

NOVEMBER 30, 2012 Harvest Room – ND State Capital Building – Bismarck, ND

At 10:00 AM on Friday November 30, 2012 Senior Board Member Gary Dewhirst called the Board to Order in the Harvest Room of the State Capital Building located at 200 East Boulevard Ave in Bismarck, North Dakota.

Present were: Gary W. Dewhirst, R.Ph. - Fran Gronberg, Public Member - Diane M. Halvorson, R.Ph.Tech. - Bonnie J Thom, R.Ph. - Gayle D. Ziegler, R.Ph. – Assistant Executive Director Mark J Hardy, PharmD. – David A. Lindel, Jr, Board Attorney

Present by telephone: Shane Wendel, R.Ph.

Absent: Executive Director Howard C. Anderson, Jr, R.Ph. and President Laurel Haroldson due to the death of her mother-in-law

Also present were many members of the public, a sign in sheet was distributed for those to document their attendance.

Pharmacist Gary W. Dewhirst introduced himself as the ND State Board of Pharmacy Senior Member and explained that he would be acting as the Hearing Officer for this Public Rule meeting.

Senior Member Dewhirst announced "It is now 10:00 AM on Friday November 30, 2012 in the Harvest Room of the State Capital Building located at 200 East Boulevard Ave in Bismarck, North Dakota. This Public meeting is to address proposed additions to the North Dakota Administrative Code Article 61-13 Controlled Substances. These proposed additions to NDAC Article 61-13 are intended to be adopted as Emergency Rules. This Public meeting has been called to allow interested individuals an opportunity to submit information and testimony concerning these rules."

North Dakota State Board of Pharmacy Assistant Executive Director Mark J. Hardy, PharmD is taking minutes of this meeting and the hearing is being taped so we do ask that you identify yourself for the record before you speak.

Senior Member Dewhirst gave an overview of the emergency rule making process and indicated that the draft of NDAC Article 61-13 and all necessary documents are available both here at the meeting and on the Board of Pharmacy's website: www.nodakpharmacy.com Assistant Executive Director Hardy gave the reasons and factors to the Members of the Board of Pharmacy that need to be considered if the Board intends to adopt the proposed language as an Emergency Rule.

Senior Member Dewhirst then opened the hearing to public comments.

Attorney General Wayne Stenehjem expressed his support for the emergency rule and asked the Board of Pharmacy to take action to schedule these controlled substances due to the danger to the public that these substances create. He provided the Board with examples of the packages that his agents have seized for viewing. He reported that his office was unaware

of any medical evidence to use these substances. His full written statement is attached to these minutes as Addendum A.

Mr. John Snyder gave an account of the incident surrounding his daughter's experience to these bath salts. Her exposure caused seizures and other medical issues that they are still dealing with. He discussed how she was able to purchase this product from a Mandan business and pointed out that these substances being marketed as "bath salts" need to be taken off the market to address the danger to the public, specifically our young population.

Mr. Snyder's daughter also gave her account of taking the bath salt she purchased. She discussed how she purchased it, with no identification required even though they knew she was underage; indicating that nobody uses these products as incense or bath salts and that the only use that she is aware of is for illicit effects.

Pharmacist Ziegler asked Ms Snyder about the effects she experienced when she ingested the substances. Ms. Snyder explained her first hand effect to the Board Mebers

The mother of Christian Bjerke, who recently passed away due to of 2C-I compound, which he ingested. Mrs. Bjerke discussed the events and complications that lead to her son's death, including that the products lead to high blood pressure and high temperature that lead to eventual organ failure and death. His autopsy indicated only the 2C-I compound in young Mr. Bjerke's blood system. She indicated that often times individuals will use candy as a carrier method for these products. She asked the Board to immediately schedule these products to help prevent future similar tragedies. Christian's father, Keith Bjerke also spoke about his son and the importance of talking to and warning children of these lethal effects. He also discussed treatment and educational methods needed to prevent these deaths in the future. He indicated that we need to go to "war" with those individuals creating and distributing these products.

Public Member Gronberg asked who the chemical companies were that are selling these products. Mr. Bjerke indicated that often these substances are being sold on the internet; imported from over-seas and local hobby chemists are creating their own concoctions.

Senior Member Dewhirst indicated that Mr. Bjerke made a strong case for the Board of Pharmacy to proceed with the adoption of these rules as an emergency measure due to the immediate impact these substances are having on the public.

Dr. Mathew Zimny discussed the impact that he is seeing with patients presenting to the emergency room because of these products. The Board asked him many questions about what he has seen in his practice. He explained how the patient presents and the challenges in treating them because it is difficult to determine what substance they have taken. Dr. Zimny also indicated that there was no medical use for these substances.

Dr. Gordon Leingang reported that he sees much of these illicit spice cannabinoids and bath salts in patients presenting in his emergency setting practice as well. He discussed the complex matter in which the patients will present to the emergency room, and that he saw



STATE OF NORTH DAKOTA
OFFICE OF ATTORNEY GENERAL

ADDENDUM A

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Wayne Stenehjem
ATTORNEY GENERAL

November 15, 2012

My name is Wayne Stenehjem, and I'm Attorney General of North Dakota.

Among other duties, I oversee the ND Bureau of Criminal Investigation, the State Crime Lab, and provide legal representation and certain enforcement assistance for state agencies, including the State Department of Health.

Synthetic drug abuse has exploded in North Dakota over the last four years which presents many unforeseen challenges for law enforcement and prosecutors in the State. In 2011, the Legislature scheduled seven chemical groups of synthetic cannabinoids, which were being sold as "incense," and several synthetic cathinones, which were being sold as "bath salts." These substances were sold as allegedly legal alternatives to controlled substances, and, despite their labels stating the products were "not for human consumption," the substances are smoked, snorted, and ingested for the purpose of getting high.

It is widely, perhaps universally, known that these products are sold solely for the purpose of human consumption and ingestion, and that they have psychoactive and mind altering effects. Some of the newer compounds have never been researched or studied on humans so users are test subjects each time they use one of these substances.

When the chemical groups were scheduled, we thought we had taken care of the problem. However, the manufacturers of these substances changed the chemical structure, making the new substances similar to, but different from, the chemical classes that were controlled.

Law enforcement, prosecutors, and medical providers began seeing the same products, labeled with such names as “New Dimension,” “Spark,” and “100% Pure Evil,” now containing a non-controlled synthetic. Reports were coming in of juveniles overdosing on very small amounts of these substances. People who were smoking these substances were combative with police. Users told police they thought they were having a heart attack; they thought their hearts were going to jump out of their chests. Police have also responded to hospital emergency rooms where users have been foaming at the mouth and incoherent.

In June 2012, in the Grand Forks area, two teenagers died and at least one other overdosed on a synthetic cathinone known as 2C-I with the street name, Smiles. In that case, witnesses described the victims as thrashing about and growling and one of the victims was pounding his head into the ground before he stopped breathing.

Unfortunately, because none of these substances are controlled, the distributors of these drugs cannot be charged with any drug trafficking crimes. We have no way, under state law, of prohibiting these dealers from selling these new substances.

These new substances have fallen through the cracks of our current statutes. In the Grand Forks case of the distribution of 2C-I which resulted in the deaths of the two teenagers, the federal government, through the controlled substance analog statute, was able to charge the distributors of 2C-I with drug trafficking offenses. A controlled substance analog is a chemical which is similar to a controlled substance, but is not itself specifically controlled. Drug Enforcement Administration chemists have confirmed that the new synthetic cannabinoids available since the 2011 legislation, including XLR-11, are analogs of the synthetic cannabinoids that are controlled. North Dakota needs a controlled substance analog statute so law enforcement and prosecutors are able to stop the distribution of substances that are similar to controlled substances, yet different enough to be “legal.”

In or around March of 2012, and on or about July 12, 2012 two North Dakota consumers reported that they purchased one gram of the product for approximately \$20. "New Dimension" has been shown to contain JWH-018, AKB 48 and URB-754, which are known synthetic cannabinoids, with a likely effect similar to those of THC, a cannabinoid naturally present in cannabis. One of the consumers used a pipe to smoke "New Dimension" and reported to law enforcement that smoking the product gives him "a euphoric relief." The second consumer smoked the product in a "joint" and reported to law enforcement that smoking the product gave him a buzz. The second consumer also allowed another person to smoke some of the joint. Shortly after, this person, a 21 year old male, called 911 in distress, breathing heavily and complaining that he felt as if his heart was going to explode, that his heart was racing and that he needed help. Police and ambulance were dispatched and they found him wandering in a field. He appeared distraught and upset and his face was flushed. He was transported by ambulance to the hospital.

The sale of street drug alternatives has had a damaging and serious effect on the public health in North Dakota and elsewhere. Street drug alternatives are known to cause serious health effects, such as agitation, extreme nervousness, nausea, vomiting, tachycardia (fast, racing heartbeat), dangerously elevated blood pressures, tremors and seizures, hallucinations, severe paranoia, and even death. The products also are extremely habit forming and may cause an intense craving to redose. The products often cause extremely violent behavior, which causes users to harm themselves or others. Users often demonstrate extreme strength, with totally irrational behavior and responses. Over the last several years, there has been a dramatic increase in emergency calls and patients being brought to emergency departments with adverse health effects resulting from ingesting or inhaling a street drug alternative of unknown content.

The street drug alternatives are marketed to target people who are experimenting with "legal highs" or who want to get high without risking positive drug test results. The products are well known among

this group of consumers as a product that may allow them to experience a high legally and without detection.

The legality of the street drug alternatives depends on the chemical structure and composition. The substance may have the same or similar effect on the human body as products banned as controlled substances under N.D.C.C. ch. 19-03.1. However, because this structure can be easily and quickly changed, the street drug alternatives avoid illegality, until regulators or the legislature can include them as a controlled substance and ban them, or prove them to be illegal as an “analogue” under 21 U.S.C. §802(32)(A). The street drug alternatives have shown to be even more dangerous and risky than the substances they attempt to mimic. However, they remain legal until they can be identified and banned by law or regulation.

My office has drafted proposed legislation to present to the next session of the legislature, but now I believe we cannot wait even three or four months to respond to this epidemic. Reports that I am receiving from law enforcement, the medical community, and citizens generally, tell me that we have an emergency situation here in North Dakota with these synthetics, and so I’m asking this Board to adopt emergency rules to add these synthetic substances to the Schedule of Controlled Substances.

Thank you.

three patients in the past two weeks present for the third time. The common theme is their severely altered mental status and extreme violence. Senior Member Dewhirst asked Dr. Leingang if these substances fit into Schedule I. Dr. Leingang indicated that he sees no medical use for these substances and that they are very habit forming, so in his opinion yes, they do fit into Schedule I. Pharmacist Thom asked if there were any reasons for not putting them in Schedule I, to which there was no reason given, particularly because there is the no legitimate medical use.

BCI Agent Ben Leingang testified on his perspective on these substances and his experiences in policing individuals that have ingested these substances. He indicated the business that sell the spice cannabinoids and bath salts have a very large influx of individuals purchasing these products. He also discussed the individuals buying these substances and the fact that they are very aggressive in their quest to obtain them. He indicated that they are taking big steps to address this epidemic and they have certainly become the substance of choice for the young adults he encounters.

Charlene Schweitzer, a forensic scientist with the North Dakota Crime Lab testified to the chemical nature of these substances and reported her experiences with the testing of these products. Ms Schweitzer indicated that many of these products come from other countries and are obtained by the individuals ingesting them or distributing them through the internet. She presented the Board two separate billboards showing the chemical structure of these spice cannabinoids and bath salts. She also discussed the ease of changing the core chemical structure to circumvent the current North Dakota Laws. She discussed the current language she assisted the Board of Pharmacy in developing, to schedule these products, based on changes to the core chemical structure that could be made and listing the actual chemicals that have been positively identified in the crime lab. She indicated North Dakota would be the first state to have this comprehensive of a rule to address the rapidly changing products. Board Members asked Ms Schweitzer if she felt the list was comprehensive enough. Ms. Schweitzer indicated that it is hard to predict what other structures they could come up with, but at this time she felt this was as comprehensive a list as possible.

Attorney General Stenehjem also voiced his opinion that the rule is as comprehensive a list as possible and that the pending legislation can address any trend that may appear in the next few months. He also indicated that there needs to be a national response to this issue as well.

Technician member Halvorson highlighted the need for action in the hope that in taking this action preventing tragic incidents similar to Mr. Synder's daughter and the Bjerke's son.

Pharmacist Wendel indicated that it is the Board of Pharmacy's job to protect the public and adopting this rule as an emergency measure is the right thing to do. The Board Members all voiced their agreement to his comment.

Senior Member Gary Dewhirst stated we have heard from those that are knowledgeable about the dangers of these substances and feel that it is our duty as the Board of Pharmacy to take action.

Motion made by Board Member Gayle Ziegler to adopt the draft version of the changes to 61-13 Controlled substances as an emergency rule based on the following findings that are taken from today's meeting:

- The chemical groups identified in the rule have a significant abuse history
- Abuse is widespread and growing across North Dakota with deaths specifically tied to these types of substances
- The medical impact of these substances on humans is largely unknown but the current users are abusing these products to get the hallucinogenic and stimulant effects they create.
- These substances and their analogs present an immediate peril to the general public of residents of North Dakota.
- By nature of the new substances chemical structure, these compounds can cause severe psychic or physiological dependence ,have a high potential for abuse, and have no accepted medical use and thus fit under the category of Schedule I substances
- The approach of scheduling these groups based off of changes that could be made to the core chemical structure is necessary to ensure we are being proactive, to the greatest extent possible, to assure the safety of the public
- Imminent peril threatens public health, safety, or welfare, which would be abated by emergency effectiveness of these rules

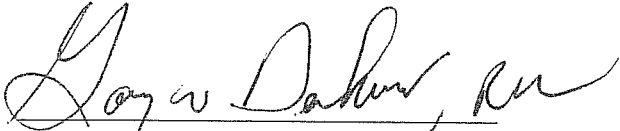
The motion was seconded by Public Member Fran Gronberg

On vote by roll call: Senior Member, Pharmacist Dewhirst – Aye Public Member Gronberg – aye Technician Halvorson – Aye Pharmacist Wendel – Aye Pharmacist Thom – Aye Gayle Ziegler – Aye

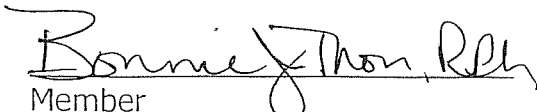
The motion carried for the Board of Pharmacy to adopt the emergency rule on the scheduling of these substances.

Senior Member Dewhirst adjourned the meeting.

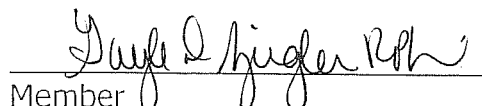
Laurel A. Haroldson, R.Ph.
President



Gary W. Dewhirst, R.Ph.
Senior Member



Member
Bonnie J. Thom, R.Ph.



Member
Gayle D. Ziegler, R.Ph.

Diane M. Halvorson RPhTech

Member

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Shane R. Wendel PharmD

Member

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Member

Fran Gronberg

Mark J. Hardy PharmD

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