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Dear Lyle Jaffe,

The letter below is an answer to the FDA rejecting my petition to make naltrexone an over the counter (OTC) drug that I mailed in. You have mentioned that I have only 30 days to appeal the decision. Is it safe to say that if someone discovers a harmless, sure fire cure for AIDS, if your ruling denying it were made, if the ruling were not disputed within 30 days, Americans would have to be denied it for the rest of eternity?

I had emailed an answer, faxed an answer, and I believe I had mailed an answer, with no reply. Would you please forward this letter to Dr. Woodcock ? I will wait 30 days before bringing the matter to court.

Charles Weber

exemption 6

Dr. Janet Woodcock, MD
Food and Drug Administration
Rockville MD 20857

Re: Docket No. 2006

0508/CP1

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Dear Dr. Woodcock;

I did make it clear that naltrexone should be used for multiple sclerosis. Numerous case histories substantiates it (see http://www.ldners.org/Articles/LDN_Medical_Hypotheses.pdf). I further made it clear that naltrexone is suspected to be at least advantageous for Crohn's disease, chronic fatigue syndrome, and cancer. Other OTC drugs are allowed if they are merely advantageous. Vitamin C is granted a 22% advantage for colds in the 2005 Physicians' Desk Reference, for instance. Vitamin D

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has been found to be advantageous statistically in several degenerative diseases beside bone growth, perhaps in some cases because of a role in magnesium absorption.

It should not be necessary to specify every other use for a harmless drug, or prove the efficacy or lack thereof for every other disease. This is more than just arrogant. It is very inhibiting to the advance of medicine. Cod liver oil actually declined in popularity for rickets in the medical profession for 150 years (Schmidt) until the discovery of vitamin D in the 20th century made it impossible to deny any longer. It has been known for years that aneurysms are caused by a copper deficiency (see http://charles_w.tripod.com/copper.html), yet very few doctors prescribe this fairly harmless drug for aneurysms, slipped discs, hemorrhoids, etc. Should copper be made prescription only until such time as a consensus is reached in the medical profession? Anacardic acids in cashew plants have been known for some time to be very lethal to gram positive bacteria, which are the usual bacteria in toothache (see http://charles_w.tripod.com/tooth.html). Yet the only ones in the world who are using cashew plants for toothache are some lay people on the Gold Coast in Africa. History is replete with instances when citizens outside of the medical profession have made important discoveries. Pasteur's linking of some kinds of diseases to bacteria as well as the derision with which he was greeted comes to mind. Only one nutritional disease discovery was ever made by a medical doctor. It would be more than just arrogant to deny citizens the opportunity to experiment with harmless molecules. Denying citizens such an opportunity would be very disadvantageous to medical advancement and prevent those in the know from using this harmless drug, low dose naltrexone, and as a result lose the efforts of millions of people gaining case histories. Evidence from millions of individual cases is easily as convincing as clinical trials of a few hundred.

As for evidence for safety, there is plenty of evidence that low dose naltrexone is safe. The only contraindication known to

date is its use during a bacterial infection. However there are excellent antibiotics that can easily correct a mistake along these lines. It is conceivable that down the road someone will discover something a little disadvantageous for this very useful drug. But if you use that criteria, no drug would be approved for over the counter because new discoveries are possible for all of them. Indeed many over the counter drugs already have serious side effects and remain OTC. Aluminum antacid causes nerve damage similar to that seen in Alzheimer's disease when in synergism with fluoride, fluoride itself sold over the counter and in water supplies. Acetoaminophen causes liver damage. Pseudoephedrine causes kidney damage and even death. Aspirin causes Reyes syndrome, stomach bleeding, and asthma. These useless drugs should be removed from OTC long before naltrexone should be. Almost any drug can be harmful if it is used stupidly enough, even water. Vitamin C will make aneurysms from a copper deficiency much more likely. So will large zinc supplements. Vitamin B-1 supplements during a potassium deficiency caused heart disease is so dangerous that it will usually result in death (Folts) or the reverse for beri-beri heart disease (Gould) (Mineno). So will phosphate (Selye) supplements (from soft drinks for instance, as well as di cal D wafers). Should these drugs be prescription only? The best way to handle such matters is by educating our children, not by having the FDA trying to hold everyone's hand and trying to guard them from every stupid decision possible to protect a handful of fools, while millions of others are denied whole technologies and as a result thousands of them stay sick and even dying. Social-organizational factors in medicine appear to favor the acceptance of theoretically glamorous, pharmaceutical, and high technology innovations over simpler and less profitable ones [Forman] even in government research. So we dare not leave experimentation solely in the hands of those able to prescribe.

Self diagnosis is a meaningless concept. Aspirin is designated for a headache for instance. However, a headache can be caused by food allergies (certain nuts have given me a headache in the past), by a tumor or aneurysm, a sinus problem, multiple sclerosis, probably by some poisons, and headache can probably be even at least accentuated by emotional stress. Aspirin does not cure any of these things, but only masks the pain. I doubt if there are many symptoms that citizens can accurately diagnose. It would be a good idea to seek medical consultation for any health problem, and I recommend it. However to deny a harmless drug to millions of people who can not afford medical diagnostic assistance, who can not reach a doctor on a weekend (or even get an appointment for several months, such last as is the case with my dermatologist), live far out in the wilderness or lack transportation, or who are independent minded, would be unconscionable even though they are not usually good at self diagnosis. There is such a thing as freedom. Besides, even the decision to seek a doctor requires some self diagnosis.

However, bringing up the subject of diagnosis is meaningless anyway since the concept of diagnosis is separate from the decision process. You can be sure that very few race down to the doctors every time they get a headache. The decision as to what to do after diagnosis still rests solely with adults regardless of who makes the diagnosis. A friend of mine recently decided to take none of those horrendous cancer treatments and elected to quietly die, since other problems unable to be solved by her doctors made life intolerable anyway. I have often turned down medicines during my own life, medicines whose only attribute were to deaden pain, reduce a fever (a fever is usually advantageous), kill an under the nail fungus using an internal medicine, or remove an irritation. If ease of self diagnosis were a criteria, I doubt if any drugs would remain OTC.

As for using the drug effectively, very few OTC drugs are effective. Most of them merely mask symptoms. The route to effective use is good instructions on the label and good education of our children. This is essential regardless of whether drugs are OTC or prescribed.

You speak of this drug as not having an approved NDA or ANDA. I was under the impression that seeking such approval was what my petition sought. Could you send the forms and instruction I will need to attain such approval? It is not necessary to mail them. Email [REDACTED]

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REFERENCES

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Selye H & Bajusz E 1958 Provocation and prevention of potassium deficiency by various ions. Proceedings of the Soc. Exptl. Biol. and Med. 98; 580-583.

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Sincerely, Charles Weber

Charles Weber

exemption 6

May 7, 2010

**Jane Axelrod
5630 Fishers Lane, Room 1061
Rockville MD 20853**

Dear Jane Axelrod,

I would like the petition to make Naltrexone an over the counter drug, docket # 2006P-0508-CPI, be reconsidered.

There is no reason why that harmless, useful drug be by prescription only.

I have included copies of other messages I sent in the past about this matter, which spell out my objections to the denial

Sincerely, Charles Weber

Charles Z Weber

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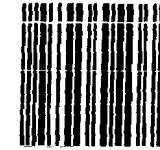
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