**2017 HOUSE JUDICIARY** 

HB 1099

### 2017 HOUSE STANDING COMMITTEE MINUTES

# Judiciary Committee Prairie Room, State Capitol

HB 1099 1/10/2017 26736

☐ Subcommittee☐ Conference Committee

Committee Clerk Signature	Thomas k					
Explanation or reason for introduction of bill/resolution:						
Relating to the definition of controlled substar	nce.					
Minutes:	1					

**Chairman K. Koppelman**: Opened the hearing on HB 1099.

Mark Hardy, PharmD, Executive Director of ND State Board of Pharmacy: Went through Testimony #1 (8:08-14:20)

**Representative Vetter**: What about the two drugs that are being scratched off the Bill. Can you tell me more about that?

**Mark Hardy**: In 2005 when the legislature put this in place they added those two drugs. At that time, they were not controlled substances. We knew there was abuse concerns on those two drugs. In 2013 and 2014 were the years those two drugs became controlled substances; not only in the state, but federally. Those two drugs are contained in the section that is referenced earlier in the actual bill 19-03.101 so technically this is just duplications in the code.

**Chairman K. Koppelman:** Could you outline for the committee what is the difference a drug that is part of the subscription drug monitoring program and a controlled substance. How are they treated and also what is the effective result of having something listed on the PDMP in terms of how it is treated if you bring in a prescription for that drug and there is a red flag.

**Mark Hardy**: (16:28) The difference between controlled substances and those reported to the subscription drug monitoring program; there isn't a big difference. It includes all our pharmacy's and also Indian health services and the VA system as well. Pharmacy's data basis systems are well versed to make that change.

**Chairman K. Koppelman**: Suppose you are a pharmacist and someone walks into the door with a prescription and it is red flagged somehow. How do you deal with that?

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**Mark Hardy**: It is always a case by case basis. There are different situations that present themselves. The appropriate answer maybe that we need to talk to your physician and talk to them about the duplicate therapy you may have going on. It is meant for it to be a tool so that they have it at their disposal.

**Representative Nelson**: How come just gabapentin and larrikin are not being included with this?

**Mark Hardy**: Gabapentin and larrikin are similar drugs. Some states don't require schedule five substances to be reported, but ND does. (19:13-20:29) Discussed the drugs and their use and abuse throughout the state.

Representative Nelson: Costs? What do we see happen when drugs become listed drugs?

**Mark Hardy**: No. When a drug becomes a federally controlled substance there are some increase cost based on the reporting that has to happen. What we are doing here is just having it as a reportable drug. There should be no increased cost to the patient in this action.

Representative Nelson: Would this change any drugs that friends may get from Canada?

**Mark Hardy**: No. The Canadian drugs is a very trending issue back before the invention of Medicare Part D. Typically, they are brand named drugs discrepancies. That will not change anything.

**Representative Hanson**: Have you visited with the ND Medical Association about this change and if so what is their opinion on it?

**Mark Hardy:** Yes. We have an advisory board that is made up as one of the medical association as well so they are aware of that change and they have no disagreement with the change.

Opposition: None

Hearing closed.

Do Pass Motion Made by Representative Maragos: Seconded by Rep. Satrom

Voice Vote: 15 Yes 0 No 0 Absent Carrier: Rep. Satrom

Date: Cikle in Porcher odate. Roll Call Vote:

## 2017 HOUSE STANDING COMMITTEE ROLL CALL VOTES BILL/RESOLUTION NO. 1099

House Judiciary	/				Comr	nittee		
□ Subcommittee								
Amendment LC# or Des	scription:							
	<ul> <li>□ Adopt Amendment</li> <li>☑ Do Pass</li> <li>□ Do Not Pass</li> <li>□ Without Committee Recomm</li> <li>□ Rerefer to Appropriations</li> <li>□ Place on Consent Calendar</li> <li>□ Reconsider</li> </ul>					lation		
Motion Made By Rep Managos Seconded By Rep Julium								
Representa		Yes	No	Representatives	Yes	No		
Chairman K. Koppel		V		Rep. Hanson				
Vice Chairman Karls	3	1		Rep. Nelson				
Rep. Blum		V			-			
Rep. Johnston		V			-			
Rep. Jones		1			-			
Rep. Klemin					-			
Rep. Magrum		V			-			
Rep. Maragos		1/			-			
Rep. Paur		1			-			
Rep. Roers-Jones Rep. Strom					-			
Rep. Simons								
Rep. Vetter		1						
rep. veller								
Total (Yes)	15		No	0_0				
VD96111								
Floor Assignment Rip. Satrom								

If the vote is on an amendment, briefly indicate intent:

Com Standing Committee Report January 10, 2017 3:06PM

Module ID: h\_stcomrep\_04\_004 Carrier: Satrom

### REPORT OF STANDING COMMITTEE

HB 1099: Judiciary Committee (Rep. K. Koppelman, Chairman) recommends DO PASS (15 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1099 was placed on the Eleventh order on the calendar.

(1) DESK (3) COMMITTEE Page 1 h\_stcomrep\_04\_004

2017 SENATE JUDICIARY

HB 1099

### 2017 SENATE STANDING COMMITTEE MINUTES

### **Judiciary Committee**

Fort Lincoln Room, State Capitol

HB 1099 2/14/2017 28337

☐ Subcommittee☐ Conference Committee

Committee Clerk Signature

Explanation or reason for introduction of bill/resolution:

Relating to the definition of controlled substance.

Minutes:

Testimony attached # 1

Chairman Armstrong called the committee to order on HB 1099. All committee members

were present.

Howard C. Anderson Jr., North Dakota State Senator District 8, testified in support of the bill. Senator Anderson read testimony from Mark Hardy. (see attachment 1)

**Senator Nelson**: "Are scheduled drugs already monitored drugs? How does it go from one place to another?"

**Senator Anderson**: "All of controlled substances dispensed in North Dakota are included in the database. We are asking to collect information on this drug, (Gabapentin) which is not a scheduled drug, so we can help those people who are abusing it, or who are prescribing it, or the patients of those doctors who are dispensing it. Eventually, the scheduling of Gabapentin may happen depending on what the information we discover."

Chairman Armstrong closed the hearing on HB 1099.

Senator Luick motioned Do Pass. Senator Myrdal seconded.

A Roll Call Vote was taken. Yea: 6 Nay: 0 Absent: 0. The motion carried.

Senator Osland carried the bill.

### 2017 SENATE STANDING COMMITTEE ROLL CALL VOTES BILL/RESOLUTION NO. HB 1099

Senate Judiciar	у				Comr	nittee	
		☐ Sub	ocommi	ttee			
Amendment LC# or	Description:						
Recommendation: Other Actions:	<ul> <li>□ Adopt Amendment</li> <li>☑ Do Pass</li> <li>□ Do Not Pass</li> <li>□ Without Committee R</li> <li>□ Rerefer to Appropriati</li> <li>□ Place on Consent Calendar</li> <li>□ Reconsider</li> </ul>				ns		
Other Actions:  Reconsider  Motion Made By Senator Luick Seconded By Senator Myrdal							
Ser	ators	Yes	No	Senators	Yes	No	
Chairman Armst	rong	X		Senator Nelson	X		
Vice-Chair Larso	on	X					
Vice-Chair Larso Senator Luick		X					
Senator Luick Senator Myrdal		X					
Vice-Chair Larso Senator Luick Senator Myrdal Senator Osland		X					
Senator Luick Senator Myrdal		X					
Senator Luick Senator Myrdal		X					
Senator Luick Senator Myrdal Senator Osland  Total (Yes)		X X X		0			

If the vote is on an amendment, briefly indicate intent:

Com Standing Committee Report February 14, 2017 10:09AM

REPORT OF STANDING COMMITTEE

Module ID: s\_stcomrep\_29\_008

Carrier: Osland

s\_stcomrep\_29\_008

HB 1099: Judiciary Committee (Sen. Armstrong, Chairman) recommends DO PASS (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1099 was placed on the Fourteenth order on the calendar.

(1) DESK (3) COMMITTEE Page 1

**2017 TESTIMONY** 

HB 1099



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STATE BOARD OF PHARMACY

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Mark J. Hardy, PharmD, R.Ph. Executive Director

### House Bill No 1099 - Controlled Substances definition for PDMP

House Judiciary Committee – Prairie Room 10:00 AM - Tuesday – January 10, 2017

Chairman Koppleman, members of the House Judiciary Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I am here to testify on behalf of House Bill 1099, which was introduced at the request of the Board of Pharmacy.

House Bill 1099 is very short piece of legislation. However, it makes a change in the definition of a "Controlled Substance" within the section of the century code pertaining to the Prescription Drug Monitoring Program [PDMP] specifically, this bill adds gabapentin, brand name Neurontin, as a reportable drug to the PDMP. Also, this legislation strikes tramadol and carisoprodol – drugs which have been reportable drugs to the PDMP since it's inception and later became scheduled Controlled Substances both federally and in the state, hence a drug defined in section 19-03.1-01.

Gabapentin is a prescription medication most often used for seizures or neuropathic pain. Beginning in 2011 the Board had heard limited reports of gabapentin abuse in limited areas in the state of North Dakota. We have been monitoring this abuse and reports across the state. Practitioners, pharmacists and law enforcement are indicating that the abuse of gabapentin has extended across the state. It seems to be a large concern for healthcare providers and law enforcement personnel that have intervened in situations of abuse.

Our Advisory Council, along with the ND State Board of Pharmacy has determined that it is now appropriate to list this drug as a reportable drug in the PDMP portion of the North Dakota Century Code.

States that currently report gabapentin to their PDMPs include Massachusetts, Minnesota and Ohio. Other states are in the process of taking this same action

Abuse reports of gabapentin include individuals inhaling the capsule powder inter-nasally to get an altered mental state or "high" similar to that of cocaine. Also, reports of withdrawal symptoms of patients that have been taking gabapentin for some time, have been reported in clinical studies. Pharmacists have reported to the Board that patients are getting gabapentin from multiple pharmacies and have been prescribed by multiple practitioners, with the intention for the medication to be abused.

1099

For your review and information, attached are some articles relative to abuse of gabapentin.

Adding this drug as a reportable drug to the Prescription Drug Monitoring Program [PDMP] means those dispensing prescriptions for gabapentin would be reporting the appropriate information to the PDMP. Those healthcare professionals prescribing gabapentin will have access to the PDMP to see the patient's prescription history and be informed if the patient is already receiving gabapentin from another prescriber and which practitioners are involved in their care, to assure there is not duplicate therapy.

For those who are unfamiliar with the Prescription Drug Monitoring Program [PDMP], I will give a brief history. In 2005 the legislature authorized the Prescription Drug Monitoring Program [PDMP] in North Dakota. In 2007 the PDMP became operational and is a HIPPA compliant online database that collects all the controlled substances and other reportable drugs dispensed. All Pharmacies licensed with the state of North Dakota are required to report daily all dispensed controlled substances to the database. The healthcare professionals have access at any time to this database through a secure online method to review the patient's medication history. The PDMP is one of the most powerful clinical tools at the prescriber's disposal to address potential prescription drug abuse, which is such an unfortunate trend across the state and across the nation. Access to the PDMP is also available to law enforcement to provide a resource for them on an open investigation to ascertain an individual's legitimate prescription profile.

The overall goal of the PDMP is the cooperation between all entities should facilitate patient therapy improvements and ensure the health and safety of our state's citizens.

We appreciate your consideration in adding gabapentin as a reportable substance in our PDMP, as in our sincere opinion it is the time to address the potential abuse of this product being witnessed across North Dakota and nationally.

I would be happy to answer any questions you may have.

www.medscape.com

# Has Gabapentin Become a Drug of Abuse?

rah T. Melton, PharmD | June 17, 2014

estion

Has gabapentin become a drug of abuse?



### Response from Sarah T. Melton, PharmD

Associate Professor of Pharmacy Practice, Bill Gatton College of Pharmacy at East Tennessee State University, Johnson City, Tennessee

Gabapentin is approved by the US Food and Drug Administration (FDA) for the treatment of epilepsy and postherpetic neuralgia.<sup>[1]</sup> It is often prescribed off-label for other pain syndromes, anxiety and mood disorders, restless legs syndrome, alcohol withdrawal, and other conditions.

Gabapentin is an analog of gamma-aminobutyric acid (GABA), a neurotransmitter that slows down the activity of nerve cells in the brain, but does not bind to GABA receptors or affect the production or uptake of GABA.<sup>[1]</sup> How gabapentin works and how it relieves pain and suppresses seizures are unknown.

Gabapentin does not exhibit affinity for benzodiazepine, opioid (mu, delta, or kappa), or cannabinoid 1 receptor sites, which are often activated in drugs of abuse. [1] Gabapentin is not scheduled as a controlled substance, indicating little potential for abuse and addiction. However, gabapentin shares characteristics of medications associated with misuse and addiction, in that it produces a withdrawal syndrome and certain psychoactive effects.

A small number of postmarketing cases report gabapentin misuse and abuse.<sup>[1]</sup> Although the rationale for abuse is unknown, some individuals describe "euphoria, improved sociability, a marijuana-like 'high', relaxation and sense of calm."<sup>[1]</sup> Other patients report feeling "zombie-like."<sup>[2]</sup>

004, a report described gabapentin misuse in correctional facilities in Florida. A recall of all gabapentin prescriptions at one of the larger correctional facilities revealed that only 19 of 96 prescriptions were in the possession of the intended patients. Subsequently, 5 inmates reported they were inhaling the powder from gabapentin (300 or 400 mg) capsules intranasally. All 5 inmates had psychiatric or pain diagnoses, as well as histories of cocaine abuse. Four of the 5 inmates reported obtaining an altered mental state or "high" similar to that from cocaine. Gabapentin was removed from the formulary, and prescribing was restricted to exceptional cases. There was no further evidence of abuse. Gabapentin has been removed from formulary in other correctional facilities as well. [4]

A 2007 report<sup>[5]</sup> described the case of a 67-year-old woman with mood disorders and a history of alcohol abuse who was prescribed gabapentin (as well as naproxen and amitriptyline) for pain from polyneuritis. Owing to tolerance, she was prescribed 4800 mg/day (over the maximum recommended dose), but further escalated her intake to 7200 mg daily. She requested gabapentin without a prescription from pharmacists and visited numerous physicians, exaggerating her symptoms, to obtain the desired quantities.

When the patient was finally no longer able to obtain gabapentin through these methods, she developed withdrawal symptoms, characterized by trembling, sweating, excitation, pallor, and exophthalmia. The withdrawal required hospitalization, where a change to alternative pain control medications was made. Within several months, the patient had resumed abuse of gabapentin.

Another report described 3 cases of gabapentin-associated withdrawal symptoms after abrupt discontinuation of total daily doses of 4800 mg, 3600 mg, and 2400 mg. [6]

Similar symptoms were reported in 2 patients with histories of alcohol abuse.<sup>[7]</sup> The first case involved a 33-year-old man taking 3600 mg of gabapentin daily, which was twice his prescribed dose. He had been obtaining gabapentin refills early to reduce his craving for alcohol and make him feel calmer.

The first case involved a 33-year-old man taking 3600 mg of gabapentin daily, which was twice his prescribed dose. He had been obtaining gabapentin refills early to reduce his craving for alcohol and make him feel calmer.

Me second case described a 63-year-old man with a history of alcohol abuse who was taking gabapentin at 4900 mg/day instead of the prescribed 1800 mg/day. After presentation to the hospital and discontinuation of gabapentin, he developed severe withdrawal symptoms. Withdrawal symptoms in these patients included disorientation, confusion, tachycardia, diaphoresis, tremulousness, and agitation. The withdrawal symptoms resolved upon resumption of gabapentin.

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The use of nonprescribed gabapentin by patients attending substance abuse clinics has also been reported. [8] A questionnaire-based survey completed by 129 respondents attending 6 substance abuse treatment clinics found that 22% of patients admitted to using nonprescribed gabapentin. As a comparison, nonprescribed use of pregabalin was 3%, benzodiazepines 47%, and cannabis 43%. Some patients taking nonprescribed gabapentin reported using the drug to become intoxicated or to potentiate the effect of methadone.

### Conclusion

On the basis of case reports and postmarketing reports, there appears to be potential for abuse, dependency, and withdrawal symptoms associated with gabapentin use. Patients involved in this misuse and abuse were using gabapentin at doses greater than those recommended, to relieve symptoms of withdrawal from other substances, and for uses that are not FDA-approved.

Providers should assess patients for drug abuse history when prescribing gabapentin, as well as monitor patients for any signs of misuse or abuse. Prescribers and pharmacists should monitor patients for the development of tolerance, unauthorized escalation of dosing, and requests for early refills or other aberrant behavior. Prescribers should consider requesting testing for the presence of gabapentin in urine drug screens if abuse is suspected.

Acknowledgment: Dr. Melton acknowledges the research assistance of Paige Graham and Charity Sands, Doctor of Pharmacy Candidates at the Bill Gatton College of Pharmacy at East Tennessee State University.

#### References

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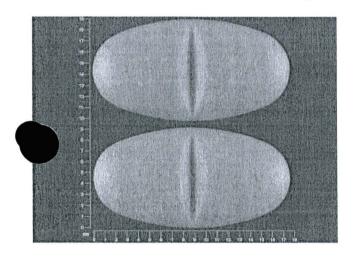


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# Gabapentin (Neurontin) Addiction

Posted on September 28, 2013 in Prescription Drug Addiction



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When Neurontin was the new drug on the block, physicians believed that they had found a real breakthrough drug to help patients with all kinds of nerve pain. The drug had fewer side effects and drug interactions than current ones on the market and was classified as non-addictive, which meant you did not have to keep extensive records on it every time you prescribed it.[i] Soon Neurontin was generating over \$4 billion a year in sales.[ii]

Then the trouble began. A whistle-blower from the drug's manufacturer claimed the company was spinning data on the drug's effectiveness and using illegal means to promote its off-label uses among physicians. When the dust settled from civil and criminal lawsuits, Pfizer paid out \$572 million to claimants.[iii] But not to worry. As soon as Neurontin became a cheap drug available generically, Pfizer marketed a close cousin of it named Lyrica, which today generates \$3 billion a year in sales.[iv]

What is Gabapentin?

Cabapentin is an analog of gamma-aminobutyric acid (GABA), a neurotransmitter that slows down the activity herve cells in the brain. This means that gabapentin has a similar structure and is made up of similar chemicals as GABA, although its effect on the body is not the same. The scientists who developed gabapentin were deliberately trying to mimic GABA.



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Gabapentin does not convert into GABA, does not inhibit it, does not alter the uptake of dopamine, and does not interact with GABA receptor cells.[v] How gabapentin works and how it relieves pain and suppresses seizures is unknown. One theory is that it increases the level of GABA by increasing the activity of glutamic acid decarboxylase, an enzyme responsible for the synthesis of GABA.[vi]

The chemical name for gabapentin is 2-[1-(aminomethyl) cyclohexyl]acetic acid and its molecule looks like this Gabapentin is not a Controlled Substance, that is, one that the United States federal government classifies as having potential for addiction and regulates under the Comprehensive Drug Abuse and Control Act of 1970. However, gabapentin shares characteristics of addictive drugs in that it produces a withdrawal syndrome and certain psychoactive effects. Its cousin drug, pregabalin, is a Schedule V Controlled Substance.

What are the Medical Uses of Gabapentin?

The United States Food and Drug Administration approved Neurontin for the treatment of seizures in adults and children, especially as a supplemental drug used for the same purpose. In 2002, the FDA approved it for treatment for pain from shingles. Horizant and Gralise are extended release versions of gabapentin that were approved for shingles pain in 2012. [vii] Gabapentin was also approved for restless leg syndrome in 2011. [viii] When gabapentin was first introduced, doctors were excited about it because it had few side effects and drug interactions compared to competing remedies, and because it was not metabolized through the liver but rather excreted through the kidneys. [ix] Physicians began to prescribe it off-label for various conditions, including hot flashes during menopause, pain from fibromyalgia, bi-polar disorder, pain after polio, neuropathic pain, complex regional pain syndrome, trigeminal neuralgia, migraines, alcohol and drug withdrawal seizures, and diabetic neuropathy. [x] Later it was proven that the manufacturers of this drug had exaggerated claims about its effectiveness for various conditions. [xii] Pregabalin, commonly sold as Lyrica, is a newer drug now prescribed for nerve pain, epilepsy and fibromyalgia, and it has largely replaced gabapentin. [xiii]

The usual dose for people over 12 years old who have epilepsy is 300mg three times a day. This can be increased to 1800mg a day. Doctors prescribe the drug to children with epilepsy based on their body weights. [xiii]

For post-herpetic neuralgia (shingles), the dose is the same as for epilepsy. For adults with restless leg syndrome, the dose is 600mg taken at five o'clock in the evening.[xiv]

Dosages for people with kidney problems may be different than these.[xv]

If you break a gabapentin tablet in order to take just half, you need to use the rest of the pill as your next dosage or else discard it.[xvi]

One unusual aspect of gabapentin is that its bioavailability decreases with the dose. For example, if you take 900mg, 60% is available to your body, but if you take 4800mg, that drops to only 27%.[xvii]

What are the Side Effects of Gabapentin?

The most common side effects of gabapentin are drowsiness, unsteadiness, sleepiness, loss of coordination, clumsiness, vision changes, and dry mouth.[xviii] Some people report the following rare side effects: edema, weight gain, swollen hands and feet, headaches, diarrhea, trouble thinking, abnormal thoughts, suicidal thoughts, fever, ataxia, diplopia, flu symptoms, shortness of breath, chest pain, mouth sores, chills, nausea, coughing, tremor, and other cold symptoms.

If you experience certain symptoms, you should call your doctor immediately because they can be a sign of a serious health condition. These can be black tarry stools, dark urine, tiredness, chest pain, suicidal mood, swollen glands, unusual bruising, rashes, or signs of an infection such as fever, cough and sore throat.[xix] Children react to gabapentin differently than adults. They may experience behavioral changes, moodiness, hyperactivity, overly emotional states, and restlessness.[xx]

What Drugs Interact with Gabapentin?

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In general, you should not take gabapentin products with medicines that slow down the central nervous system and make you drowsy. These may be anti-histamines, narcotic painkillers, sleeping pills, muscle relaxants, anti-ety medications, and drugs for depression and seizures.[xxi] Gabapentin products will react with drugs used during surgeries, even dental procedures.[xxii] Do not take gabapentin products with morphine (Kadian, MS Contin), naproxen (Aleve) or hydrocodone (Lortab, Vicodin).[xxiii]

Drugs containing gabapentin will interact with ketorolac, aluminum carbonate, aluminum hydroxide, aluminum phosphate, dihydroxyaluminum amino acetate, dihydroxyaluminum sodium carbonate, ginkgo, magaldrate, magnesium carbonate, magnesium hydroxide, magnesium trislicate, and morphine sulfate liposome. If you combine gabapentin with tobacco and alcohol and then take certain other drugs, you may cause an unpleasant or difficult reaction.[xxiv]

If you take any common antacids like Maalox and Di-Gel that contain aluminum or magnesium, you need to wait two hours before taking gabapentin.[xxv]

Which People Should not Take Gabapentin?

Gabapentin products have not been determined safe for pregnant or breast-feeding women or children, even though doctors sometimes prescribe it for children with epilepsy. People with histories of depression, mood or mental disorders, and kidney diseases usually do not take gabapentin because it can make these conditions worse.[xxvi] These drugs are used with caution for people with liver or heart diseases.[xxvii]

What Lawsuits Have Ensued Over Gabapentin?

At first the United States Food and Drug Administration approved Neurontin for only for epilepsy but by the year 2000, 78% of prescriptions that doctors wrote for Neurontin were for conditions other than seizure orders. The new drug was widely prescribed "off label" for more than a dozen conditions, including omyalgia, nerve pain, migraines, menopausal symptoms, bipolar disorder, and even attention deficit disorder in children.[xxviii] Between 2000 and 2004, Neurontin was generating \$1 to \$4 billion in sales a year for its manufacturers, which were first Warner-Lambert and later Pfizer drug companies.[xxix]

In 2002, Dr. David Franklin, an employee of Warner-Lambert, went to authorities to report that his company was promoting Neurontin for uses not approved by the FDA. While it is not illegal for doctors to prescribe drugs for unapproved uses, it is illegal for a drug company to advertise and promote them for unapproved uses. [xxx] Dr. Franklin testified that Warner-Lambert paid to doctors to present themselves as authors of studies written by non-doctors employed by the company. He said that the company also paid doctors to speak to other doctors about the off-label uses of Neurontin, and offered physicians expensive retreats and dinners at expensive restaurants to promote the drug.[xxxi]

As criminal and civil lawsuits were filed against the company, more negative information came out. Pfizer had apparently delayed or suppressed publication of studies that were negative or neutral about Neurontin, and exaggerated any positive claims. For example, three double-blind studies showed that Neurontin did not improve the symptoms of bipolar patients any better than sugar pills, but the company manipulated the studies and how symptoms were defined in evaluating the success of Neurontin. Of the 12 studies of the drug's effect on migraine headaches, two negative ones went unpublished, and some of the positive studies involved only patients who had taken 2400mg or more of the drug.[xxxii] In other studies, patients could easily figure out that were not in the placebo group, and ordinarily this would have meant that the study could not be published. Company spokespeople denied all the charges, but Pfizer ended up paying out \$430 million in claims to states enrolled in the Medicaid program.[xxxiii] In 2011, Judge Patti Saris of the U.S. District Court in

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Boston ordered Pfizer to pay Kaiser Health \$142.1 million for duping the company into prescribing Neurontinfor migraines and bipolar disorder.[xxxiv]

In 2004, gabapentin became available as a cheap generic drug,[xxxv] which drastically reduced its value as a money-maker for Pfizer. Pfizer introduced a similar but more potent drug called Lyrica, which was approve the FDA in December 2004. Lyrica was approved for seizure disorders and pain from fibromyalgia, but it is now prescribed for many other conditions "off-label," especially all kinds of chronic pain. Today Lyrica ranks 19th among all prescription drugs, and generates more than \$3 billion a year for Pfizer.[xxxvi]

Gabapentin doubles the risk for suicidal thoughts and behaviors, but the risk is still low. In one study of 27,863 patients on Neurontin and 16,029 on a placebo, 0.43% of the ones on the real drug became suicidal compared to 0.24% on the sugar pill.[xxxvii]

Gabapentin has some potential for abuse because it has psychoactive effects. Once you have been on it for a while, you may experience a difficult withdrawal syndrome when you try to stop taking it.

Gabapentin causes drowsiness and incoordination, which means that you are at an increased risk for accidents, and probably should not drive when you take this medication.[xxxviii]

Gabapentin increases the risk for sudden death after seizures in patients who have epilepsy. It can cause certain dangerous and sometimes even fatal reactions. Symptoms of this condition can be fever, rash, painful lymph glands in the neck and armpit, unusual bleeding, and yellow eyes and skin.[xxxix] Both of these reactions are extremely rare.

Gabapentin may slightly increase your risk for cancer.[xl]

Does Gabapentin Show up on Urine Tests?

What are the Risks of Taking Gabapentin?

Gabapentin has a half-life of about five to seven hours, which means it should completely clear the body value as the body value. Standard urine tests do not test for it because it is not a controlled substance.

What is a Gabapentin Overdose?

Symptoms of a gabapentin overdose may be appearing drunk and disoriented, with slurred speech and double vision.[xli] Such overdoses are very rare.

What is Gabapentin Withdrawal or Discontinuation Syndrome?

When gabapentin was first introduced, scientists believed that it could not cause a withdrawal syndrome. Since that time, there have been many case studies of people who experienced such difficult symptoms when they tried to stop using the drug that many had to go back on it. For example, one 81 year old woman with bipolar disorder took Neurontin for five years, and developed severe cold symptoms when she stopped. On the tenth day after stopping Neurontin in a gradual way, she had terrible chest pain, hypertension, and mental changes that were difficult to manage. She was back to normal within one day of taking the drug again.[xlii]

In another case study, a 53-year-old woman vomited a black substance like coffee grounds and developed abdominal pain and black stools after stopping gabapentin. By days four and five, she developed restlessness, anxiety, agitation, disorientation, confusion, headaches, and extreme sensitivity to light. When her doctor administered gabapentin again, she was calm and normal within a day.[xliii] Another such study found that a 41-year-old male developed insomnia, headaches, heart palpitations, and excessive sweating after stopping Neurontin, but his symptoms went away when he went back on it.[xliv]

It has now been proven that gabapentin can build up in the body and cause a severe withdrawal syndrome similar to the ones for benzodiazepines and alcohol. The syndrome can last for weeks and even months, depending on the levels you took the drug and for how long you took it. Symptoms are agitation, confusion, disorientation, sensitivity to light, headaches, heart palpitations, and hypertension, chest pain. If you were taking

gabapentin for epilepsy, your seizures will probably come back. Some people develop seizures during withdrawal even if they never had one before.[xlv]

What is Gabapentin Addiction?

heory, gabapentin should not be addictive because it has no affinity for the nerve receptors associated with addictions to marijuana, benzodiazepines or opiates. It was marketed as non-addictive, but post-marketing studies showed that some people were abusing it. In the early 2000s, the drug was being sold to thousands of people with sales were over a billion dollars a year. Some of these patients were asking their doctors to increase their amounts (self-escalation) as they developed physical dependencies on Neurontin. When they tried to quit, they entered a withdrawal syndrome that caused them to go back to the drug. The new conclusion about gabapentin, as one expert put it, "The dependence and abuse potential for gabapentin has not been evaluated in human studies." [xlvi]

The United States Drug Enforcement Agency does not list gabapentin as a drug of concern, even though it is being sold on the Internet illegally. Its street name is "morontin" because it makes you "dopey."

What Treatments are Available for Gabapentin Addiction?

Because the withdrawal syndrome for this drug can produce unpleasant and even dangerous symptoms, you need to consult your doctor or an addiction specialist at a drug rehabilitation clinic about how you can safely stop taking the drug. The usual method is to wean a patient from the drug by gradually lowering the dosage, but this does not always prevent the withdrawal syndrome.[xlvii] If you have tried unsuccessfully to quit taking gabapentin, you should seek professional help.

The state-of-the-art treatment for drug addiction is to enter a residential treatment center where your withdrawal can be done under medical supervision. If you are addicted to other drugs or alcohol as well as gabapentin, the detoxification process will become even more complicated.

ce you have completed detoxification and your body is completely clear of drugs, you need to remain at the center for a few weeks or more so that you can undergo therapy to learn to live a drug-free life. You will work one-on-one with a therapist who can help you with any psychological problems you may have that contribute to your drug abuse. You may learn how to deal stress through non-pharmaceutical means such as running or other sports, yoga, meditation, journaling and so forth. You may have classes in the chemistry of drugs and why they can get such a hold on people's lives. You will learn how to avoid relapsing into drug abuse or alcoholism, even if you have a genetic tendency or long family history of such problems. Most drug rehab programs offer activities that are fun to do as well as ways of self-exploration, such as social gatherings, sightseeing, outdoor sports, and participating in art, drama and music. Once you return home, you usually remain in support meetings in your community and in individual and family counseling to help you stay on track.

How Can I Tell if I am Addicted to Gabapentin?

If you can answer yes to any of these questions, you may want to consider talking to your family physician or an addiction specialist at a residential treatment center about your concerns with gabapentin.

Are you taking gabapentin without a doctor's prescription?

Do you ask your doctor to keep increasing your dose?

Do you buy gabapentin from the Internet or other illegal sources?

you experience withdrawal symptoms when you stop taking gabapentin?

Have you tried to quit taking gabapentin on your own but failed?

Do you consider yourself to be someone who abuses drugs or alcohol?

Do you use gabapentin along with alcohol or other drugs as a way of treating emotional pain?

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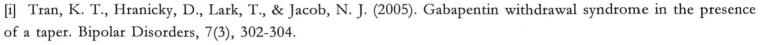
Are you taking gabapentin even though you experience unpleasant side effects and even though you are unsure if it is effective for you?

If money were no object, would you enter an intense program to help you deal with drug problems?

Do your friends or family members criticize you because of your drug abuse?

Do you feel guilty about how you use drugs?

Are you trying to cut down on your use of gabapentin or other drugs?



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[xiii] "Gabapentin," Medline, Information from the National Institutes of Health, see

http://www.nlm.nih.gov/medlineplus/druginfo/meds/a694007.html

[xiv] Ibid, see also "Neurontin," the RX List, see http://www.rxlist.com/neurontin-drug.htm [xv] Ibid.

[xvi] "Neurontin," the RX List, see http://www.rxlist.com/neurontin-drug.htm

[xvii] "Gabapentin," Medline, Information from the National Institutes of Health, see

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HB 1099



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### House Bill No 1099 - Controlled Substances definition for PDMP

Senate Judiciary Committee – Fort Lincoln Room 9:30 AM - Tuesday – February 14, 2017

Chairman Armstrong, members of the Senate Judiciary Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I am here to testify on behalf of House Bill 1099, which was introduced at the request of the Board of Pharmacy.

House Bill 1099 is very short piece of legislation. However, it makes a change in the definition of a "Controlled Substance" within the section of the century code pertaining to the Prescription Drug Monitoring Program [PDMP] specifically, this bill adds gabapentin, brand name Neurontin, as a reportable drug to the PDMP. Also, this legislation strikes tramadol and carisoprodol – drugs which have been reportable drugs to the PDMP since it's inception and later became scheduled Controlled Substances both federally and in the state, hence a drug defined in section 19-03.1-01.

Gabapentin is a prescription medication most often used for seizures or neuropathic pain. Beginning in 2011 the Board had heard limited reports of gabapentin abuse in limited areas in the state of North Dakota. We have been monitoring this abuse and reports across the state. Practitioners, pharmacists and law enforcement are indicating that the abuse of gabapentin has extended across the state. It seems to be a large concern for healthcare providers and law enforcement personnel that have intervened in situations of abuse.

Our Advisory Council for the PDMP, along with the ND State Board of Pharmacy has determined that it is now appropriate to list this drug as a reportable drug in the PDMP portion of the North Dakota Century Code.

States that currently report gabapentin to their PDMPs include Massachusetts, Minnesota and Ohio. Other states are in the process of taking this same action

Abuse reports of gabapentin include individuals inhaling the capsule powder inter-nasally to get an altered mental state or "high" similar to that of cocaine. Also, reports of withdrawal symptoms of patients that have been taking gabapentin for some time, have been reported in clinical studies. Pharmacists have reported to the Board that patients are getting gabapentin from multiple pharmacies and have been prescribed by multiple practitioners, with the intention for the medication to be abused.

For your review and information, attached are some articles relative to abuse of gabapentin.

Adding this drug as a reportable drug to the Prescription Drug Monitoring Program [PDMP] means those dispensing prescriptions for gabapentin would be reporting the appropriate information to the PDMP. Those healthcare professionals prescribing gabapentin will have access to the PDMP to see the patient's prescription history and be informed if the patient is already receiving gabapentin from another prescriber and which practitioners are involved in their care, to assure there is not duplicate therapy.

For those who are unfamiliar with the Prescription Drug Monitoring Program [PDMP], I will give a brief history. In 2005 the legislature authorized the Prescription Drug Monitoring Program [PDMP] in North Dakota. In 2007 the PDMP became operational and is a HIPPA compliant online database that collects all the controlled substances and other reportable drugs dispensed. All Pharmacies licensed with the state of North Dakota are required to report daily all dispensed controlled substances to the database. The healthcare professionals have access at any time to this database through a secure online method to review the patient's medication history. The PDMP is one of the most powerful clinical tools at the prescriber's disposal to address potential prescription drug abuse, which is such an unfortunate trend across the state and across the nation. Access to the PDMP is also available to law enforcement to provide a resource for them on an open investigation to ascertain an individual's legitimate prescription profile.

The overall goal of the PDMP is the cooperation between all entities should facilitate patient therapy improvements and ensure the health and safety of our state's citizens.

We appreciate your consideration in adding gabapentin as a reportable substance in our PDMP, as in our sincere opinion it is the time to address the potential abuse of this product being witnessed across North Dakota and nationally.

I would be happy to answer any questions you may have.

# Has Gabapentin Become a Drug of Abuse?

Sarah T. Melton, PharmD | June 17, 2014

Question

Has gabapentin become a drug of abuse?



#### Response from Sarah T. Melton, PharmD

Associate Professor of Pharmacy Practice, Bill Gatton College of Pharmacy at East Tennessee State University, Johnson City, Tennessee

Gabapentin is approved by the US Food and Drug Administration (FDA) for the treatment of epilepsy and postherpetic neuralgia.<sup>[1]</sup> It is often prescribed off-label for other pain syndromes, anxiety and mood disorders, restless legs syndrome, alcohol withdrawal, and other conditions.

Gabapentin is an analog of gamma-aminobutyric acid (GABA), a neurotransmitter that slows down the activity of nerve cells in the brain, but does not bind to GABA receptors or affect the production or uptake of GABA.<sup>[1]</sup> How gabapentin works and how it relieves pain and suppresses seizures are unknown.

Gabapentin does not exhibit affinity for benzodiazepine, opioid (mu, delta, or kappa), or cannabinoid 1 receptor sites, which are often activated in drugs of abuse.<sup>[1]</sup> Gabapentin is not scheduled as a controlled substance, indicating little potential for abuse and addiction. However, gabapentin shares characteristics of medications associated with misuse and addiction, in that it produces a withdrawal syndrome and certain psychoactive effects.

A small number of postmarketing cases report gabapentin misuse and abuse.<sup>[1]</sup> Although the rationale for abuse is unknown, some individuals describe "euphoria, improved sociability, a marijuana-like 'high', relaxation and sense of calm."<sup>[1]</sup> Other patients report feeling "zombie-like."<sup>[2]</sup>

In 2004, a report described gabapentin misuse in correctional facilities in Florida.<sup>[3]</sup> A recall of all gabapentin prescriptions at one of the larger correctional facilities revealed that only 19 of 96 prescriptions were in the possession of the intended patients. Subsequently, 5 inmates reported they were inhaling the powder from gabapentin (300 or 400 mg) capsules intranasally. All 5 inmates had psychiatric or pain diagnoses, as well as histories of cocaine abuse. Four of the 5 inmates reported obtaining an altered mental state or "high" similar to that from cocaine. Gabapentin was removed from the formulary, and prescribing was restricted to exceptional cases. There was no further evidence of abuse. Gabapentin has been removed from formulary in other correctional facilities as well.<sup>[4]</sup>

A 2007 report<sup>[5]</sup> described the case of a 67-year-old woman with mood disorders and a history of alcohol abuse who was prescribed gabapentin (as well as naproxen and amitriptyline) for pain from polyneuritis. Owing to tolerance, she was prescribed 4800 mg/day (over the maximum recommended dose), but further escalated her intake to 7200 mg daily. She requested gabapentin without a prescription from pharmacists and visited numerous physicians, exaggerating her symptoms, to obtain the desired quantities.

When the patient was finally no longer able to obtain gabapentin through these methods, she developed withdrawal symptoms, characterized by trembling, sweating, excitation, pallor, and exophthalmia. The withdrawal required hospitalization, where a change to alternative pain control medications was made. Within several months, the patient had resumed abuse of gabapentin.

Another report described 3 cases of gabapentin-associated withdrawal symptoms after abrupt discontinuation of total daily doses of 4800 mg, 3600 mg, and 2400 mg. [6]

Similar symptoms were reported in 2 patients with histories of alcohol abuse.<sup>[7]</sup> The first case involved a 33-year-old man taking 3600 mg of gabapentin daily, which was twice his prescribed dose. He had been obtaining gabapentin refills early to reduce his craving for alcohol and make him feel calmer. When further refills were denied, he abruptly stopped taking the gabapentin and suffered acute withdrawal symptoms.

The second case described a 63-year-old man with a history of alcohol abuse who was taking gabapentin at 4900 mg/day instead of the prescribed 1800 mg/day. After presentation to the hospital and discontinuation of gabapentin, he developed severe withdrawal symptoms. Withdrawal symptoms in these patients included disorientation, confusion, tachycardia, diaphoresis, tremulousness, and agitation. The withdrawal symptoms resolved upon resumption of gabapentin.

The use of nonprescribed gabapentin by patients attending substance abuse clinics has also been reported.<sup>[8]</sup> A questionnaire-based survey completed by 129 respondents attending 6 substance abuse treatment clinics found that 22% of patients admitted to using nonprescribed gabapentin. As a comparison, nonprescribed use of pregabalin was 3%, benzodiazepines 47%, and cannabis 43%. Some patients taking nonprescribed gabapentin reported using the drug to become intoxicated or to potentiate the effect of methadone.

#### Conclusion

On the basis of case reports and postmarketing reports, there appears to be potential for abuse, dependency, and withdrawal symptoms associated with gabapentin use. Patients involved in this misuse and abuse were using gabapentin at doses greater than those recommended, to relieve symptoms of withdrawal from other substances, and for uses that are not FDA-approved.

Providers should assess patients for drug abuse history when prescribing gabapentin, as well as monitor patients for any signs of misuse or abuse.

Prescribers and pharmacists should monitor patients for the development of tolerance, unauthorized escalation of dosing, and requests for early refills or other aberrant behavior. Prescribers should consider requesting testing for the presence of gabapentin in urine drug screens if abuse is suspected.

Acknowledgment: Dr. Melton acknowledges the research assistance of Paige Graham and Charity Sands, Doctor of Pharmacy Candidates at the Bill Gatton College of Pharmacy at East Tennessee State University.

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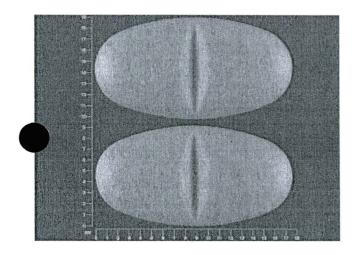


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# Gabapentin (Neurontin) Addiction

Posted on September 28, 2013 in Prescription Drug Addiction



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When Neurontin was the new drug on the block, physicians believed that they had found a real breakthrough drug to help patients with all kinds of nerve pain. The drug had fewer side effects and drug interactions than current ones on the market and was classified as non-addictive, which meant you did not have to keep extensive records on it every time you prescribed it.[i] Soon Neurontin was generating over \$4 billion a year in sales.[ii]

Then the trouble began. A whistle-blower from the drug's manufacturer claimed the company was spinning data on the drug's effectiveness and using illegal means to promote its off-label uses among physicians. When the dust settled from civil and criminal lawsuits, Pfizer paid out \$572 million to claimants.[iii] But not to worry. As soon as Neurontin became a cheap drug available generically, Pfizer marketed a close cousin of it named Lyrica, which today generates \$3 billion a year in sales.[iv]

What is Gabapentin?

Gabapentin is an analog of gamma-aminobutyric acid (GABA), a neurotransmitter that slows down the activity nerve cells in the brain. This means that gabapentin has a similar structure and is made up of similar chemicals as GABA, although its effect on the body is not the same. The scientists who developed gabapentin were deliberately trying to mimic GABA.

Gabapentin does not convert into GABA, does not inhibit it, does not alter the uptake of dopamine, and does not interact with GABA receptor cells.[v] How gabapentin works and how it relieves pain and suppresses seizures is unknown. One theory is that it increases the level of GABA by increasing the activity of glutamic acid decarboxylase, an enzyme responsible for the synthesis of GABA.[vi]

The chemical name for gabapentin is 2-[1-(aminomethyl) cyclohexyl]acetic acid and its molecule looks like this: Gabapentin is not a Controlled Substance, that is, one that the United States federal government classifies as having potential for addiction and regulates under the Comprehensive Drug Abuse and Control Act of 1970. However, gabapentin shares characteristics of addictive drugs in that it produces a withdrawal syndrome and certain psychoactive effects. Its cousin drug, pregabalin, is a Schedule V Controlled Substance.

What are the Medical Uses of Gabapentin?

The United States Food and Drug Administration approved Neurontin for the treatment of seizures in adults and children, especially as a supplemental drug used for the same purpose. In 2002, the FDA approved it for treatment for pain from shingles. Horizant and Gralise are extended release versions of gabapentin that were approved for shingles pain in 2012. [vii] Gabapentin was also approved for restless leg syndrome in 2011. [viii] When gabapentin was first introduced, doctors were excited about it because it had few side effects and drug interactions compared to competing remedies, and because it was not metabolized through the liver but rather excreted through the kidneys. [ix] Physicians began to prescribe it off-label for various conditions, including hot flashes during menopause, pain from fibromyalgia, bi-polar disorder, pain after polio, neuropathic pain, complex regional pain syndrome, trigeminal neuralgia, migraines, alcohol and drug withdrawal seizures, and diabetic neuropathy. [x] Later it was proven that the manufacturers of this drug had exaggerated claims about its effectiveness for various conditions. [xii] Pregabalin, commonly sold as Lyrica, is a newer drug now prescribed for nerve pain, epilepsy and fibromyalgia, and it has largely replaced gabapentin. [xii]

The usual dose for people over 12 years old who have epilepsy is 300mg three times a day. This can be increased to 1800mg a day. Doctors prescribe the drug to children with epilepsy based on their body weights. [xiii]

For post-herpetic neuralgia (shingles), the dose is the same as for epilepsy. For adults with restless leg syndrome, the dose is 600mg taken at five o'clock in the evening.[xiv]

Dosages for people with kidney problems may be different than these.[xv]

If you break a gabapentin tablet in order to take just half, you need to use the rest of the pill as your next dosage or else discard it.[xvi]

One unusual aspect of gabapentin is that its bioavailability decreases with the dose. For example, if you take 900mg, 60% is available to your body, but if you take 4800mg, that drops to only 27%.[xvii]

What are the Side Effects of Gabapentin?

The most common side effects of gabapentin are drowsiness, unsteadiness, sleepiness, loss of coordination, clumsiness, vision changes, and dry mouth.[xviii] Some people report the following rare side effects: edema, weight gain, swollen hands and feet, headaches, diarrhea, trouble thinking, abnormal thoughts, suicidal thoughts, fever, ataxia, diplopia, flu symptoms, shortness of breath, chest pain, mouth sores, chills, nausea, coughing, tremor, and other cold symptoms.

If you experience certain symptoms, you should call your doctor immediately because they can be a sign of a serious health condition. These can be black tarry stools, dark urine, tiredness, chest pain, suicidal mood, swollen glands, unusual bruising, rashes, or signs of an infection such as fever, cough and sore throat.[xix] Children react to gabapentin differently than adults. They may experience behavioral changes, moodiness, hyperactivity, overly emotional states, and restlessness.[xx]

What Drugs Interact with Gabapentin?

In general, you should not take gabapentin products with medicines that slow down the central nervous system and make you drowsy. These may be anti-histamines, narcotic painkillers, sleeping pills, muscle relaxants, anti-xiety medications, and drugs for depression and seizures.[xxi] Gabapentin products will react with drugs used during surgeries, even dental procedures.[xxii] Do not take gabapentin products with morphine (Kadian, MS Contin), naproxen (Aleve) or hydrocodone (Lortab, Vicodin).[xxiii]

Drugs containing gabapentin will interact with ketorolac, aluminum carbonate, aluminum hydroxide, aluminum phosphate, dihydroxyaluminum amino acetate, dihydroxyaluminum sodium carbonate, ginkgo, magaldrate, magnesium carbonate, magnesium hydroxide, magnesium trislicate, and morphine sulfate liposome. If you combine gabapentin with tobacco and alcohol and then take certain other drugs, you may cause an unpleasant or difficult reaction.[xxiv]

If you take any common antacids like Maalox and Di-Gel that contain aluminum or magnesium, you need to wait two hours before taking gabapentin.[xxv]

Which People Should not Take Gabapentin?

Gabapentin products have not been determined safe for pregnant or breast-feeding women or children, even though doctors sometimes prescribe it for children with epilepsy. People with histories of depression, mood or mental disorders, and kidney diseases usually do not take gabapentin because it can make these conditions worse.[xxvi] These drugs are used with caution for people with liver or heart diseases.[xxvii] What Lawsuits Have Ensued Over Gabapentin?

At first the United States Food and Drug Administration approved Neurontin for only for epilepsy but by the year 2000, 78% of prescriptions that doctors wrote for Neurontin were for conditions other than seizure sorders. The new drug was widely prescribed "off label" for more than a dozen conditions, including fibromyalgia, nerve pain, migraines, menopausal symptoms, bipolar disorder, and even attention deficit disorder in children.[xxviii] Between 2000 and 2004, Neurontin was generating \$1 to \$4 billion in sales a year for its manufacturers, which were first Warner-Lambert and later Pfizer drug companies.[xxix]

In 2002, Dr. David Franklin, an employee of Warner-Lambert, went to authorities to report that his company was promoting Neurontin for uses not approved by the FDA. While it is not illegal for doctors to prescribe drugs for unapproved uses, it is illegal for a drug company to advertise and promote them for unapproved uses. [xxx] Dr. Franklin testified that Warner-Lambert paid to doctors to present themselves as authors of studies written by non-doctors employed by the company. He said that the company also paid doctors to speak to other doctors about the off-label uses of Neurontin, and offered physicians expensive retreats and dinners at expensive restaurants to promote the drug.[xxxi]

As criminal and civil lawsuits were filed against the company, more negative information came out. Pfizer had apparently delayed or suppressed publication of studies that were negative or neutral about Neurontin, and exaggerated any positive claims. For example, three double-blind studies showed that Neurontin did not improve the symptoms of bipolar patients any better than sugar pills, but the company manipulated the studies and how symptoms were defined in evaluating the success of Neurontin. Of the 12 studies of the drug's effect on migraine headaches, two negative ones went unpublished, and some of the positive studies involved only patients who had taken 2400mg or more of the drug.[xxxii] In other studies, patients could easily figure out that hey were not in the placebo group, and ordinarily this would have meant that the study could not be published. Company spokespeople denied all the charges, but Pfizer ended up paying out \$430 million in claims to states enrolled in the Medicaid program.[xxxiii] In 2011, Judge Patti Saris of the U.S. District Court in

Boston ordered Pfizer to pay Kaiser Health \$142.1 million for duping the company into prescribing Neurontin for migraines and bipolar disorder.[xxxiv]

In 2004, gabapentin became available as a cheap generic drug, [xxxv] which drastically reduced its value as a money-maker for Pfizer. Pfizer introduced a similar but more potent drug called Lyrica, which was approved the FDA in December 2004. Lyrica was approved for seizure disorders and pain from fibromyalgia, but it is now prescribed for many other conditions "off-label," especially all kinds of chronic pain. Today Lyrica ranks 19th among all prescription drugs, and generates more than \$3 billion a year for Pfizer. [xxxvi]

What are the Risks of Taking Gabapentin?

Gabapentin doubles the risk for suicidal thoughts and behaviors, but the risk is still low. In one study of 27,863 patients on Neurontin and 16,029 on a placebo, 0.43% of the ones on the real drug became suicidal compared to 0.24% on the sugar pill.[xxxvii]

Gabapentin has some potential for abuse because it has psychoactive effects. Once you have been on it for a while, you may experience a difficult withdrawal syndrome when you try to stop taking it.

Gabapentin causes drowsiness and incoordination, which means that you are at an increased risk for accidents, and probably should not drive when you take this medication.[xxxviii]

Gabapentin increases the risk for sudden death after seizures in patients who have epilepsy. It can cause certain dangerous and sometimes even fatal reactions. Symptoms of this condition can be fever, rash, painful lymph glands in the neck and armpit, unusual bleeding, and yellow eyes and skin.[xxxix] Both of these reactions are extremely rare.

Gabapentin may slightly increase your risk for cancer.[xl]

Does Gabapentin Show up on Urine Tests?

Gabapentin has a half-life of about five to seven hours, which means it should completely clear the body wit 38 hours. Standard urine tests do not test for it because it is not a controlled substance.

What is a Gabapentin Overdose?

Symptoms of a gabapentin overdose may be appearing drunk and disoriented, with slurred speech and double vision.[xli] Such overdoses are very rare.

What is Gabapentin Withdrawal or Discontinuation Syndrome?

When gabapentin was first introduced, scientists believed that it could not cause a withdrawal syndrome. Since that time, there have been many case studies of people who experienced such difficult symptoms when they tried to stop using the drug that many had to go back on it. For example, one 81 year old woman with bipolar disorder took Neurontin for five years, and developed severe cold symptoms when she stopped. On the tenth day after stopping Neurontin in a gradual way, she had terrible chest pain, hypertension, and mental changes that were difficult to manage. She was back to normal within one day of taking the drug again.[xlii] In another case study, a 53-year-old woman vomited a black substance like coffee grounds and developed abdominal pain and black stools after stopping gabapentin. By days four and five, she developed restlessness, anxiety, agitation, disorientation, confusion, headaches, and extreme sensitivity to light. When her doctor administered gabapentin again, she was calm and normal within a day.[xliii] Another such study found that a 41-year-old male developed insomnia, headaches, heart palpitations, and excessive sweating after stopping Neurontin, but his symptoms went away when he went back on it.[xliv]

It has now been proven that gabapentin can build up in the body and cause a severe withdrawal syndrome similar to the ones for benzodiazepines and alcohol. The syndrome can last for weeks and even months, depending on the levels you took the drug and for how long you took it. Symptoms are agitation, confusion, disorientation, sensitivity to light, headaches, heart palpitations, and hypertension, chest pain. If you were taking

gabapentin for epilepsy, your seizures will probably come back. Some people develop seizures during withdrawal even if they never had one before.[xlv]

What is Gabapentin Addiction?

theory, gabapentin should not be addictive because it has no affinity for the nerve receptors associated with addictions to marijuana, benzodiazepines or opiates. It was marketed as non-addictive, but post-marketing studies showed that some people were abusing it. In the early 2000s, the drug was being sold to thousands of people with sales were over a billion dollars a year. Some of these patients were asking their doctors to increase their amounts (self-escalation) as they developed physical dependencies on Neurontin. When they tried to quit, they entered a withdrawal syndrome that caused them to go back to the drug. The new conclusion about gabapentin, as one expert put it, "The dependence and abuse potential for gabapentin has not been evaluated in human studies." [xlvi]

The United States Drug Enforcement Agency does not list gabapentin as a drug of concern, even though it is being sold on the Internet illegally. Its street name is "morontin" because it makes you "dopey."

What Treatments are Available for Gabapentin Addiction?

Because the withdrawal syndrome for this drug can produce unpleasant and even dangerous symptoms, you need to consult your doctor or an addiction specialist at a drug rehabilitation clinic about how you can safely stop taking the drug. The usual method is to wean a patient from the drug by gradually lowering the dosage, but this does not always prevent the withdrawal syndrome.[xlvii] If you have tried unsuccessfully to quit taking gabapentin, you should seek professional help.

The state-of-the-art treatment for drug addiction is to enter a residential treatment center where your withdrawal can be done under medical supervision. If you are addicted to other drugs or alcohol as well as gabapentin, our detoxification process will become even more complicated.

Once you have completed detoxification and your body is completely clear of drugs, you need to remain at the center for a few weeks or more so that you can undergo therapy to learn to live a drug-free life. You will work one-on-one with a therapist who can help you with any psychological problems you may have that contribute to your drug abuse. You may learn how to deal stress through non-pharmaceutical means such as running or other sports, yoga, meditation, journaling and so forth. You may have classes in the chemistry of drugs and why they can get such a hold on people's lives. You will learn how to avoid relapsing into drug abuse or alcoholism, even if you have a genetic tendency or long family history of such problems. Most drug rehab programs offer activities that are fun to do as well as ways of self-exploration, such as social gatherings, sightseeing, outdoor sports, and participating in art, drama and music. Once you return home, you usually remain in support meetings in your community and in individual and family counseling to help you stay on track.

How Can I Tell if I am Addicted to Gabapentin?

If you can answer yes to any of these questions, you may want to consider talking to your family physician or an addiction specialist at a residential treatment center about your concerns with gabapentin.

Are you taking gabapentin without a doctor's prescription?

Do you ask your doctor to keep increasing your dose?

Do you buy gabapentin from the Internet or other illegal sources?

To you experience withdrawal symptoms when you stop taking gabapentin?

Plave you tried to quit taking gabapentin on your own but failed?

Do you consider yourself to be someone who abuses drugs or alcohol?

Do you use gabapentin along with alcohol or other drugs as a way of treating emotional pain?

Are you taking gabapentin even though you experience unpleasant side effects and even though you are unsure if it is effective for you?

If money were no object, would you enter an intense program to help you deal with drug problems?

Do your friends or family members criticize you because of your drug abuse?

Do you feel guilty about how you use drugs?

Are you trying to cut down on your use of gabapentin or other drugs?

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