

**Proposed regulations:** The proposed regulations would have, in my opinion, placed my life in jeopardy, in the past when I was on oral opioids. I am currently using a pain pump but my pain is far from being under control. I depend on Medicare, and if these regulations are implemented, I will most likely suffer more in the future, should the current measures (pain pump and biologics) fail to manage my pain.

**Pain intensity 7; worst pain intensity last week 9; usual pain intensity (average in last week) 7; least pain intensity (in last week);**

Everyone genetically metabolizes medications differently. My pain management physicians in TX, IL, and IN didn't understand that my optimal morphine is liquid. When they forced me to use oral instead of liquid like my internist and pain management physicians prescribed for the 6 years we lived in Arizona they cut down on the effectiveness of the drug to manage my pain and I suffered for 8 years needlessly. When my pain management physician at OSMC, Elkhart, refused to implant my pain pump because of high pressure tactics being used by the state of Indiana and the federal government he placed me in harms way after promising me for 4 years that if every other method of treatment failed he would implant my pain pump.

I have several hundred friends whose physicians have arbitrarily cut off opioid use or require them to come to a pain management clinic once every week for a 7 day prescription requiring them to spend up to ½ day on Tuesday, Wednesday or Thursday. When my pain management physician arbitrarily cut down my oral morphine sulfate tablets I would have been at high risk if I had not been able to find a neurosurgeon who would implant a pain pump and a pain management physicians who would manage the refills.

When I read, for example, the state of Indiana legislation regulating opioids, the CDC and/or FDA guidelines, they read like they have been written by the pharmaceutical industry, government bureaucrats, and/or by individuals or companies who would personally profit from the outcome, not by chronic pain patients or consciences pain management physicians who treated me in AZ, TX and IL whose only desire was to manage my chronic pain as effectively and efficiently as possible and provide mw with the highest quality of life possible.

## **HISTORY**

I am a chronic pain patient with a primary diagnosis of uveitis secondary to ankylosing spondylitis a chronic inflammatory autoimmune disease.

I have relied upon a high dose of opioid medications since the week of 02/15/2002 to manage my chronic incurable intractable invisible persistent pain, allow for increased function, preserve my way of life, and remain productive.

I was awakened early morning 02/15/2002 with the most pain I had ever experienced in 62 years. I thought I was having a heart attack. My internist told me he would meet me at the emergency room of our local hospital. They checked me for heart and nothing came up. They then thought I had kidney stones but when I still had the same amount of pain after I passed the kidney stones they took an MRI and diagnosed me with degenerative disc disease and my 1<sup>st</sup> herniated disc.

For the first 6 months I wanted to find the best treatments for **DDD and my 1st herniated disk at L2/3**. My symptoms included pain, numbness, tingling and muscle weakness. I wasn't overweight at 6'3", 206 pounds but I needed to strengthen and stretch my muscles and ligaments that support the spine.

**I didn't use tobacco products.** My internist suggested several treatment options available to help reduce my pain and symptoms. The first step was to find effective treatment for my **chronic pain**. Based on my medical history and lifestyle **my internist and a spine care specialist recommended a conservative approach**. I owed a consulting firm, was in the middle of a campaign and **wanted to avoid surgery if I could**.

My physicians started with a regimen of **conservative (nonsurgical) treatments to ease the symptoms of my herniated disc**. My treatments included over-the-counter, nonsteroidal anti-inflammatory drugs (NSAIDs); physical therapy; the application of heat and/or ice; and regular exercise.

**When over-the-counter, nonsteroidal anti-inflammatory drugs (NSAIDs); physical therapy; the application of heat and/or ice; and regular exercise proved unsuccessful** at relieving my herniated disc symptoms my internist and spine specialist recommended drugs commonly used to treat herniated discs including **pain relievers oxycodone and hydrocodone, the muscle relaxants carisoprodol and cyclobenzaprine and oral morphine sulfate tablets.**

**When I received little or no relief** from medication and other nonsurgical treatments relieving my herniated disc symptoms my internist and spine specialist recommended **chiropractic care, acupuncture, massage, herbs and exotic botanicals.**

**When these conservative, complementary and alternative methods proved ineffective after 6 months** my internist, spine specialist, and naturopathic physician that was managing my chiropractic care, acupuncture, massage, herbs and exotic botanicals recommended a minimally **invasive, outpatient procedure they considered a safer and effective alternative to traditional open back surgery and a discectomy and stabilization surgery** was done on **11/01/2002.**

**In 2005, my pain management physician implanted a Spinal Stimulator in my back.**

**When medication, lifestyle modifications and other nonsurgical herniated disc treatments proved ineffective after 7 years** my internist, naturopathic physician, pain management physician recommended **open spine surgery.**

**Before consenting to open spine surgery, I consulted with a neurologist** to conduct many diagnostic tests to confirm nerve damage. The neurologist conducted diagnostic tests and **confirmed nerve damage. At that point my neurologist recommended I consider open spine surgery.**

My orthopedic surgeon performed an open spine surgery in 2009, at a Carbondale, IL hospital (i.e. we lived at Lake of Egypt, IL while I was employed by a not-for-profit, religious television network as senior development officer where I was responsible for direct mail, newsletters, and semi-annual telethons which raised \$15 million per year) addressed a number of issues such as scar tissue from the discectomy performed November 1, 2002, repaired the herniated disk and performed my 1<sup>st</sup> spinal fusion at L2/3. I needed a new battery for my Spinal Stimulator. Since there had been advancement in SCS my orthopedic surgeon replaced my Spinal Stimulator and moved my battery from my back to my abdomen because the battery was on my belt-line and it was painful to have it there.

We moved to Elkhart County, IN where I grew up in November 2009 after my health failed and I was forced to retire after owning my advertising, direct marketing, and financial development guidance firm from 2002 to 2004 and 2005 through May 15, 2008.

My neurosurgeon in Elkhart performed my 2<sup>nd</sup> spinal fusion L3/4 on January 10, 2010 at Elkhart General Hospital requiring 5 days of inpatient hospitalization and 6 months of outpatient physical therapy at OSMC, Elkhart,

Before November 1, 2012 my diagnoses included degenerative disc disease, herniated disc, Neuropathic pain (burning, shooting, tingling electric; foot pain and numbness), Nociceptive pain (musculoskeletal pain, aching, deep), Radicular pain (lumbar radiculopathy radiates along a nerve due to inflammation or irritation of the nerve root and extends from the spinal cord to the buttocks and down the legs; muscular weakness leads to deconditioning), Lumbar Radiculopathy (Low Back pain, Lumbar Spinal Stenosis, and Peripheral Neuropathic Pain (hands, feet; numb, tingling, pins, needles, electric, burning). and Sacroiliac Joint (SI Joint).

Additionally on or before November 1, 2012, other specialists diagnosed, if not included above, Back Pain, Degenerative Lumbar (Low Back) Spondylolisthesis, Discogenic (Disc-related), Chronic pain, Headache pain (forehead, eyes, upper back, neck; tight band, pounding, throbbing, dull), Lower Back Pain, Lumbar, Middle back pain, Neck pain, foot pain and numbness), Sacroiliac Joint (SI Joint), Sciatica, Spinal Fractures, Spinal Stenosis, Spondylosis, Stress, Tailbone Pain, and Upper back pain.

On November 1, 2012, the University of Illinois Eye Clinic, Chicago diagnosed me with uveitis secondary to ankylosing spondylitis. At the end of one day of diagnostic tests they informed my wife and I that I likely would never get out of my wheelchair and be blind within 3 to 6 months.

After November 1, 2012 and before December 2016 my orthopedic surgeon in Elkhart & Mishawaka performed day surgeries, back surgeries requiring inpatient hospitalizations and up to one month of inpatient rehabilitations for spinal fusion and failed spinal fusion surgeries of L2/3, L3/4 and L4/5. Compression and/or Wedge Spinal Fractures, (T-12) and Failed Back Surgery Syndrome.

I have been taking up to 295 mg. of liquid morphine sulfate extended release per day (2002-2005) or 295 mg. oral morphine sulfate tablets extended release per day (2005 -2017) and 30 mg. of oral morphine sulfate immediate release for flares. My internist and pain management physicians prescribed morphine sulfate over this 15-year period because nothing else would manage my pain which ranged from 2 to 9 on a scale of 1 to 10 with 10 being the highest.

**My physicians have consistently prescribed because a high dosage of extended and immediate release opioids, proved to be required to manage my chronic pain. While there was always a concern for taking prescribed opioids for chronic pain no other opioid or nonopioid medication compared with the effectiveness of morphine sulfate.**

**Medications:** Acetaminophen Celebrex, , Cymbalta, Ibuprofen , **Gabapentin**, meloxicam, Tylenol, Norco, methadone, MS Contin, Oxycontin, Percocet, tramadol, baclofen, **cyclobenzaprine**, capsaicin cream, **diclofenac**, lidocaine, Neurontin, Lyrica  
**Bold=** Current medications for chronic pain

**Invasive medical treatments**, Epidural steroid injections, facet injections, radiofrequency ablation, spinal cord stimulators (2005, 2009, 2015, 2017), morphine pain pump implanted in my right hip 8/22/2017; 11 back surgeries since 2002, 5 since 2010.

**Non-invasive treatments**, cold/heat, physical therapy

**Complementary and alternative therapies**, acupuncture,

**Pain intensity** **7**; worst pain intensity last week **9**; usual pain intensity (average in last week) **7**; least pain intensity (in last week);

**Primary Pain locations** Arm (R/L/BL), Back (low, mid, upper), Buttocks, Foot (R/L/BL); Generalized joint; Generalized joint; Groin; Hands (R/L/BL) Generalized muscle; Head; Hip (R/L/BL); Knee (R/L/BL); Leg (R,L/BL); Neck; Shoulder (R/L/BL); Wrist (R/L/BL)

**Primary Pain Duration** 02/15/2002 through present

**How does pain impact my life:** Mobility, recreation, sleep, mood, relationships, social, physical, sexual, work, school,

**If I wasn't on my medications as prescribed, using an implanted spinal stimulator (2005-present time) and a morphine pain pump implanted 8/22/2017 I would not have my pain under control or I would be dead. Clearly the benefits of the medication, spinal stimulator and morphine pain pump outweigh the risks.**

**Activities:** While my pain and mobility challenges what I'm able to do at the present time I'm able to shower with the help of a shower chair, shave 2x a week, dress, prepare smoothie meal

replacement, manage my 9 prescriptions, travel to and from for medical appointments, fitness club ½ day 2x a week for 3 ½ hours (bike, swim, dry sauna, wet sauna, jacuzzi) volunteer when I'm able at Elkhart County Clubhouse, Goshen, using transportation services since I haven't driven since August 1, 2016; watch TV, read on 32" monitor., listen to audio books, go out to lunch with my wife on occasion, meet with a friend on Wednesday evening for 60 to 90 minutes, mini-cleanup in kitchen, make coffee 2x a day. I work on my computer several hours a day.

**Sitting** is the hardest. I can **stand** longer than I can sit. I find it uncomfortable to **lay** in bed some nights because of Charlie horse, cramps, restless leg syndrome. I can walk up to several blocks in nice weather. T

**Pneumonia**: his past January was the 1<sup>st</sup> January since 2016 when I wasn't diagnosed with or being treated for **pneumonia**.

**Work or Employment**: While I was bedridden in 2002 and much of 2003 I was able to work in my field full-time + from 2004 to 2009. After I was forced to retire I joined online support groups for people with invisible persistent excruciating. chronic pain, people who have had spinal stimulator surgeries and people who have had pain pumps implanted. I advocate for people with chronic pain and uveitis secondary to ankylosing spondylitis. leave your job, lost your house, your family, car, etc. Share

**Blood pressure**: My average blood pressure is 130 over 75. My pulse is normal at rest. When I ride stationary bicycle 4 miles in 36 minutes my heart rate averages 80 with a high of 90.

**Medication effects**: The only adverse effects I've experienced is that the Tylenol in NORCO about killed my liver. Hospitalized and placed in medical coma for several days while IV's cleansed my liver. Labs normal now. Unable to take Tylenol.

**Therapies**: I've completed mindfulness, CBT therapy, DBT Therapy, counseling for past 15 months.

**Compliant/Model Patient**: All my physicians would vouch that I have been a model, compliant patient committed to wholeness of body, mind, soul, spirit

**Pharmacy**: I've used Walgreens Pharmacy, Bristol and Cassopolis, Elkhart since the fall of 2009.

**Medication management**: I keep my medications in cabinet. Karen and I are the only people who live in our apartment except for once a year at Christmas our married son and family visit us from Manitoba Canada. **I've never lost or had any medications stolen. I do not allow others to use my medication and I do not keep excess medication.**

**My story narrative**: Larry Lee Miller, 77, born 03-26-1940, Elkhart General Hospital; grew up in Shipshewana and Middlebury; one sister, Janet; married on 12-19-1964, 53 years, Karen Eileen (Stephey), grew up 3 miles west of Bremen, IN on a spearmint & peppermint farm; 4 sisters, Donna Jean, Janice, Glenice and Linda; Elementary Education degree from Bethel College,

Mishawaka, IN; 1 child, Craig (Stephey) Miller; 2 grandchildren, Berrigan, 19, freshman at University of Winnipeg, and Wil, 13, freshman at Neelin High School); USAF 1963-1969 honorable discharge, responsible for base laundry; 48 year career strategic planning, financial guidance (bonds, 1st mortgage, bridge and construction loans; resource development or fundraising (annual, capital, special gift, estate planning); GIK, special events; direct mail, sharathon's, telethon's; student recruitment; over 400 clients, over 4,000 campaigns, over \$400 million net to nonprofit organizations. My internists and pain management physicians managed my pain by prescribing the right complement of OTC drugs, Rx's including 325 mg. per day of opioids, alternative, complementary, and western medical practices from 1966 to 2009.

When I was forced to retire after a 48-year career, we lost our home. business, over \$65,000 dollars a year of income, fringe benefits and over \$1,000,000 of real estate property and other assets. We moved back "home" to be closer to Karen's four sisters because we, my sisters-in-laws and my brothers-in-law needed more support. Karen's youngest and oldest sisters and one of my brothers-in-law have passed away since we moved back from breast or kidney cancer, Parkinson's, and/or strokes.

**\*\*\*\*\* The federal government, the state of Indiana, Medicare, my BC/BS supplement and my former PMP's denied the right complement of OTC drugs, Rx's including opioids, alternative, complementary, and some critical western medical practices and I have lived with chronic nerve, and musculoskeletal pain in the range of 7 to 9 on a pain scale of 1 to 10 since 2009 when the parties reduced my opioids from 325 mg. to 225 mg. to 120 mg. to 60 mg. to 30 mg. a day. When they reduced my opioids, I started to ask my PMP's to authorize a morphine pain pump. They refused to authorize it.**

**On October 25, 2012 my ophthalmologist was concerned that I was losing my eyesight for my 3<sup>rd</sup> time since 1966** because of another attack of uveitis. He admitted me to the University of IL Medical Center, Eye Clinic, Chicago about two hours west of Elkhart. On October 29, 2012 friends of ours drove Karen and I to Chicago for an appointment at 9 AM on November 1. At the end of a full day of tests they diagnosed me with uveitis secondary to ankylosing spondylitis. At the **end of the day the director of the clinic told Karen and I that likely I would never get out of my wheel chair and be blind within 3 to 6 months.** They started to treat my uveitis, gave me a prescription for eye drops and referred me to my ophthalmologist for monitoring. Thy referred me to a rheumatologist in South Bend and shipped my file overnight so the rheumatologist could review it before my appointment the following Monday.

Friends drove us to South Bend for a 10 AM appointment. The rheumatologist said that she had **reviewed my records and would not treat me for ankylosing spondylitis. When I asked why she told Karen and I that I was too high risk, there was no cure and no treatment given the stage of my disease.** Our friends drove us home. In the weeks ahead, **I was assessed by an agency for the blind, signed up for white cane training instead of braille, applied for and secured a grant for the redesign of my home office and acquired all new computer hardware, software, printers, desk that rises from 36 inches to 48 inches and office chair that is designed for individuals with ankylosing spondylitis. I dictate and convert speech to text, convert text**

to speech, and started talking and listening instead of typing and reading. I'm seriously visually impaired and have inoperable glaucoma and cataracts.

About 30 days later I found a rheumatologist at the Elkhart Clinic who said he was treating over 100 patients with an inflammatory arthritis diagnosis. He recommended that we start with a remicade infusion once every 5 weeks and a minimum dose and prescribed methotrexate. Within 30 days my AS was in remission and over several months I was able to use a walker and then a cane instead of my wheel chair most days.

On May 30, 2015 I was diagnosed with pneumonia which hung on for 15 months. In 2016 my AS attacked my heart and I started treatment with a cardiologist. I now see an internist and 8 specialists. My AS has continued to destroy my spine. I have had 11 back surgeries since 2002, 5 since 2009 for spinal fusions and failed fusions.

On August 1, 2016 I decided to drive to Pokagon State Park, in Angola, IN, about 45 miles east of Elkhart on the Indiana toll road to check out the park for a prospective client's seminar/conference.

I was driving 65 to 70 mph on I-80/90, felt just fine and about 4 miles west of Angola and the exit for the park I blacked out and our van ran off the right side of the toll road into a ditch. The van had turned over about 45 degrees and it took me several minutes to open the door and get out of the van. When I got out of the van I saw a state highway patrol car with flashing lights and a patrolman walking towards me. I passed out before he reached me. He saw that the van was totaled and called Angola EMS and according to the reports they couldn't resuscitate me and diagnosed me with cardiac arrest, respiratory arrest and a collapsed lung. The hospital ER physician in Angola couldn't resuscitate me and decided to life flight me about 50 miles north to a level 1 trauma center. The trauma center hospital kept me in a medical coma for about 12 to 15 hours and started to treat my injuries. They didn't have my medical records, so they didn't know about my autoimmune disease and my medications. The highway patrolman drove Karen to Ft. Wayne to the trauma center. When I woke up at noon on 08/02, 2016 I was wired up every which way, had IV's in both arms, was on oxygen and Karen was standing beside my bed holding my hand. She said, "I love you, I want you to live, get well " At that point I was surprised, glad to be alive but I had a lot of questions. I had a "do not resuscitate card" in my billfold which no one found. I didn't remember anything. After 3 days the hospital discharged me, and our friends drove Karen and I home about 70 miles southwest.

Three days later I woke up and was in the worst pain than I had ever been in and asked Karen to take me to the ER. The ER physician asked me questions and I volunteered about my automobile accident, the drug overdose, the hospitalization and treatment in Ft. Wayne although I only knew what was on my discharge papers. He asked me if the trauma center hospital took blood tests. The ER physician or his staff called EMS in Angola and the hospitals in Angola and Ft. Wayne. The Elkhart ER physician ordered blood tests and discovered that the Tylenol in Norco had destroyed my liver over several months of use. Apparently since I had taken morphine sulfate for 15 years I had become dependent on morphine and the over dose of morphine didn't do any damage. He told Karen and I that he and the hospital would do what they could, but he couldn't make any promises. He told Karen and I that I could die within the first



24 hours but that if I made it 3 days he felt I had a chance for recovery. He said, "you guys better say your good byes" before I signed off on treatment and before his nurses placed me in a medical coma. Minutes later I was in a coma. They started IV's to cleanse my liver.

It took 3 days to cleanse my liver, but they saw that I was making progress every day. After 3 days I was diagnosed with an opioid induced mood disorder and prescribed Lexapro. I've been in CBT and DBT therapy for the last 11 months.

I've learned that I or anyone can't avoid suffering but I can and am learning how to cope with it, find meaning in it, and find a purpose higher than my pain and suffering. I've moved forward with the full support of my family, hundreds of friends, and a new PMP who conducted a trial for a morphine pain pump last September and upon passing authorized one of my neurosurgeons to implant a morphine pain pump 09-22-2017.

I'm hopeful that by the end of the year my brain will accept the full benefit of the morphine pain pump. My PMP tweaks my dose and frequency every month. For the first time since 2009 I feel like I'm moving in the right direction, recovering, and becoming whole in mind, body, spirit and relationships. Every morning that I wake up I thank God for a bonus day. I could die tomorrow. My AS is still raging and taking its toll.

**Thank you for providing me the opportunity to express my concerns and advocate for individuals whose only desire is to be served by those who wish them wellness and wholeness in every area of life – body, mind, soul, spirit and relationships.**