Testimony
House Bill 1430
House Human Services Committee
February 4, 2015; 9:00 a.m.
North Dakota Department of Health

Good morning chairman Weisz and members of the House Human Services Committee. My name is Terry Dwelle. I am the State Health Officer for the North Dakota Department of Health. I am here to testify in opposition to House Bill 1430.

The Food and Drug Administration (FDA) has been a critical part of the health care system since 1906. FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods and feed and veterinary products.

The FDA's role of rigorous oversight of medications has protected the American public from several medications in the past that would have caused significant harm to our citizens. I would like to remind the committee of just two of those drugs; thalidomide and laetrile.

Thalidomide was developed and patented in 1954 by a German pharmaceutical company. The initial clinical trials found that thalidomide was a particularly effective antiemetic (anti-vomit medication) and had an inhibitory effect on pregnancy associated morning sickness. In 1957, the company launched an aggressive marketing campaign which proclaimed thalidomide a "wonder drug." There was significant public sentiment around the approval and use of this wonder drug in the United States, but the FDA refused to approve thalidomide for marketing and distribution, though they did release some for clinical testing purposes.

While initially considered safe, the drug was eventually responsible for the deaths of over 2,000 children and serious birth defects in more than 10,000 children. The birth defects were serious, with many children suffering from phocomelia (born without arms and legs) after expectant mothers used the drug primarily early in pregnancy to treat morning sickness. Unfortunately, 17 of the 10,000 children were from the United States, many of whom apparently received their thalidomide exposure from drugs obtained in Europe. This disastrous experience underlines the

importance of a rigorous drug evaluation and approval process. Even drugs that appear to be helpful at first, if not fully tested, can do much more harm than good.

Laetrile, or amygdalin, provides another example of how the FDA protects us from the consequences of taking untested drugs. Amygdalin was first discovered in 1830. It was used as a cancer treatment in Russia in the 1840s and in the United States in the 1920s, but its use was discontinued after it appeared to be poisonous.

In the 1950s, a purportedly non-toxic, synthetic amygdalin was patented for use as a meat preservative, and was later marketed as laetrile for cancer treatment. In 1972, a major cancer treatment center in the United States, Memorial Sloan Kettering Hospital, demonstrated in several clinical trials in mice covering 14 different types of cancer that laetrile showed no more effect on cancer than a placebo. In other words it did not work. The FDA prohibited the interstate shipment of laetrile in 1977. Following an FDA ban of the interstate shipment of laetrile in 1977, a public outcry regarding the availability of the drug for cancer treatment led to the legalization of the use of laetrile in 27 states. Many people made special trips to Mexico to obtain laetrile.

A 1982 trial by the Mayo Clinic of 175 patients found that tumor size increased in all but one patient, and the authors reported that "the hazards of amygdalin (laetrile) therapy were evidenced in several patients by symptoms of cyanide toxicity or by blood cyanide levels approaching the lethal range." The ultimate conclusion from studies from multiple institutions over a number of years was that "amygdalin or laetrile is a toxic drug that is not effective as a cancer treatment." Laetrile has now disappeared from medical use once again.

The history of the use of laetrile demonstrates the value of using FDA trials to evaluate and determine whether drugs work and whether they produce side effects. As with thalidomide, laetrile ended up doing more harm than good.

With regard to the use of cannabis, the FDA has approved two medications that are derivatives from cannabis; dronabinol (Marinol) and nabilone (Cesamet). Both nabilone and dronabinol are approved for treatment of nausea and vomiting mainly associated with chemotherapy, and dronabinol is approved to stimulate the appetite for those AIDS patients who have anorexia (loss of appetite). There is also an oromucosal (nasal) spray that is currently under clinical trials in the United States. So some testing on drugs derived from cannabis has been done and some drugs have been approved, but the approved uses at this time are limited.

I have attached the drug monographs for both of these drugs. The monographs summarize the detail FDA requires for determining appropriate use, efficacy and safety, to assure clinicians will be helping and not hurting patients when they prescribe these drugs. The monographs also include critical drug information for clinicians, including the following: how the drug is supplied; pharmacologic actions; indications for use; contraindications; administration and dosage; storage and stability; interactions with other substances; lab test interferences; adverse reactions; warning and precautions, including such things as what to monitor clinically when a patient is on the drug and whether the drug is safe in pregnancy or in women breast feeding; disease related concerns; concurrent drug usage issues; and key education to provide to the patient and family. This is the kind of information the FDA feels is necessary to protect patient health.

HB 1430 allows the use of cannabis products for "debilitating medical conditions" as defined on page 2, 19-24-01 (8). This provision by-passes the FDA process for determining efficacy and safety of drugs and puts a tremendous liability on the state and any of the practitioners prescribing them.

Page 12, 19-24-05, requires the department of health to consider petitions to add serious medical conditions or conditions' treatments in a manner required by department regulation and to add or deny these petitions within one hundred eighty days of submission. Since the FDA has not produced monographs for any medical use of marijuana that would be allowed by HB 1430, the Department of Health would need to generate this information in order for the practitioners defined on page 5, 19-24-01 (20), to prescribe to "qualifying patients". Generating adequate monographs for the use of medical marijuana, as envisioned by HB 1430, will require that the Department of Health perform the duties of the FDA, something that would take an astronomical level of resources and infrastructure, way beyond the current capacity of the department.

The fiscal note for HB 1430 was prepared by the Department of Health with input from the Attorney General's Office. It shows revenue and expenditures of $3,860,674 and 24.5 FTE for the 2015-17 biennium and revenue and expenditures of $3,627,494 for the 2017-19 biennium. Costs are related to the registration of designated caregivers and qualifying patients and the regulation of medical cannabis establishments. Note that these figures do not include the financial and staffing resources necessary to add conditions or a condition's treatment to the list of debilitating medical conditions as defined on page 2, 19-24-01(8).

It is far beyond the current capacity of the department to do the research and laboratory testing necessary , in place of the Food and Drug Administration, to add such conditions or treatments. We are unable to estimate the costs for these activities at this time. According to www.drugs.com (http://www.drugs.com/fda-approval-process.html), "It takes, on average, 12 years and over $350 million to get a new drug from the laboratory onto the pharmacy shelf. Only one in 1000 of the compounds that enter laboratory testing will ever make it to human testing."

I encourage you to recommend that House Bill 1430 not be passed. This concludes my testimony. I am happy to answer any questions you may have.