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### **Chandra's Story**

I was diagnosed with SLE Lupus 17 years ago. Over the years, I have also been diagnosed with Sjogrens Syndrome, RA and Osteoarthritis. My inflammation that causes me severe pain, was treated with Cymbalta for many years until suddenly my blood tests showed that my kidneys were being damaged. I have stage 3 kidney disease because of taking Cymbalta for too long. My nephrologist determined through blood tests and an ultrasound of my kidneys, Cymbalta, not Lupus was the cause of my kidney damage.

My rheumatologist prescribed Limbrel 500 to treat my inflammation. It works as well, if not better than Cymbalta. I can't take any NASIDs because of my kidney disease. I am allergic to Morphine and Oxycodone. I wouldn't want to take any addictive medication for pain anyway. I don't know what I'm going to do now that I don't have Limbrel 500 to take for my inflammation! I suppose I will have to suffer and stay in bed since I will be in so much pain I won't be able to move. The FDA doesn't think of all the patients that need this medication!!! My doctors do regular blood testing, as all doctors should, to make sure my organs are not being damaged by my auto immune diseases or medication. Now that medical records are electronic, the FDA should be more assured that doctors are following all the rules. I have all confidence in my physicians, but the FDA has let me down more than once. Why don't the the patients ever have a say with the FDA? After all, we are the consumers and the ones that need this medication. I for one, feel that before a medication is pulled from the market, that a panel of patients that take the medication should be consulted and heard. We are perfectly capable of deciding whether or not we want to continue to take a medication after a study is done showing side effects. Especially when the the damage is reversible when the medication is discontinued. I am willing to back your company and testify before congress and the FDA that this medication is necessary for the lives of the patients that have taken it.

Sincerely,  
Chandra

### **Phyllis' Story**

I have osteoarthritis. I've already had hip replacement surgery because the pain became unbearable. I have been told I now need knee replacement surgery due to the same condition. I also have a GI disease which prohibits me from taking NSAIDs. Having had the one surgery, my hope is to postpone the knee surgery as long as possible. I've had shots, used topical ointments; my orthopedist has worked with me patiently to find other treatments. We landed on Limbrel 500 and it worked

wonders! Over the course of several weeks, my pain begin to lessen; I began to feel like I actually had two legs to walk on! Now I can no longer get my prescription. Even after a week, my pain is starting to worsen. I need this medication. What I began to think of as a miracle drug has been abruptly taken away. I can find no reasonable explanation. Clearly no one in the decision making tree has osteoarthritis or has had to have joint replacement surgery. My New Years hope is Limbrel will once again be available to those of us who desperately need it!

### **Bridget's Story**

I am a new user of Limbrel, just got a new RX from my dr who apparently did not know about the FDA pressured recall either. I have been using Limbrel for 2+ months now and have had no side effects. I have liver enzymes checked regularly as I have a syndrome that can elevate them, and my enzymes are in the normal range. I cannot afford to take it twice a day as originally prescribed because the out of pocket cost was \$850, so I was taking it only once a day. There was some noticeable reduction in pain. I have osteoarthritis of the knees (both) and no medications for pain or inflammation. This was a godsend for me. Many meds I cannot take, not that there are many anymore for osteoarthritis. I use the \$99 coupon Limbrel's mfr provided on their website (my pharmacy nor my orthopedist told me about a coupon or that my insurance would not cover it). My understanding is that no insurance covers it. I use another medical food for another condition and it helps me tremendously. Again, paying out of pocket. I just heard that Primus has removed Limbrel from the market pending further negotiation with the FDA. I honestly do not understand the FDA anymore. There are so many dangerous drugs prescribed every day (like Percocet and Oxycontin for example) which warrant some action on everybody's part to reduce the availability of the drugs, and the frequency at which they are prescribed and the low prices many patients pay for those prescriptions, yet they hound companies like this making unique products serving a valuable purpose at very low risk. I doubt that plant based antioxidant vitamins are causing anyone to get pneumonia or elevated liver enzymes. Those patients that did may very well have comorbid conditions. I urge the FDA to review the paperwork submitted by Primus, eliminate all duplicated records which are skewing data, and help the company get this very helpful product back on the market.

### **Ashe's Story**

I am 68. I started taking Limbrel around 5 years ago. It was prescribed back pain and sciatica caused by a degenerated L5-S1 spinal disc. The result was phenomenal; far better relief than any result I had obtained from NSAIDS (Limbrel had no side effects) or gabapentin (which had terrible side effects). I refuse opiates. An added benefit was my hands-I am a semiprofessional classical guitarist and lutenist who needs to practice many hours per day. Music is my life! I have creeping osteoarthritis from wear and tear from 55 years of practice. Suddenly, I could practice for hours without pain. 2 years ago, when I retired from my engineering job and switched from BCBS to Medicare, coverage

for Limbrel ceased. I tried to go without it for several months, but it was clear that I needed Limbrel. I went back to my doctor, got the prescription refilled, and was preparing to pay cash out of my pocket when the Transition Pharmacy's miracle appeared. Now the FDA wants to ban Limbrel? What-are the NSAID companies bribing them to do this? Without Limbrel, I AM SCREWED. MY LIFE IS OVER!

### **Barbie's Story**

I developed OA after a car accident several years ago which caused two compression fractures in my back. I was prescribed several different pain medications throughout the years . I didn't trust any of them, nor did I like the idea of using opioids for pain management. I have always felt that natural is better. Medical foods are indeed healing, at least in my experience. I was prescribed Limbrel and it definitely worked. I love my Limbrel! I have NEVER had a reaction of any kind while taking it. I take Rhuemate along with Limbrel and actually feel like my overall health and pain issues are improving greatly. There is nothing wrong with my liver and feel the FDA has provided zero proof for what they claim, I believe the information is false. Frankly, I do not have very much faith in the FDA. I believe the FDA is not looking out for our health, instead they are protecting Big Pharma's wealth by only allowing medications that cause more sickness, (which keeps us coming back for even more medications). I am absolutely fed up with the FDA. I want to continue my Limbrel. I have no fear that it will cause harm to my body, it is after all FOOD. I feel cheated out of a medication (a FOOD medication) that actually works on my pain without causing organ damage like the other "FDA approved" painkillers do.

#frustratedwiththeFDA

### **Curtis' Story**

I have suffered from osteoarthritis (OA) for many years. In 2003, due to severe OA in my right hip I had a hip replacement surgery. In 2013 I had the same in my left hip. In the interim I began to have OA pain, stiffness and limited range of motion in the joints of my hands, shoulders, elbows, knees and feet, everywhere except my ankles and wrists. Due to other medical conditions I'm unable to take any ANSAID type medication to help with my OA pain.

During the past 15 years, living with such pervasive OA pain and stiffness was very difficult and limited my activity. My feet and knees hurt when I walked, or went up stairs, my hands hurt when I grasped something, any movement involving a joint caused serious pain. Life was rarely enjoyable. Then about a year ago I saw Dr. Dimitri Karayev, of the Los Angeles Center for Rheumatology. He prescribed Limbrel and after about 2 months all of my OA pain was gone, I had greater range of motion and no stiffness. My blood was checked every 2 months and everything was good. I had no side effects.

It was absolutely remarkable. Limbrel changed my life, I felt rejuvenated and more youthful. I had my life back!

But now the FDA has taken Limbrel away from me. I've been without it for 10 days now and my OA pain is coming back. Soon I'll be suffering the pain and stiffness like it was before Limbrel. Please don't ruin my life allow me and others who can take Limbrel without side effects to take it.

### **Dennis' Story**

My name is Dennis and I have been using Limbrel for 10 years. When my aging Mother was using Celebrex and her stomach started bleeding, as is one of the side effects of the drug, she was very upset and did not know what to do, I suggested she also use Limbrel and her stomach healed and her arthritis was treated with no side effects from the Limbrel. I am now 71 and this great product for arthritis is being taken off the market by the FDA for unsubstantiated and trumped up side effects is outrageous, especially since Celebrex and other drugs have much more side effects than does Limbrel. Another case of government largess and deep pockets of giants like Pfizer Pharma lobbying against small competitors like Limbrel, who make a better product that works well with much less severe side effects. The FDA is in bed with BIG Pharma and that is no secret. That is why we have an opioid epidemic and good solutions like Limbrel are taken away from the American public. I want my Limbrel back on the market. I depend on it and will not take Celebrex. I know what Celebrex did to my Mother. This is simply outrageous that Celebrex gets a nod while Limbrel which has negligible side effects gets the full force of the FDA's wrath. It's almost unconscionable that the under the table payoffs to the FDA's bureaucrats is allowed to happen in the United States of America.

### **Kathleen's Story**

I am a 62yr old female with pretty severe arthritis. I have had 15 orthopedic operations including hip replacement and a revision of the same hip. I have a lot of stiffness and soreness. Limbrel has changed my life. I could stop taking prescription anti-inflammation medicine. I am able to turn my neck without crunching noises and pain. My hands don't hurt. Every single joint feels better. I also feel mentally sharp and focused. I had changed my diet to include flavinoids wherever possible-as much as possible-for the overall health benefits. It is impossible to eat enough. Limbrel fixed that. I am so sad that a healthy option has been taken away. It seems they would rather give you painkillers than something healthy. It doesn't make sense. I have been taking Limbrel 500 for 4 months and I have ZERO side effects. The FDA is really not acting in my best interest. Please continue to push them. I need Limbrel.

### **Rivian's Story**

I have lived with spinal arthritis since my 30's. I am now 66, and also live with fibromyalgia and systemic lupus. Having been on NSAIDs for 30 years, my kidney function was finally affected, and I attempted to go off the drugs. The result was horrific. The pain made life intolerable. My rheumatologist then called me and

suggested Limbrel, which I researched and was delighted to see it was food-based and would not affect any of my organs. The first week of taking the product was a little rocky, but I improved steadily until I felt even better than I had on the NSAID I had taken previously. My blood tests bore out the validity of Limbrel, as I had the best results I'd seen in a decade or more. The idea of not being able to take Limbrel is extremely disturbing, as I have no alternative except to go back on an "approved" medication that will kill me, versus one that will not. This makes no sense whatsoever. The FDA must realize that there are many of us for whom longtime use of the well-lobbied NSAIDs have resulted in real kidney damage. Yet they see no problem there, and focus instead on a new product that is far better yet is out of the mainstream of pharma manufacturing. I plead with the FDA to return Limbrel to the market with the necessary caveats as required.

### **Deidre's Story**

I have been taking Limbrel for approximately 3 years. It has been VERY effective for me. I have had osteoarthritis for about 30 years & getting progressively worse. I initially used bovine cartilage, & then moved onto glucosamine chondroitin increasing the dosages every few years. It was finally not helping me anymore. In 2014 or early 2015 I complained to my GP & he suggested I try Limbrel with the caveat that it worked for some patients & not others. He warned that it might take 2 weeks. WELL, within days I felt considerable relief! Since there is no cure for this disease & I am determined to stay very physically active, it was a "Godsend". I play weekly tennis, ski in the winter, golf in the summer, mow my own lawn, etc. I would not be able to do all this if I were in the pain I was in prior to Limbrel. Six months ago I recommended it to a friend who was at the point of limping--in such pain. She, fortunately, received considerable relief when she started taking Limbrel & has continued to do so. Financially, I am able to pay the \$50/month (a discounted amount) thank God but I am sure there are many "Seniors" who can't. We need this prescription food. Remember, it is not a steroid, ibuprofen, an opiod, etc. all of which cause damage to the liver, lining of the stomach or addiction!

### **Rita's Story**

I am writing with my experience using Limbrel 500 to manage my severe osteoarthritis (OA) of my right knee and moderate OA of my left knee. The OA began in 2003 after a vehicle accident where I injured my right knee which led to an arthroscopic surgery and long, difficult recovery. I started using voltaren cream and graduated to Celebrex in 2009 when the pain became very strong. After a few short months on the Celebrex I began to have symptoms of high racing pulse and very high blood pressure (HBP). After numerous medical tests it was determined the Celebrex caused the heart issues. Infact my new cardiologist threw the Celebrex in the garbage can and I was told I needed a new pain Med for OA. My orthopedist then suggested a new product Limbrel to try. In 2010 through 2013 I used the Limbrel

with great success. The pain was down. I was back to getting out and working a full day with no or minor pain. The pain management was as good or better than Celebrex without the heart problems (I still have the HBP but the other side effects like racing heart rate abated when i stopped using Celebrex). In 2014 CVS stopped covering Limbrel so my doctor put me on another type of NSAID, Duexis, given the bad Celebrex experience. I was on duexis for about 6 months when I developed a skin rash. After few months, I was diagnosed by my dermatologist with Lichen Planus. It was posed that Lichen Planus came from NSAID, duexis. Once I stopped duexis, the Lichen Planus went away within a few days. At that point, it was determined I am allergic to that type of NSAID. THUS my doctor wrote an exception letter to CVS for Limbrel and I had it covered until this recent problem with FDA warning and removal from market. Clearly. I need Limbrel for the pain and inflammation. I have no other anti inflammatory medication I can take as I either need to risk more heart damage w Celebrex or live with Lichen Planus if I use the other NSAIDs. I do not want to risk opioid addiction.

In terms of Limbrel. I have been on it 2009 to 2013 and 2014 to 2017. I have had quarterly liver blood tests to monitor my liver enzymes and all is good. In terms of hypersensitivity pneumonia. After 8 years of use, I am not concerned.

Please return Limbrel to the market. There are hundreds of thousands of people like me who are doing well on Limbrel and depend on it as we have bad experience with other anti inflammatory products. Regarding the Limbrel side effects. Regarding the liver concerns, require quarterly liver monitoring for preventive care. Regarding the hypersensitive pneumonia, increase awareness at the onset of treatment to monitor for it. I am deathly allergic to farm raised salmon. The way I found out. By eating farm raised salmon and having to go to hospital. Should the FDA outlaw farm raised salmon because me and a handful of people are allergic. Probably not. Same thing with Limbrel, don't put a handful of negative side effects ahead of the tremendous benefit it provides to hundreds of thousands of Limbrel users.

### **John's Story**

I've been using Limbrel 500mg twice a day for about 5 months for debilitating arthritis in my hands and overall inflammation in my joints. I was at the clinic today for a check up and told the NP that Limbrel has been a minor miracle in that it has completely removed the swelling and inflammation in my hands I had each morning. I was getting to where I could barely hold a coffee cup and now I have complete freedom of movement in my fingers and knuckles. I was then told the product was recalled and was floored. I cannot use NSAIDS due to the inflammation they cause my gastro intestinal system so the discovery of Limbrel then it's real success in reducing the swelling a inflammation has had a positive impact on my quality of life. I've waited till the end of this testimonial to mention I had been taking Oxycontin 10mg for nearly 8 years with success but was trying to find another avenue for pain and inflammation relief. With the crackdown on opioids and now placing Limbrel on recall you the FDA have negatively impacted my well being and my quality of life.

### **Jeff's Story**

I have severe arthritis in my hands and trigger finger issues due to long term Type 1 diabetes. I am allergic to aspirin and NSAIDs, so I cannot take any of the new, effective treatments. The pain in my hands was so bad I had several surgeries for trigger finger release and carpal tunnel with only moderate success. My rheumatologist suggested that I try Limbrell and he said it works very well for some people and not at all for others. I was very lucky and began to feel relief from the constant pain almost immediately. I noted no side effects from the medication. During the last several years each time I would have difficulties getting the medication there would be a return of extreme pain and swelling in my knuckles. I dread a future without the pain relief offered to me through the Limbrell if it is taken off the market.

### **Jennifer's Story**

I have RA. I was in terrible pain every morning. My rheumatologist suggested I try Limbrel. He said that for some of his patients it works wonderfully, for other it doesn't seem to do anything. That night I took one Limbrel 500. The next morning was the first time I got out of bed without pain. I have been taking Limbrel 500 since then, and I haven't had the pain I used to have before starting Limbrel. Since Limbrel 500 is no longer available, I expect to have that terrible pain again.

It is my belief that the FDA is not allowing the production of Limbrel 500 because the big pharmaceutical companies that the FDA works for has insisted that the FDA destroy a supplement that works well. These pharmaceutical giants want to leave us no alternative than to pay their super-inflated prices for drugs that cause serious side effects, "including death" as their advertisements say.

If the FDA has reliable, undeniable evidence that Limbrel 500 causes a danger, they should have to disclose proof of their findings publicly. Since they are being paid handsomely to unilaterally destroy the competition of the drug companies, I am sure we will see no proof or justification for this action.

### **Barbara's Story**

I need Limbrel back. Where is the FDA's proof of claims? I personally feel Limbrel has helped me greatly. The quality of my life has increased through Limbrel. Is this the reason they are taking it away from us? Because it SAFELY works? FDA approves thousands of drugs that cause extensive ailments and even death, yet they disapprove of a medical food that absolutely helps people like me. I have lost all faith in the FDA. I demand the FDA provide us with proof of their claims.

### **Mary's Story**

I've been taking Limbrel for over two years for my OA. It is far superior to the other drugs, such as Vioxx, for my joints. I have not experienced any of the symptoms of liver dysfunction or chest difficulties. Limbrel has allowed me more freedom of movement with less pain, has enhanced my standard of living and my husband and I have been able to travel overseas. My primary

care physician has liver function tests done every six mos., with no abnormalities reported. If FDA has knowledge of adverse reactions, they need to share it with Primus in order to correct the problems. Sounds like some hanky-panky going on at FDA

### **Harry's Story**

AFTER 20 YEARS OF SEVERE ARTHRITIS PAIN, I FINALLY FOUND SOMETHING THAT REDUCED MY INFLAMMATION AND PAIN FROM LEVEL 8 ON A DAILY BASIS TO A LEVEL 1-2.

A MIRACLE FOR ME. NO ADVERSE EFFECTS AFTER DAILY USE FOR 3 YEARS.

FDA SEEMS TO HAVE NO PROBLEM HAVING EVERY DOCTOR IN THE WORLD HAND ME A BOTTLE OF OPIOIDS, BUT THIS FOOD BASED MIRACLE IS BEING DENIED ME.

### **Hein's Story**

I have been taking Limbrel 500 for over 10 years and it has made my arthritis pains very manageable. I am now 93 and hope that I will be able to continue taking Limbrel ad infinitum. Lets convince the FDA to release the drug to the 450 000 satisfied users; 194 cases with issues is .05% not a very significant number

### **Joan's Story**

I have been using Limbrel for about two years and think that it had helped me . My physician treated me with hyloronic acid injections on my left knee and I went only once more than a year ago. I was treated with the same injections on my right knee, going every six months for about four times. After that the treatments no longer helped and I had to have the knee replaced. My fear is that the right knee will begin giving me the same problem, and since I am 90 years I don't want to have further surgery. I never had any side effects, and only enjoyed being pain free. I hope the FDA will not drag its feet, and allow Limbrel to continue helping people with osteoarthritis.

### **Nancy's Story**

I switched to Limbrel after years of significant side effects from regular NSAIDs. Those side effects required i take other medications. From the first bottle of Limbrel I was significantly healthier for my side effects were gone and my joint stiffness and swelling were under control. I implore the FDA to make Limbrel available to all the great numbers of osteoarthritis sufferers who have greatly benefited from taking Limbrel such as myself. Also, taking Limbrel cuts the amount of opioids one has to take due to the stuffiness and swelling of OA. Please do what's best for the patient even if it's not in favour with politicians and non-medical food supplement pharmaceutical companies.

**Nina's Story**

I have an ulcer and cannot tolerate any other anti-inflammatory, not even aspirin. My rheumatologist had a hard time finding this one. Now that it's off the market, there is no anti-inflammatory I can take for any condition, acute or chronic.

**Amalia's Story**

I am 54 years old. I have osteoarthritis and since I started taking Limbrel 500 I don't need to take pain medicine anymore. I can go up and down the three levels of stairs in my house without my knees hurting.

I noticed the difference when I ran out of Limbrel and I didn't take it for couple of weeks. My knees started hurting again and I had trouble climbing the stairs. As soon as I resumed taking Limbrel, I noticed the difference in the quality of life that I achieve by taking it.

**Diane's Story**

Limbrel was suggested to me because I cannot take NSAIDS due to kidney disease and gastric discomfort. I would like to be able to try it because I suffer from osteoarthritis in my knees and back. Unfortunately before I could even see if it would help like was removed from the market. Bring it back. People like me need the help!!!!

**Raymond's Story**

I tried to take NSAID drugs but had so many side effects that I could not take them at all while OA continued to increase. Then one day my doctor told me about Limbrel and how patients that could not take the NSAID drugs were able to take it. He said it was a food base anti-inflammatory drug that lots of patients were able to take. He wrote a prescription and I started taking it. In a short while I could feel the benefits and when I had to stop taking it, for surgery, I could tell a lot of difference. I can't imagine how it will be not taking it at all.

When I started taking Limbrel the insurance paid for it but then they stopped and I had to pay out of pocket. I sure hope this is a short time with the FDA.

**Rosemary's Story**

i have terrible osteoarthritis on my right thumb and hand. Limbrel had really been helping me. Instead of throbbing right hand and thumb I could finally sleep at night! Why can't I use it anymore?

**Sandra's Story**

I'm 51 ,I have osteoarthritis ,I have sensitive stomach and this are the only pills on the market for me.limbrel does not hurt my stomach. I been taking limbrel for about 4 ,5 YEARS, no side effects and I really need them, but for winter even more.it is really sad that my only choice can be taken away..

**Susan's Story**

I have been taking Limbrel 500 for quite some time and with much success. I had been experiencing a high level of pain and with the diet for fibromyalgia and Limbrel, most of the pain has gone. Without the diet and Limbrel my pain returns. I was shocked to hear that my medication was recalled.