service delivery at hospitals. This program offers hospitals evidence-based guidelines in the following areas: stroke, heart failure, resuscitation, atrial fibrillation (A-fib), and coronary artery disease.

The GWTG program is associated with improved efficiency of care. In turn, it will lower costs through decreased length of stay. The AHA is proposing an Interim study to look at Nevada's hospital and healthcare systems practicing GWTG strategies. The intent of the study is to help Nevada’s policymakers to

better understand gaps in evidence-based service delivery. The Committee can make recommendations on how the State can make improvements and close gaps.

SENATOR STONE:
How can you not support something like this? Obviously, we want to have better access to cardiovascular care. You mentioned it is a cardiovascular issue. Heart issues are the No. 1 killer, not only in the U.S. but the world. Improved intervention and access to test people to find out if they are at risk for one of these problems is certainly admirable.

Will the Department of Health and Human Services (DHHS) implement the study? I assume it may be a budget issue for DHHS to cover the cost of that study.

CHAIR DOÑATE:
The way the Legislature is structured, each Chamber gets a certain allocation of studies they want which requires a commission, et cetera. An alternative is to direct the Joint Interim Standing Committee on Health and Human Services, which the Senate will chair during the Interim, to take on this consideration.

I asked the bill sponsors to provide additional specifics about their intended legislation, like turning it into a bill draft request for the next Legislative Session. We do have to consider that, but usually it is taking on the ownership of the Standing Committee and the staff.

MR. ROBBINS:
This bill will have to go to the Joint Interim Standing Committee on Health and Human Services. If the Legislature directs the Executive Branch to do something, then it would have to be in a regular bill, not a concurrent resolution. This will be in the Joint Interim Standing Committee.

KATIE RYAN (Dignity Health-St. Rose Dominican):
We are a GWTG member, and we support S.C.R. 5. I am also a member of the AHA's Advocacy Committee.

MS. COOPER:
I am aged 62 and was diagnosed with a heart condition. It took a couple of years to figure out my condition. I want this bill to go forward, especially for

those who have hereditary heart disease. I am not sure how long I am going to be around, but it is important to continue research on this, especially if it is hereditary.

People who have hereditary heart disease, like me, wait several years to get a diagnosis. The health insurance was not covering a lot of the cost. I am now in a battle with my insurance company and am changing insurance to get my treatment. This bill needs to pass.

P.J. BELANGER:
I am certified as a health and wellness educator, and in kinesiology. I have been studying natural healing since I was 16 years old, and I am now 60 years old. I have been battling autoimmune diseases my entire life, one of which is causing problems to my heart. I am dealing with Graves' disease and goiters on my thyroid. In 2019, I survived two heart attacks.

I strongly support this bill. If I had known prior to 2019 that the autoimmune diseases would affect my heart, I could have prevented the heart attacks. I should note that the first heart attack was medical trauma-induced during a colonoscopy. However, the second heart attack was not. I support this bill because I am dealing with A-fib after surviving the heart attacks. It is important to know not only what is going on with my heart but what lifestyle changes I can make to thwart any future problems. As a nutritionist and a natural healing educator, I was excited to hear the explanation in the presentation. Education is a big part of the equation.

MATTHEW WILKIE:
I am a 13-year local area pharmacy professional. I am in full support of S.C.R. 5 which urges State agencies to expand comprehensive cardiovascular screening programs. As we all know and have heard, cardiovascular disease is the leading cause of death in the U.S. It is crucial that we take proactive steps to identify patients at risk of cardiovascular events. Earlier, I applauded this resolution and urge the Committee to pass it.

CHAIR DOÑATE:
We will close the hearing on S.C.R. 5 and open the hearing on A.B. 188.

ASSEMBLY BILL 188: Revises provisions governing investigational treatments. (BDR 40-567)

ASSEMBLYWOMAN HEIDI KASAMA (Assembly District No. 2):
I am honored to present A.B. 188 along with my colleagues. It is a critical expansion of existing right-to-try laws. This bill seeks to address the pressing issue faced by patients diagnosed with life-threatening diseases or conditions who have exhausted all approved treatment options.

The Right To Try Act, both at the federal and state level, has long provided these patients with the opportunity to access investigational treatments. However, it is now time to evolve and adapt the law to the changing landscape of medical innovation. As we stand here today, advances in medical technology have led to the development of personalized treatments based on an individual's genetic information. These treatments are becoming increasingly vital for patients with rare and ultrarare diseases, who have been left with no other options.

Unfortunately, the FDA regulations are not well suited to handle these cutting-edge personalized treatments. They often act as a barrier to lifesaving medications that patients desperately need. It is our responsibility to address these shortcomings and create a more flexible, patient-centric regulatory framework. Assembly Bill 188 represents a significant step in the right direction.

By building upon the success of right-to-try laws, this bill aims to foster an environment that gives access to the latest cutting-edge technologies. It enables patients to access therapies specifically tailored to their genetics. Across the Country, patients facing terminal illness have been able to access treatments that have undergone basic FDA safety evaluations but have not yet been fully approved. This is all thanks to the right-to-try laws. These laws have improved and saved the lives of individuals suffering from illnesses such as cancer, amyotrophic lateral sclerosis (ALS) and COVID-19.

Medical innovation is rapidly outpacing regulations established decades ago for a different era of medicine. The FDA approval process was not designed with individualized treatments in mind. As such, it can take an unacceptable amount of time for these lifesaving medications to reach these patients.

In conclusion, as lawmakers, we need to recognize and adapt to the evolving landscape of medical treatments. We need to expand the right-to-try laws. Through A.B. 188, we can ensure that patients in dire need have access to the most advanced personalized treatments available without being hindered by

outdated regulations. Let us put patients first allowing them the right to try and fight for their lives.

SENATOR MARILYN DONDERO LOOP (Senatorial District No. 8):
I am honored to be here to present A.B. 188. Today, I want to express my sincerest gratitude to the tireless efforts and unwavering dedication that has been poured into this bill. It is a significant milestone in our ongoing journey to adapt and evolve the law to meet the changing landscape of medical innovations. By fostering an environment that provides access to cutting-edge treatments tailored to an individual's genetics, we can offer hope to those with rare and ultrarare diseases who have been left with no other options.

I did the multiple sclerosis bill, and it is one of the diseases that needs other options. I would also like to thank everyone involved for their hard work and dedication. I am honored to be a part of this effort. I am confident that our collective resolve will propel A.B. 188 toward success.

I have known Annette Whittemore, who is in the audience, for a long time. I trust her rare and unusual concern for those with other diseases. She has spent a lifetime working for people who need these treatments to get better or to live with their disease

NAOMI LOPEZ (Vice President for Healthcare Policy, Goldwater Institute):
I am grateful for the opportunity to present on this critical issue. It is protecting a person's right to try and save one's own life without first begging the federal government for that permission. I will briefly present an overview of the bill and the proposed amendment (Exhibit F).

Imagine a scenario where there is a revolutionary treatment for a rare disease. It is tailored to your own genetic profile. It offers you a glimmer of hope; however, you are unable to access it despite your doctor's recommendation. It is all due to outdated federal regulations hindering the approval of such a groundbreaking genetic treatment.

Nevada has a golden opportunity to spearhead change and save lives. In 2015, the State approved its original right-to-try law. Now it can advocate for new legislation called right to try for individualized treatments. The federal barriers to lifesaving treatments are real. Nevada has already demonstrated leadership with its 2015 Right To Try Act, when it granted patients the right to seek treatments

deemed safe enough for clinical trials. In 2018, the Right To Try Act was signed into federal law and remains in force today.

We have an important opportunity to provide a new pathway to accommodate today's rapid advancements in medicine, such as gene therapy. This type of advancement is not covered by the original law and needs the passage of the right to try for individualized treatments. This proposal does not alter the function or future success of the original right-to-try law. Instead, it establishes a new, secure and physician-directed pathway for those patients with rare and ultrarare diseases. It is for those who lack treatment options in clinical trials and whose doctor is recommending a personalized treatment.

Under this proposed legislation, patients may seek the recommended treatment from a facility operating under the Federalwide Assurance (FWA) for the protection of human subjects which ensures compliance with federal laws and regulations governing human subjects in research. This well-established system offers additional safeguards for patients. Nevada can continue to lead in providing the right treatment to the right patient at the right time.

Assembly Bill 188 removes government red tape which limits patients under their doctor's care who are seeking modern treatment options. Patient safety and informed consent are ensured without additional taxpayer investment. Nevada lawmakers possess the authority and the legislative vehicle to harness today's potential medical innovations that would further benefit patients.

Exhibit F was drafted by Senator Doñate and Assemblywoman Kasama. It is a preamble to establish the importance of doctors adhering to federal regulations regarding informed consent in health care. It aims to promote ethical research practices, protect patient autonomy and foster transparent and trustful relationships between doctors and patients. The original right-to-try adherence to these important principles allows the law to work and be successful.

Patients who would qualify for the right to try for individualized treatment would need to meet several criteria. The patient is someone who has been diagnosed with a life-threatening or severely debilitating illness. He or she would have considered approved treatment options and have a recommendation for an investigative individualized treatment from the physician. The patient would be provided a written informed consent regarding the risks associated with taking this investigational treatment.

The treatments available under this law are not specified in the law. Rather, it must be investigational and individualized to the specific patient. The treatment must be based on an analysis of the patient's genomic sequence, human chromosomes, gene products, enzymes, et cetera. There are multiple layers of protection for patients under this law. The facility has to be operating under the FWA regulated by the U.S. Department of Health and Human Services (USDHHS). These regulations have been in place for decades are effective and working.

No one is compelled to participate. A physician is not required to provide a recommendation. A manufacturer or researcher is not required to create a treatment. The patient is not required to participate. The Institutional Review Board (IRB) of the facility holding an FWA has complete authority to reject a proposed treatment. However, if the facility does allow it, then it will be required to monitor the treatment. At its discretion, the facility can halt the treatment.

No one is compelled to pay for these treatments. Under the original right-to-try law, private and government payers have paid for right-to-try treatments, but it is not a requirement. Payment is done at the discretion of the payer on a case-by-case basis.

This bill has some liability protections. As in the original right-to-try law, it requires compliance with the law as well as good faith. Nothing would undermine the Board of Medical Examiners or stop negligence or bad faith behavior. As State lawmakers, you have the authority and the responsibility to provide additional avenues for treatment. There are no moon shots for rare and ultrarare diseases, but you can provide that for patients.

SENATOR JAMES OHRENSCHALL (Senatorial District No. 21):
I speak in support of this legislation. I was looking back at the minutes from 2015, when the right to try was considered by this Legislature. It had bipartisan cosponsors and passed nearly unanimously in both Houses. Since the original bill passed, it has helped our constituents. If S.B. 188 passes, it will help other constituents.

A few days ago, I heard a story on National Public Radio about a disease called Duchenne muscular dystrophy. A new drug with gene therapy has proven to be promising and effective. There was an eight-to-six vote a few days ago to

recommend FDA approval. However, approval is not guaranteed. This is a good example of when we could help our constituents because sometimes the FDA moves more slowly than we would hope. There could be effective treatments helpful to Nevadans. In some cases, it could be lifesaving. This bill will help our constituents have that opportunity.

Often, we have Nevadans with serious illnesses, and they travel to centers of excellence in other states to get on a trial. It would be beneficial if they could stay here with their providers and receive the same opportunity. I would ask the Committee to consider A.B. 188.

SENATOR STONE:
This bill provides hope, and it will save some lives. In my prior stint as a legislator in the state to the west of us, I was coauthor of basically the same bill. It took a couple attempts to get it through, but it was signed into law. I am excited that you are here today to present this bill.

Many times, when a drug is being investigated by the FDA, it finds other uses for that drug. For example, when sulfa drugs were being investigated, the FDA found a side effect was lowering blood sugar. It brought out an entirely new class of drugs called sulfonylureas to treat type 2 diabetes. Assuming this bill becomes law, will it allow for the off-label use of drugs being investigated—and drugs being approved by the FDA—for individualized treatment as a physician sees fit for that patient?

MS. LOPEZ:
The off-label issue is a bit separate. Both Arizona and Tennessee have passed legislation allowing for truthful sharing of scientific information with payers, patients and insurers. Off-label use has been allowed in right-to-try cases. Epitopoietic Research Corporation, or ERC, is a company that has developed a treatment for glioblastoma. The treatment has been in the right-to-try program and seemed more effective in lengthening the life span of these patients over the regular Phase II trial. That treatment is being considered by the European Medicines Agency. The right-to-try program, which included an off-label use of a drug, was included in the cocktail for those glioblastoma patients, and the outcomes were much stronger.

This bill does not specifically address off-label use. However, if the provisions of this bill are met in terms of the creation of the individualized treatment, and for

example a cocktail added to this treatment, then it would be allowed. This is already allowed under the right-to-try federal law.

SENATOR STONE:
Thank you for your response. With the mention of gene therapy and looking at a person's genome and gene replacements, it means the technology is going to take us to places that will cure a lot of diseases. I hope this happens in my lifetime; but certainly, it will happen in my children's or grandchildren's lifetimes.

I am excited about this bill, and I applaud you for bringing it forward. If possible, I would love to be added to this bill.

ASSEMBLYWOMAN KASAMA:
I would be honored to have you added to this bill. If staff could note that Senator Lisa Krasner also requested to be added, we can include both of you.

CHAIR DOÑATE:
The amendment was part of my recommendation. It is not a full amendment to the bill because amendments may come during the hearing. In terms of the bill language, the first thing that caught my eye was in section 2 of the bill. It establishes the provision that a "manufacturer of an investigational drug, biological product or device may provide or make available." Then it strikes out the word "terminal" and adds "life-threatening or severely debilitating disease." What is the rationale for changing the wording?

MS. LOPEZ:
The change was made to be consistent with federal right-to-try laws that use the term life-threatening.

CHAIR DOÑATE:
There is a national debate on this topic. We have people with a terminal disease, diagnosed to have so much time left. We have people with a life-threatening disease, and we could save their lives based on their situations. We also have a segment of those with a debilitating disease.

Most of the debate is in the debilitating part because of concerns on how much is too much. An example would be diabetes. Is that considered a debilitating disease?

MS. LOPEZ:
The word terminal is more commonly used in the insurance realm. Of course, it is used medically but mainly for insurance purposes. The word life-threatening is more expansive, and it includes diseases. Examples are Alzheimer's disease, Parkinson's disease, ALS and Duchenne muscular dystrophy. It is a broader term than just six months left to live.

The term severely debilitating is something that cannot be reversed. It applies to many illnesses where there is no chance of restoring the patient's health. Examples are motor function, intellectual function and loss of limbs. The term severely debilitating is used in federal law, medical literature and the medical community.

This law gives an IRB in the facilities with the FWA, as well as physicians, the latitude to determine what is, in fact, severely debilitating. This should not be left to me or lawmakers since we are not medical professionals. It should be left to those patients who are facing these grave illnesses, the IRB and the physicians. The Boards would have to approve and oversee the treatment. In addition, the Board would need to confirm the physician's attestation that the patient is facing a severely debilitating or life-threatening illness.

CHAIR DOÑATE:
To what extent is debilitating? Under this bill, could diabetes be considered severely debilitating?

MS. LOPEZ:
I do not believe there is a lot of controversy or discussion nationally on these definitions. There is not a list of severely debilitating illnesses. However, patients are facing severely debilitating illnesses with certain irreversible symptoms. For example, a patient who was diagnosed with borderline diabetes would not be eligible for the right to try for individualized treatments.

I am not a physician and do not have a medical background or training. The law was crafted so people with a medical background make those decisions.

CHAIR DOÑATE:
What about something like chronic pain? Would that be considered severely debilitating?

MS. LOPEZ:
Universally, chronic pain is not viewed as a severely debilitating illness. However, if a physician treats a patient who could attest to that, he or she could go to a qualified facility, researcher or company to seek treatment.

The decision is not left in the hands of any of us but in the hands of medical providers caring for their patients and the IRB that operates within these facilities. The facility would be under an active FWA.

CHAIR DOÑATE:
I work in healthcare settings, as many of our Committee members do. We always think about the unintended consequences of these policies. We find ourselves in the unusual position where we want to make sure patients have access to care, but it could be a market for bad actors with unintended consequences. We want to make sure that consumer protections are in place.

One of the national articles about the right-to-try laws stated that on its face, it seems as though the right to try would streamline the process and make it easier for patients. However, the FDA approves almost all requests for investigational treatments received through its long-standing expanded access pathways. Has that conversation come up nationally? What would be your response?

MS. LOPEZ:
We did hear those arguments just before the right to try became a federal law. Enormous time and effort and stakeholder processes went into developing the rules and regulations around the federal right-to-try law. It was done thoughtfully and carefully. Since right to try became federal law, it has become more common and is being used. It is successful.

That was several years ago, and we are not seeing those concerns any longer. We want to make sure patients are protected. That is why we have several layers of protection for patients in this bill. We want to ensure that the right patient gets the right treatment at the right time.

A lot of patients do not have options in our Country. These patients are going overseas for effective treatments. Others are going to Tijuana, which is unfortunate. We do not believe the same level of care is given to patients in Mexico. When we look at the FDA process, the individualized treatments are

usually outside of the scope for rare and ultrarare disease patients. There is not an effective timely process under the FDA.

In part, this is the reason we use the USDHHS protections for human research subjects. We use the FWA because of its superior patient protection and treatment in a timely manner. Treatments for rare and ultrarare diseases do not have clinical trials and, in many cases, no commercialized product. There are not enough people for a trial. We are talking about a lot of cases where there is no commercial interest. It is not that the researchers and scientists do not care about the patients; it is just not feasible. We are establishing a new pathway separate from the FDA because there are no clinical trials for these diseases.

We hear a lot about moon shots and warp speed. For approximately 30 million rare and ultrarare disease patients, this does not exist. However, this is your opportunity to create a moon shot for these patients.

The Riley family in Phoenix, Arizona, was the inspiration for this bill. They have three daughters. When their second daughter, Olivia, was a toddler, she started regressing both physically and mentally. It took them a long time to get the clinical diagnosis, metachromatic leukodystrophy. In Italy, there was a promising gene therapy treatment. One of their state senators called me to find out if the treatment was an option in this Country. I responded it was not, and there are no clinical trials for it. Only Italy was performing the research.

Since it is genetic, they had their newborn baby tested, and she was also positive for this disease. The Italian gene therapy treatment is only effective before symptoms appear. In a couple of months during the COVID-19 pandemic, the family had to raise hundreds of thousands of dollars and relocate to Italy for several months. Their baby daughter received the treatment, and she turned three in January. Sadly, Olivia was already showing symptoms and is now in hospice care.

This is why A.B. 188 is a moon shot for these patients.

CHAIR DOÑATE:
I had the chance to review a few of the documents that the Goldwater Institute distributed. One of the documents stated that "the FDA is often standing between patients and their treatments." In some cases, it stands in the way of alleviating symptoms or providing a potential cure for patients.

Arguments against the policy reports your company released are complaints for the length of time it takes to bring a drug to market or to get access to the drug via the expanded access program. Nationally, a person can receive the drug within 30 days, if needed. We have to find a balance for patients needing a drug in a short time span due to life-threatening or terminal illnesses. Patients should have access to informed consent and the ability to comprehend what is in front of them.

However, we do have a larger liability question. What happens if we pass this bill and give patients access to these medications. Then the FDA says people should not take this medication because it is doing more harm than good. It would take over due to a federal provision in place. If we pass this law, does it prevent the federal government or FDA from stepping in? How are other states reacting?

MS. LOPEZ:
The FDA does have an expanded access program and a compassionate use program. The time required for getting an application to the FDA when its clock starts is significant. There have been cases where the FDA tried to override the medical recommendation on dosage. For example, a case in Texas was rejected for the expanded access program. Although it was a state law, it was before federal law had passed. The basis for the rejection was that the FDA did not need any additional data. These were patients facing neuroendocrine cancer. The provider had a treatment waiting for the final FDA green light. His patients had to travel to Germany for the treatment. One patient was a veteran who mortgaged his house to save his life.

The FDA statistics are based on when its clock starts and cases where it asks that the application be rescinded. I would question that level of tracking. The right-to-try movement has created some improvements in the FDA process. We think that has sped up and are aware of some positive reforms in that area.

Individualized treatments are not treatments evaluated by the FDA. For example, a young woman named Jaci Hermstad lost her identical twin sister, Alex, when they were 17 years old. Alex passed away from childhood ALS, and Jaci was facing her own fight against this cruel and debilitating disease. The doctors and medical researchers caring for her created an individualized treatment just for her. They were in a race against time because her disease was causing her to regress physically and mentally. The FDA process was taking a long time, and

she was losing her mobility. Her breathing was being affected, like others, she ended up relying on manual means to breathe. Time was running out when U.S. Representative Steve King and Speaker of the House Nancy Pelosi teamed up to run a private bill to grant Jaci permission to move forward and access treatment.

Before the bill passed, the FDA relented and granted Jaci access. It might seem like a rare political alliance with these two lawmakers working together across the political aisle, but it is not all that surprising. When one considers they were serving patients under a qualified doctor's care, it was just good policy. Jaci's doctors saw improvement when she finally got access. However, by the time it was approved for access, her disease had progressed too far, and she passed away in 2020.

The treatment pioneered by Jaci is now in Phase III clinical trials. The right to try for individualized treatments will allow families like Jaci's to have a safe expedited pathway that you can create and allow in Nevada. Patients will no longer have to beg the federal government for permission to seek treatment.

CHAIR DOÑATE:
I will go ahead and allow our Legal Counsel to reply on the FDA procedure versus the case of liability, et cetera.

MR. ROBBINS:
It is important to recognize that State law cannot trump federal law. Something done under this bill will not prohibit the federal government from coming in if it violates federal law. It has the authority to enforce the federal law. However, the federal government cannot force a state to enforce federal law.

Federal right-to-try laws are not as broad as what we have in this bill. If something done was within the scope of the federal right-to-try law, FDA enforcement would not occur. It would be legal under federal law.

CHAIR DOÑATE:
I fear that by enabling this type of legislation, there could be unintended consequences or a market that could exist by enabling this type of legislation. Does the bill have any provisions to monitor outside of the IRB for a particular institution? Would the State have some level of oversight to track patients receiving these drugs and some level of surveillance? Does that exist in the bill

right now? I did not see it and wanted to make sure it does. How have other states enacted something similar in which they track the patients.

MS. LOPEZ:
Your fear of bad actors is completely legitimate. In response to this concern, we took great care and many steps by engaging with stakeholders. We want to ensure multiple layers of patient protections. Under this law, we are using regulations from the USDHHS Federalwide Assurance.

The way protection for human subjects and research works is they can fall under the FDA, the USDHHS or be exempt entirely. We decided to use USDHHS regulations for a variety of reasons. Although I am not an attorney, federal law provides a floor for individual protections. State laws can go beyond federal constitutional protections. We are using the right to try to save one's own life, individual liberty and medical autonomy. This is in conjunction with State legislation and State constitutional protections.

To advance this law, we learned from the Texas right-to-try law. From my earlier example, the provider who treated almost 180 patients under the Texas law knew of a possibility the FDA may react. The provider had a treatment under clinical investigation by the FDA, and he was waiting for the final FDA green light. The FDA did not react.

We contend that the FDA does not have jurisdiction over what is deemed an individualized treatment given state laws as well as state constitutional protections. These are arcane and detailed items. The bills drafted are concise and specific. Do you rely on prior court precedents?

CHAIR DOÑATE:
Are there any requirements? I am referencing arguments made nationally. States passed this law, but there is no tracking mechanism of these patients and how many have gone through an investigational drug treatment program.

I do not see it in the bill. Are there any Statewide reporting mechanisms? Did you consider if an institution prescribes this medication, it should report the names, the drugs prescribed and the time line, et cetera to perhaps the Board of Medical Examiners or the State Board of Osteopathic Medicine? I am asking what those conversations have been.

MS. LOPEZ:
There are no requirements that treatments be reported to the State. There are a lot of requirements that the IRB continuously and closely monitor treatment throughout the entire process. The IRB has the power, authority and requirement to end treatment if they are concerned. Nothing requires IRB approval in the first place.

To answer your questions on bad actors, this is why we use the FWA. There are not ways to get out of the FWA when compared to some of the human protections for research under the FDA. Those are more arcane laws, rules and regulations. This approach has multiple layers of protection and has been effective for decades. It is more stringent and carefully crafted than anything else available.

CHAIR DOÑATE:
I understand that perhaps the federal government does not respond as fast as we need under provisions in place for certain patients, especially for those with a debilitating disease. We can explore this avenue.

However, I have grave concern with a bill that does not have requirements or reporting mechanisms back to the State. We need to surveil and monitor as to how these program initiatives are progressing. If we remove requirements that the FDA had overseen before, an infrastructure should be in place to monitor Statewide. I do not trust the IRB process or the informed consent process. It does not consider if the patient understands what he or she is getting delivered.

If patients have a debilitating disease, they take medication that can change the trajectory of their illness. There are ethical questions as to what occurs if you are in that scenario. Part of my recommendation on the proposed amendment was to preserve informed consent. We need to make sure the patients understand their rights that they have. They need to comprehend it and be provided in a language they understand. They are given an inherent right because now we are removing the FDA authorization. If patients participate in this program, then they need to understand the full risks from some treatment programs.

Patients should be provided scenarios that could occur based on what the providers know from other patients. For example, patients could be told if they have symptoms like heart racing when taking this medication, they should call

their physician or an around-the-clock hotline. We would need to have some level of trust or at least consumer protection for these patients.

It is important for the Board of Medical Examiners (BME) to have some level of authority as to how this is being regulated. Is one a tradeoff for the other? If we are not getting it quick enough, then we must find some infrastructure to develop it properly in the State.

SENATOR STONE:
Thank you Chair, you have brought up some valid points. I want to inform people on the FDA process for a new drug application. It takes a year or two to get the application submitted. Then it is years of studies for the FDA to prove efficacy and safety. Typically, safety is the first thing it studies.

When someone submits an investigational drug, it likely has gone through the process to some degree. I imagine that if it qualifies as an investigational drug, the advice of a physician who studied the drug pharmacology would be followed. This physician has consulted with the drug company that is codifying the doctor's intended use. This assumes the patients' reactions to the drugs would be reported to the drug company. Is that correct?

MS. LOPEZ:
I would like to clarify that individualized treatments of this kind do not fall under the purview of the FDA. These are not in clinical trial or Phase I, II or III. For the most part, we are talking about treatments unlikely to be a clinical trial because it does not have enough patients or will not be commercialized.

Created many decades ago, the FDA process was intended to create treatments for large populations. We are now in a different era of medicine. We are not using 1950s medication, but we are still using a regulatory process based on 1950s medicine. When we are talking about the right to try for individualized treatments, we are talking about a treatment especially for that individual patient. For example, it is based on his or her own genetic material made specifically for the person. There is no process for this kind of medicine.

Several weeks ago, a senior FDA official admitted during a national conference that a lot of new drug applications were pending with only minor administrative problems. However, the FDA did not have the capacity to clear applications because it did not have the capacity for additional remote meetings.

This is when the medicine is moving faster than the regulatory process. We do have ways of protecting patients. As I mentioned, we have the FDA approach and the USDHHS approach. The latter has a robust and stringent regulatory process governing the protection of human subjects and research. We are using the federal law that USDHHS has to protect patients. Many cases of treatments on human subjects do not fall under either. We want to avoid that situation and be where the strongest protections would apply. This is how we created A.B. 188.

SENATOR STONE:
Obviously, a patient will be informed of risks associated with taking a non-FDA-approved drug, which should be spelled out. The physician and the drug company will be held harmless if anything happens to that patient. I do not see any lack of documentation giving a patient the full story about the treatment and the risk of taking it.

When patients have been told they are terminal and have used all conventional therapies, then to me it is worth taking the risk. Especially if their physician has an idea that can save their life. I do not have a problem if it gets reported to the State. Patients and their families do not care about the reporting process. They only care about getting access to that drug. It may be the silver bullet to save the patient's life. Therefore, this bill is one to support.

SENATOR TITUS:
I see a misconception about what this bill is doing. When Senator Stone was in pharmaceutical school and I was in medical school, we had evidence of a clinical trial on 10,000 nurses who took the birth control pill and ended up with breast cancer. It required 10,000 patients to do that trial.

We have to change our mindset when we think about individualized treatment. There will not be a study of 10 people or 100 people because everybody's genetics are unique. A person has biological markers with a single treatment plan for that person. Although I share Senator Doñate's concern about accountability, we cannot have the setting where you treat ten patients with X drug and nine people improve. That is not how this works.

If I am hearing this correctly, the science is moving toward treating people based on their own unique genetics and the disease process they have. I have learned in my 40 years of practicing medicine that everyone responds differently

to a medication, even those that had a 10,000-person trial. Some of it works, and some of it does not; this is due to the patient's genetics. We need to start looking at a patient's genetics and make a treatment plan accordingly. I am supportive of this concept because it is something we need to do.

When it comes to accountability, the company and its products need some consistency on how you make a diagnosis. A provider may have 100 patients and the doctor formulates a plan for each patient. We need some accountability because what happens if no one improves or suddenly dies within a week of seeing the provider? Obviously, there is an issue. People who are desperate will do anything to improve their health. As Senator Doñate asked, how do we handle quackery with people doing online advertising that claims they can save a patient?

We need some reassurance that patients have an informed consent model and they truly understand the treatment is unique to them. Correct me if I am wrong about this. We need to ensure patient protection where the provider has a signed document that the patient understands. There is no other model to use. How are the results recorded to determine the success of the entire concept? How do you report it? What is the accountability piece of how successful you are? Anecdotal patient testimonies are sometimes subjective.

MS. LOPEZ:
You are correct that we are in a new era of medicine and innovation is happening fast. The U.S. is losing ground to countries like Germany and Japan. For example, in Germany, peptide vaccines are now normal. Japan has regenerative treatments receiving provisional approval after being in Phase I for seven years. United States patients do not have access to these treatments, and it puts them in a vulnerable position. They have to go to Tijuana for gene therapy or Mexico for their child's brain cancer treatment. We need to recognize that if Nevada does not create safe protected pathways for patients, then we are putting them at even more risk. Nevadans are under your authority due to State law when you pass these types of bills.

As far as tracking treatments and outcomes, it is important to point out that the original right-to-try law had a lot of discussions about this. These are not trials but individualized treatments. Under the original right-to-try law, the federal law requires reporting. However, the rules for federal reporting were approved in 2019, one year after the bill was signed into law. We did not receive the rules

until this past fall. The right to try has been occurring for years without the reporting requirements. In compliance with the final rules, no outcome data is required because these are not trials.

Treatments exist for patients who do not meet the inclusion criteria for a trial or are too sick to participate. These are patients to whom the value of the clinical data is not the same as an actual trial. Therefore, under the federal law and the final rules promulgated this past fall, there are no outcome requirements. Assembly Bill 188, the right to try for individualized treatment, uses the same approach. The IRB has the responsibility and the obligation to closely monitor these treatments, ensuring they are carried out in the manner as planned or shutting them down under its authority.

We are talking about a small number of treatments overall. The value of data from multiple sites is likely to be zero. These are individualized treatments for different diseases. For example, an individual treatment for a rare cancer could have 300 mutations. Once the genetic information is received, it may be 300 to the three-hundredth power.

The FWA rules in place for decades have worked incredibly well. Given it has been around for years, we can have a lot of trust in it. The USDHHS has created informed consent requirements. It is strict, and the IRB reviews them. The informed consent must be done in the language that patients or their agents understand. The right to try was turned into federal law because of the strict protections in the original law.

The right to try for individualized treatments will not be successful without strict protocols and informed consent to make sure patients know the risks and possible outcome. We went to great lengths to ensure this bill will be successful. We want patients to be protected. We want this to ultimately be the law of the land. I am confident we have protections in this bill. I would not want to have it any other way.

ASSEMBLYWOMAN KASAMA:
This legislation has a whole section on informed consent, and the bill adds individualized treatments. Section 2 provides specific information on the outcomes and changes in your treatment or your health. There is a whole section in the bill about informed consent. In 2015, this was already established when the original bill passed.

SENATOR TITUS:
I have been on the BME in the past and part of an investigative team. I am still the county health officer for our county. Public health is an issue. While I was still on the BME, Clark County had an event where a gastroenterologist was performing simple colonoscopies. However, the medical team was not using all the proper protocol, and a number of patients got hepatitis. Having a regulatory process in place allowed us to investigate and identify the number and names of patients exposed.

I want to verify the reporting process since providers will use a variety of treatments. There can be adverse outcomes apart from the original disease process itself. I want to ensure adequate monitoring of these establishments in case there is an outbreak of whatever. Things can happen with the processes. We need the ability to make sure patients are protected.

CHAIR DOÑATE:
We have touched on a lot of concerns held nationally. We discussed informed consent and cases of patients having a limited understanding. The informed consent language in the bill needs to be part of a standard preamble. It would need to be simplified in a one-page document that could be translated into any language. The form should be in the appropriate language the patients understand and at their reading level.

Health literacy matters. For example, given my education level, I understand the word comprehension. Others who did not graduate from high school or finish middle school, like my father, have a different circumstance, especially when it is translated into another language. The consent form needs to have an appropriate reading level for the patient. Public health uses the reading level of an eighth grader. In addition, it needs to be in the appropriate language.

The bill needs some provisions for accountability and tracking. It should at least be reported to the BME or the State Board of Osteopathic Medicine. We should have some level of regulations on how these drugs will be rolled out. My preference is to use the word terminal in lieu of life-threatening. I would ask you to have an offline discussion with other Committee members on these terms. If we need to come back and expand it, then we can consider it at that time.

Other states that have passed this legislation have discussed the consequences of this legislation. Today, we questioned what will happen if we pass the bill.

I am concerned this lowers the trust we have in the FDA approval process. We have the approval process for a reason. I understand the individualized aspects, especially as messenger RNA technology comes out and these drugs could potentially implement lifesaving technologies.

We need to question health insurance coverage, which was not raised today. For example, a patient goes to the hospital because of taking medication believing it would save his or her life. In the end, the patient's health is worse than before the medication. How does that interact with patient insurance, et cetera?

In hindsight, a lot of factors exist in health care. Some were introduced in other bills, specifically Senate Bill (S.B.) 203 that looks at the motivations of bad actors in health care. No provision in place right now protects against them.

SENATE BILL 203 (1st Reprint): Prohibits certain gifts by a manufacturer or wholesaler of drugs or medical devices to a practitioner. (BDR 54-50)

The easiest way to do it is to limit this bill only to research facilities in the State and reverse the wording back to terminal from life-threatening. We need to make changes to informed consent, add a reporting mechanism to the appropriate governing body and establish regulations. Then we can see how it goes. We need to have information on patients whose lives were saved and the technologies implemented. I can see both sides, but we need to avoid unintended consequences and protect patients. Those are my recommendations for changes in case this bill gets a work session.

HIDETO PETER KASAMA:
Based on my own experience, I am here to testify in support of this bill. About a year ago, I was diagnosed with stage IV stomach cancer. The tumor was almost an inch thick. The first oncologist was from the old school of thought and was not open to new methods or new treatment technologies. We felt that based on some of the mistakes he made that this was not the place to be, so we searched for a new oncologist. My wife worked hard to find one, and I am glad that she did. Otherwise, I would not be here today to give this testimony.

I went to Dr. Rupesh Parikh at Comprehensive Cancer Centers. He immediately told me that we need to incorporate immunotherapy along with the chemotherapy. The first two or three chemotherapy sessions were hard on me.

I could not do anything for almost a week after a treatment. One of the side effects was loss of appetite, and I lost 35 pounds. I am not a big guy, so the weight loss was serious.

My doctor told me to see a surgeon to remove the tumor surgically. I made an appointment and, after reading my file, the surgeon told me not to do the surgery. She informed me that the tumor was spreading to my liver and lymph nodes. She went on to tell me the tumor was getting darker, which is a clear indication the tumor was spreading out of the stomach. I asked her what I could do. She basically responded that I needed to count my days and make arrangements with hospice. I would be gone in a few months. That was the verdict I received. I was desperate and started drafting a final letter from heaven to my wife. I wanted to survive, and I needed something to give me hope.

A Duke University professor at the Duke Cancer Center Brain Tumor Clinic injecting poliovirus into cancer patients has achieved strong results. Almost ten years ago, a young lady had a brain tumor. At first, the chemotherapy treatments worked, and she was in remission. However, a year later when she was aged 21 it came back with a vengeance, and she was almost dying. I had the same mentality when you have no options. A person will grab at anything to survive.

The young lady went to see this doctor at the Duke Cancer Center Brain Tumor Clinic. They injected her with about a half a tablespoon of a poliovirus. It took six and a half hours to inject it into her brain, and it worked. She is totally free of cancer.

Think of the person in a desperate situation with no options and a prognosis that he or she will be gone in a few months. The doctor gives you a treatment plan, but do you have the technical knowledge or the time to verify the methods? Do you know if it is in the process of a federal investigation? As a patient, I do not care. I just want to try it and see what happens. This is what A.B. 188 is about.

Given the successful application of the poliovirus into the tumor, the FDA gave Duke Cancer Center Brain Tumor Clinic breakthrough designation the following year. They will be able to treat patients on a commercial basis without FDA certification. This is what A.B. 188 is all about. I felt I had no options and wanted to grab something to survive.

Immunotherapy turned things around for me. I started to eat and gained weight and energy. I was able to fight off the cancer. The Duke University professor's theory was that cancer cells create an outer film that the body's immune system cannot penetrate but the poliovirus can. When patients ingest poliovirus, their body thinks it being attacked by polio. It will mobilize a colony of white cells to fight the virus. In the meantime, it also kills the cancer tumor. The patient uses his or her own immune system to fight against the cancer cells. I am in support of this bill.

LISA SANTWER (Comprehensive Cancer Centers of Nevada):
I am here to speak on behalf of Dr. Rupesh Parikh who is Peter Kasama and Helen O'Hanlan's physician. Comprehensive Cancer Centers of Nevada serves thousands of cancer patients in Las Vegas. We support A.B. 188 because it allows or expands individualized investigational treatment for a patient diagnosed with a life-threatening or severely debilitating disease.

New advances in precision medicine are rapidly altering the way physicians diagnose and treat cancer. Availability of biomarker testing, which factors in a patient's genomic and cellular profile, means truly customized treatments are closer than ever before. Based on a patient's genomic and cellular profile, physicians can determine that a treatment for a certain cancer type could be effective in treating an entirely different cancer type. This gives stage IV cancer patients more options to fight their disease and preserve their life.

This is the case with Dr. Parikh's patient, Peter Kasama. I also want to speak directly about another patient of Dr. Parikh's, Helen O'Hanlan, who is here to provide her own testimony. Ms. O'Hanlan is a stage IV granulosa cell tumor cancer patient. When Dr. Parikh first met her, she was out of options. Her type of cancer had only been treated by surgery. Based on Ms. O'Hanlan's tumor makeup, Dr. Parikh and his colleague, Dr. Dan Curtis, met and recommended a treatment called CyberKnife. Even though this treatment had never been used before on her type of cancer, the doctors felt it could work for the eight tumors debilitating her body.

The problem surfaced that CyberKnife was not yet considered a proven treatment for Ms. O'Hanlan's type of cancer. After some convincing, she agreed to the CyberKnife procedure, and to date it has worked miracles. She has had three CyberKnife procedures to eliminate the eight tumors in her body.

However, two weeks ago, we learned Ms. O'Hanlan will need to use it again. Before trying CyberKnife, she has had a dozen surgeries with the last one nearly killing her. We knew CyberKnife had been incredibly effective for a number of conditions locally and throughout the world. The doctors thought it should be looked at through a new lens. Since Ms. O'Hanlan had failed multiple chemotherapy treatments and used CyberKnife, the doctors decided to add in off-label letrozole to see if it could give better control. The combination of CyberKnife and letrozole have worked to keep her disease contained. We have learned from Ms. O'Hanlan that this treatment can work for those with her genetic makeup.

She is a great example of why it is so important for a patient to have the right to try when faced with a stage IV cancer diagnosis. We all have a voice and can generate many more success stories just like Ms. O'Hanlan's with the support of this bill.

HELEN O'HANLAN:
I am a stage IV cancer patient, and I support A.B. 188. I have been fighting cancer for 15 years with the first 8 years in Chicago, Illinois. I have had seven recurrences of stage IV granulosa cell tumor, a rare form of ovarian cancer. I have had 12 surgeries to remove them, 3 different chemotherapies and handfuls of medications. Seven years ago in Chicago, I was told there were no other treatment options. I moved to Las Vegas to be near family and friends for end-of-life care and to essentially die.

In 2017, I returned to Nevada and established care with Dr. Parikh at Comprehensive Cancer Centers of Nevada. Dr. Parikh took over my care and with his colleague radiation oncologist Dr. Dan Curtis, they pioneered a treatment for my rare ovarian cancer called CyberKnife. It is a high-energy X-ray machine that delivers targeted radiation beams to destroy tumor cells. It was going to be pain-free and easy. I wanted to keep fighting, so I did it.

Luckily for me, the doctors were right. I am still a stage IV cancer patient, but I am monitored and tested. We are on top of it and ready to treat my cancer. Since coming to Comprehensive Cancer Centers of Nevada and using CyberKnife, I have gone five years with no tumors. Two weeks ago, we found out I have another tumor. However, we are at a different time. Although CyberKnife is effective, works and is painless, it is not technically approved for my type of cancer. However, I have Dr. Parikh and can get access to it.

There are many people with my type of cancer throughout the Country. They do not have access, and I am sad as I watch them die. I am grateful for my doctors thinking outside the box and pioneering this treatment that works for my rare cancer. I am an example of why it is important to support A.B. 188. Hopefully, this opens doors for many other cancer patients so we can fight.

ANNETTE WHITTEMORE (Whittemore Peterson Institute):
Our Institute is dedicated to individuals impacted by infections associated with chronic diseases, including myalgic encephalomyelitis, commonly known as chronic fatigue syndrome; chronic tick-borne diseases: post-acute Severe Acute Respiratory Syndrome or SARS; and Long COVID.

I support A.B. 188. It has the potential to improve and save lives by allowing individuals to access cutting-edge treatments that might otherwise be unavailable. My late mother-in-law suffered a major stroke days before a new therapy was FDA-approved. I have often wondered if this law had been in place if she would have lived. The doctor stated the clot-busting drug was already on their shelves, but their hands were tied. She died four days later. How many people have died waiting? Are we trying to protect them to death?

We are talking about allowing the use of lifesaving and life-altering treatments in a timely manner. We need to give each one of us the right to make that choice. I want you to consider backing this bill. It ensures patients facing life-threatening or severely disabling diseases a broader access to innovative therapies after exhausting all other options. This bill presents a compassionate and responsible approach to addressing the urgent need of patients. Please support the passage of this legislation.

JOSHUA SMITH:
My brother had acute lymphoblastic leukemia, and he went through three rounds of chemotherapy without success. His tumor had a specific genetic marker that would have allowed a specific therapy. Unfortunately, he could not receive it because of existing laws. My brother did not make it, and I was frustrated by the whole thing.

The heart of this bill is the FDA has no capacity to regulate or approve through any mechanism a targeted therapy for an individual person. A lot of the discussion today was frustrating because it has nothing to do with the FDA.

The FDA does not have the capacity to approve or regulate these treatments. That is why this bill is so important.

I urge you to look at the heart of it. Please understand it is for that one person who cannot go through a clinical trial. It cannot be approved for anything like that. I encourage everybody to look at it and consider passing this bill.

JANET CAMPBELL:
I am in support of A.B. 188. I came to the hearing in March on this bill. I know it has been going on for a long time. All the conversation I heard today, reiterates the fact that all bills are a long process. I am in favor of this bill if anything can be done for rare cases. It should not be what if somebody is not helped, but what if somebody is helped? It is an entirely different thing when a person's last hope is the decision that a doctor or the government makes.

If you need the right verbiage, then you need to do it. We need to get on with the program and give these people some hope and help. Unfortunately, it cannot help my friend who has been diagnosed this year with ALS. Her diagnosis took so long, and it is progressive; therefore, she cannot be helped. She was able to try a few things as were the doctors to see if they could make it work. This is exactly the kind of bill that people like her need. Some of the care or medications she will get can help her end-of-life care. Be more humane.

MS. BELANGER:
I am a prime candidate for what is called ablation treatment. I have goiters on my thyroid that causes my deviated windpipe. I have lots of choking episodes which are life-threatening. The disease itself is not fatal; however, the symptoms are life-threatening. I have been treating and shrinking the goiters all naturally. The medical industry does not offer me anything but being butchered. I am not willing to be butchered so that I can be a slave or a prisoner to the pharmaceutical industry for the rest of my life.

I have done my research. I am a nutritionist by trade and have been doing this for 44 years. I went into natural healing to save myself because I overcame Lupus in my thirties.

If I could get the ablation treatment, I could have been done with this years ago. I would not have these life-threatening choking episodes. I have a deviated windpipe because the goiters are pushing my windpipe over. The ablation

treatment is successful in Italy, Sweden, Germany and other countries. People are getting reduction in goiter size for up to five … (unintelligible statement).

Let us have these trials, experimental or whatever you want to call it in the U.S. If the FDA is doing anything to block these types of things in the U.S., then it needs to be alleviated for people like myself.

JASON GRENINGER:
I support A.B. 188. I have personal experience and empirical data with a person having a reversal of mantle cell lymphoma, which is a non-Hodgkin lymphoma. It had metastasized to her stomach, lungs and neck. She was sent to hospice in her elder years. All the cancer was removed, and she was cured. She was even removed from oxygen at one point.

I worked in surgery for 33 years, including University Medical Center trauma. I was also part of the kidney transplant team and did not think these things were possible. It turns out there are possibilities with some medicines. For example, there is a cannabis suppository treatment taken voluntarily at the time.

Things need to be available to move forward. We can find things that work despite a few charlatans in the world. Please support A.B. 188.

WIZ ROUZARD (Deputy Director, Americans for Prosperity):
I have submitted my written support (Exhibit G) of A.B. 188.

In terms of accountability, Chair Doñate brought up some great questions. The current bill will help us to achieve accountability, and it is a work in progress. It is a first step to achieving it without compromising individuals who are fighting time. They cannot also fight bureaucracy.

Doctors play a significant role in comforting Nevadans in making those types of decisions. We urge you to support this bill.

ASSEMBLYWOMAN KASAMA:
Thank you for allowing me, my cosponsors and all who worked so hard to present this bill. Tomorrow, we will submit our responses to your concerns. Let us not delay and pass this bill during this Session. We did not have opposition testimony. This is the time that we need to help people. We want to make sure

that our regulations are not falling behind the advancements in medicine. This is to keep up with the wonderful advances in medicine.

It is obviously a personal bill for me. Individualized treatments have saved my husband, and we want everybody to have those opportunities.

CHAIR DOÑATE:
I have two documents (Exhibit H) in support of A.B. 188. We will close the hearing on A.B. 188 and move on to the work session. We will begin with A.B. 11.

ASSEMBLY BILL 11 (1st Reprint): Revising provisions governing hospitals. (BDR 40-382)

JENNIFER RUEDY (Policy Analyst):
I have a work session document (Exhibit I) describing the bill.

CHAIR DOÑATE:
I will entertain a motion for this bill.

SENATOR NGUYEN MOVED TO DO PASS A.B. 11.

SENATOR LANGE SECONDED THE MOTION.

SENATOR TITUS:
This bill is well intended; however, it is going to have a dramatic adverse effect on health care in Nevada. We desperately need providers. I will be a no on this bill and will continue to be an advocate to not let this bill pass.

SENATOR STONE:
Nevada has a significant shortage of medical specialists, and many doctors find it challenging to go into private practice. They have to pay rent and handle personnel and malpractice issues. It is easier for them to work at an entity like a hospital. If this bill passes into law, it will limit the number of medical specialists working in Nevada who are employed by hospitals to provide specialized care. I worry this does the opposite of what the bill intended to do. For those reasons, I remain opposed to the bill.

THE MOTION CARRIED. (SENATORS STONE AND TITUS VOTED NO.)

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CHAIR DOÑATE:
Let us move on to A.B. 114.

ASSEMBLY BILL 114 (1st Reprint): Revises provisions governing the Nevada Early Childhood Advisory Council. (BDR 38-788)

MS. RUEDY:
I have a work session document (Exhibit J) describing the bill and its amendments.

CHAIR DOÑATE:
I will entertain a motion for this bill.

SENATOR NGUYEN MOVED TO AMEND AND DO PASS AS AMENDED A.B. 114.

SENATOR TITUS SECONDED THE MOTION.

THE MOTION CARRIED UNANIMOUSLY.

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CHAIR DOÑATE:
Let us move on to A.B. 265.

ASSEMBLY BILL 265 (1st Reprint): Revises provisions relating to mental health. (BDR 39-96)

MS. RUEDY:
I have a work session document (Exhibit K) describing the bill.

CHAIR DOÑATE:
I will entertain a motion for this bill.

SENATOR NGUYEN MOVED TO DO PASS A.B. 265.

SENATOR TITUS SECONDED THE MOTION.

THE MOTION CARRIED UNANIMOUSLY.

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CHAIR DOÑATE:
Let us move on to A.B. 311.

ASSEMBLY BILL 311 (1st Reprint): Revises provisions governing health care. (BDR 40-983)

MS. RUEDY:
I have a work session document (Exhibit L) describing the bill.

CHAIR DOÑATE:
I will entertain a motion for this bill.

SENATOR TITUS MOVED TO DO PASS A.B. 311.

SENATOR STONE SECONDED THE MOTION.

THE MOTION CARRIED UNANIMOUSLY.

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CHAIR DOÑATE:
Hearing no public comment, this meeting is adjourned at 5:57 p.m.

RESPECTFULLY SUBMITTED:

_____
Mary Ashley,
Committee Secretary

APPROVED BY:

_____
Senator Fabian Doñate, Chair

DATE:_____

EXHIBIT SUMMARY				
Bill	**Exhibit Letter**	**Introduced on Minute Report Page No.**	**Witness / Entity**	**Description**
	A	1		Agenda
	B	1		Attendance Roster
A.B. 169	C	3	Assemblywoman Michelle Gorelow	Proposed Amendment 3644
A.B. 169	D	4	Senator Fabian Doñate	Proposed Amendment
A.B. 169	E	7	Senator Fabian Doñate	Three Letters of Support
A.B. 188	F	12	Naomi Lopez/ Goldwater Institute	Proposed Amendment
A.B. 188	G	35	Wiz Rouzard/ Americans for Prosperity	Letter of Support
A.B. 188	H	36	Senator Fabian Doñate	Two Letters of Support
A.B. 11	I	36	Jennifer Ruedy	Work Session Document
A.B. 114	J	37	Jennifer Ruedy	Work Session Document
A.B. 265	K	37	Jennifer Ruedy	Work Session Document
A.B. 311	L	38	Jennifer Ruedy	Work Session Document