Interview with Dr. Jaquelyn McCandless: Low Dose Naltrexone (LDN), past study, prospective study

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Abstract

Naltrexone is a generic, FDA approved opioid antagonist that when used in ultra-tiny doses (less than 1/10th the ordinary dose) acts as an immune modulator/enhancer to optimize the immune functioning of those who are immune-compromised, as autistic persons are known to be. It also operates as a neurohumoral agent that has effects on cognition, socialization, and language. Naltrexone must be compounded to obtain ultra tiny doses, called Low Dose Naltrexone (LDN) and can be made into a cream for children or small capsules for adults, to be used one time daily at bedtime. It is non-toxic, non-invasive, effective, and inexpensive. A recent study at Penn State on Crohn's Disease has shown it to be effective and safe; a second study on Crohn's at Penn has just been approved; a study at UCSC on LDN is starting on multiple sclerosis and one at Stanford on fibromyalgia. A study on autistic children has been approved in Israel; a study on HIV+ persons in Africa to show the effectiveness of LDN to prevent progression to full-blown AIDS is being proposed. In this interview Dr. McCandless discusses LDN and the results of the use of this agent in her autism practice and in her informal study of autistic children and their parents.

Keywords: Low Dose Naltrexone (LDN), endorphins, autism, HIV+AIDS, autoimmunity, immunomodulation, CD4+

We are pleased to welcome back to Autism One Radio Dr. Jaquelyn McCandless. Dr. McCandless wrote "Children With Starving Brains: A Medical Treatment Guide for Autism Spectrum Disorder" to help parents and doctors better understand the biomedical approach as promoted by Defeat Autism Now (DAN).

Dr. McCandless started the physician program at DAN in 2003 and currently teaches and lectures in this and other countries. She is certified by the American Board of Psychiatry and Neurology.

Dr. McCandless, thank you for joining us again on Autism One Radio.

You're very welcome Teri. I am happy to have an opportunity to be here again.

Dr. McCandless, the subject of today's show is naltrexone; Low Dose Naltrexone (LDN), past study, prospective study. But what is naltrexone?

Naltrexone is a medication. It's actually used for opiate and alcohol antagonism. It has been used for treating opiate, drug and alcohol addiction since the 1970's and has been FDA approved since 1985. Naltrexone is available in both the brand name ReVia and generic form. And that all comes in 50 mg tablets.

Is this something that can be compounded?

Yes. In fact, we do compound it. It comes in a white powder. It's very inexpensive. And we have it compounded both in capsules and in the transdermal cream.

So capsules and transdermal cream. In a very broad sense, what does naltrexone do that relates to the needs of children with Autism Spectrum Disorders?

Well that's a great question. What a lot of people don't know, or what mainstream people don't know who don't have autism in their family, is that the immune system of autistic children is definitely compromised.

Since the 1970's, many studies have shown a lot of immune dysregulation and various kinds of abnormalities in the blood of autistic children. And definitely, as we've gone on into the knowledge of toxicity levels with heavy metals, we know that their immune system is not working efficiently. They have a deficiency of glutathione, which is a very important aspect of immunity and getting rid of toxins. So the fact is that we have discovered in the last 10 or 15 years that the endorphins, produced by LDN—play a great role in the immune system. What happens with the endorphins has a great deal to do with the levels of the immune system functioning properly.

All right, I'm curious. I'm intrigued. How would naltrexone relate to glutathione?

Well, it started way back; well, when Dr. Karl Reichelt in Norway and Dr. Paul Shattock in the U.K. were doing a lot of research on opioids, they learned from their research that wheat and milk created large peptides that wouldn't break down into amino acids but broke down irregularly into opioid-like compounds that would go to the brain. They called them caseo-opioids and gluteo-opioids. So they thought if they could get an opioid antagonist like naltrexone into the children it would counteract these opioids in their brain and wouldn't have to be placed on a restrictive diet. That's how they first started being interested in naltrexone as an opioid antagonist, so it could op-

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pose the casein and gluten-producing opioids in people's brains. They and a lot of other scientists all over the world did work on this. However, it never quite fully worked and was more or less put aside because they were using naltrexone in the regular doses. And naltrexone, in fact all of the opioids and opioid antagonists, have a bi-phasic aspect which means, at high doses, they have a very different effect than they do at low doses. At high doses, it actually would interfere with the function of the immune system, but that was not known until the last decade. So even though they might help with the opioid addictions, the immune system doesn't function well on high opioids. Yet, when they give very low doses, naltrexone enhances the immune system. This was first discovered by researcher Dr. Ian Zagon on animals and discovered by Dr. Bernard Bihari in humans. Dr. Bihari, a New York physician and Harvard graduate, was working with dying AIDS patients in 1985, most of whom were narcotic addicts. Many of the narcotic addicts were exchanging dirty needles and contracting the AIDS virus; in the U.S. probably 50 percent of AIDS victims are users of narcotics.

Dr. Bihari was working in this hospital with these patients giving them naltrexone; these AIDS patients were dying and he was taking blood from them every three hours and giving them naltrexone to help their addiction because they were going through horrible withdrawals. And the addictions were helped and yet their immune systems kept getting worse and worse. He knew about the animal studies by Dr. Zagon who was showing that smaller doses actually seemed to help the immune system. So Dr. Bihari started using smaller and smaller doses, mapping out what happened with the immune system. The lower the dose got, the better the immune systems functioned. He found, through his experiments, an ideal dose between 1.75 mg and 4.5 mg; these were tiny doses because the regular pill is 50 mg. So he started using this dose calling it "low dose naltrexone or LDN," and many of those AIDS patients that he was working with in 1985 are still alive today.

This is fascinating. So not only did the AIDS patients' immune systems not get worse while their addiction ceased, but their immune systems actually improved?

Yes. What happens is when you get just a little bit of an opioid antagonist, you fool the body. You fool the pituitary gland into thinking it's not going to get its regular dose of opioids and the body has this big outpouring of endorphins. The endorphins go to the opioid receptors all over the body and heighten or modulate the immune system. Their effect is a direct effect on the immune system itself, not relating to the disease but only to any deficiency in the immune system functioning.

Both our innate and our adaptive immune systems are heightened by this outpouring of endorphins that come from a very tiny dose. It's as if the body is reacting as if you're going to give a big dose and it puts out all these endorphins in an attempt to counteract the antagonist that last for 18 to 20 hours. These endorphins are floating around the blood stream for a couple of days, optimizing the immune system functioning. And what's amazing about it is that if you have too many of one kind of immune cell, it will lower them. If you don't have enough, it will raise them. So we call it an immunomodulator because it optimizes the immune system with this tiny dose.

If you give the regular dose, the immune system is suppressed and many lymphocytes are not functioning properly and the immune system gets worse. So that's why using this in a regular dose, even though it helped the opioid antagonism issue, it injured the immune system.

So actually, after awhile, the only thing that they continued using naltrexone in full doses was for SIB (self-injurious behavior) and it does seem to help that in some children; it helps children not injure themselves. Once we learned it harms the immune system, we tried to find other ways to help the immune system so children with SIB who benefit can use naltrexone.

Actually very little was done about naltrexone except for isolated studies for about a decade. There were a few studies here and there, but nothing significant for children, though studies for its narcotic antagonism for adults continued. Another reason for few studies on children besides its seeming lack of effectiveness was poor compliance with the children. Naltrexone is extremely bitter and most autistic children can't swallow capsules and they were having a hard time getting cooperation in the studies because the kids did not want to take this horribly bitter stuff.

So for the autistic kids with whom I wanted to try the low dose naltrexone, I got the idea of making it up into a transdermal cream. We've all been using a lot of transdermal creams in our DAN! biomedical work with the kids. So I asked Dr. Tyrus Smith at Coastal Compounding if he would create a transdermal cream for us to use with the kids. This has two great advantages. One is they don't have to have this bitter stuff; there's this nice cream that goes on your body instead of orally. The second is, because of the circadian rhythms, this "out-flush" of endorphins that heightens the immune system happens very early in the morning: around 4 a.m. in the morning. So therefore, the ideal time that Dr. Bihari found for taking LDN—and it only has to be used once a day—is after 9 p.m. and before 2 a.m., with 11p.m. being the optimal time. Parents apply it to their sleeping children when they retire. It's extremely important for people to understand it is not to be used in the morning or the afternoon for optimal benefit.

Even if your child has sleep challenges?

Even if your child has sleep challenges because, I suppose the reason you asked that is because when kids first start taking this, sometimes there is a transition period of a few days to a week—or it can go up to 10 days—where they may have some trouble sleeping because it acts as a psycho-stimulant for some kids. But I'll tell you what I've found out from all my work. When I did my first study on 15 children that were mostly my patients, they were all on very strict diets—about which I am very strict, and I didn't have a lot of bad effects from this in the first group. A few of the smaller kids had to go down to smaller doses. But when I started putting it out into the general population and a lot of other children started using it, then I would have maybe between 10 to 15% of the children who would have an extreme hyperactive reaction. Some children would even have a negative reaction with aggression.

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So I started questioning them about the diet and most of the children who had the bad reactions were the ones who were not on a restrictive diet. What clearly was happening is that they were getting an opioid withdrawal effect from this tiny amount of the opioid antagonist. They were like drug addicts who are not getting their fix because, all of a sudden, their opioids that are in their brain from the bread and milk that they're eating are antagonized by the naltrexone.

How fascinating.

Very fascinating because it has turned out to be a marvelous diagnostic tool. When parents who think their kids are just fine yet they're still autistic, but they are not particularly showing any bad reaction to the diet, find out that they have this bad reaction to LDN, the parents have to reconsider the diet issue. I asked them to reconsider the diet. And many of them have found that once they go back to a very strict diet, not only are they fine with LDN, but a lot of their other symptoms start improving too.

We all know the diet is so hard. I have an enormous respect for the difficulty in keeping these kids on a restricted diet, particularly when you have older kids and the family's eating other things. And yet over and over, I have found out that if a child (or an adult, for that matter) has a bad reaction to LDN, the diet really needs to be considered again. In my ten years of working in this field, I have learned over and over that healing usually starts with eliminating casein, gluten, and soy from the child's diet.

Now I'm not saying there aren't some other endogenous opioids that come from walnuts and peas and various other things that do have some peptides in them. We can never get rid of all the peptides because you know, you have to eat.

But we do know that if we can cut out wheat and milk and soy and, for many kids, corn, that does take away most of the big peptides that are causing the damage in the inflammation of the gut and the opioids in the brain; so if we can give a good diet, and also use enzymes, very few of the kids have much negative reaction to LDN.

Now I heard a doctor once say that if your child is ill, say for example with a cold, you want to be careful about taking the LDN. Is that your opinion as well?

Oh no, not at all.

Yes. From what you're saying, it seems contradictory to me because the LDN would be helpful to the immune system.

Of course. I don't know where anyone got that idea because it actually heightens the immune system. There's another phenomenon which is that most of our children are hyper-immune. You'll hear many parents say, "My other kids get sick all the time, but my autistic child never gets sick."

Absolutely, I hear parents say that.

That is not a good thing. It means that the immune system is in hyper-alert all the time. It's functioning at highest level. Over and over I've tested children for secretory IgA, and as they have many other evidences of gut inflammation, the IgA goes very, very high, and then it drops. The immune system reaches a state of exhaustion and then their immune secretory IgA is very low and they're sick all the time. So the kids can go from never being sick until the immune system finally gets exhausted and then they are sick all the time.

The problem with this also, when the child is in this hyper-immune state, is that they're not building up the usual antibodies to pathogens. Like most of us will encounter a pathogen, we'll build up antibodies to it so the next time we're exposed to that illness, our body naturally starts into a fight as the immune system has a memory of that illness and protects us from it.

In the hyper-immune state, the kids are not building up these antibodies. So then when the immune system finally gets exhausted from working overtime in the hyper-immune state, then they're susceptible to everything and they have not built up any of the kind of memory antibodies to fight things that most of us do in ordinary life.

So it's extremely important for people not to be so content because their kids never get sick because it means they're in a hyper-immune state and that is not good because the immune system is working overtime and it tends to push people into the T-2 level which is more characteristic of autism, Alzheimer's, cancer, basically the autoimmune sorts of disorders. It's what they call the adaptive immunity.

The innate immunity, T-1, is where the body automatically reacts when any pathogen is exposed, macrophages and various designated lymphocytes go to that area and kill that pathogen right away intra-cellularly and that's where the work needs to be done.

The adaptive immunity is more in the extra-cellular fluids and basically we want children to have more of a T-1 or a balance between the T-1 and the T-2. But these children that are hyper-immune are mainly T-2 and they're very susceptible to exhausting their immune systems and then getting really sick and not being able to fight many diseases.

So what we discovered is that when we give the LDN, there almost immediately starts an adjustment of the immune system back toward a more healthy way of functioning. Very often, maybe 15-20% of the children may show a flare-up of yeast or bacterial infection or viral flare-up such as a cold sore when they first start taking LDN. They need to be given natural yeast fighting and bacteria-fighting remedies to help this transition. Probiotics are very important for this, avoidance of sugar, and natural anti-yeast and anti-bacterial substances help get them through this usually short-lived adjustment period. When this first started happening, I was intimidated and I would say, "Oh, back off or cut down the LDN." And parents would say, "Oh no, I don't want to stop because he's playing with his brother for the first time." And I can't tell you how many fathers have written to me and told me they have a relationship with their child for the first time.

There definitely are two aspects to the LDN. Almost immediately there are positive social effects. When I started all this work, I did not give that the emphasis; I was mainly wanting to improve the immune system of these children. It takes four to six months really for the immune system to finally make an adjustment. That's not an overnight thing, though it starts work-

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ing right away because you can note from the illnesses that show up that the immune system is starting to make its adjustment. My colleague and friend, Teresa Binstock, used the word "perturbation." There's a perturbation—a disturbance of the immune system from its old way of being to now; with this endorphin rush, there's a new way of the immune system reacting, so the child goes through a transition period. It's usually quite brief, and has never been reported as contagious.

Parents will say that as soon as that brief first illness is over, they get a big flush of cognitive enhancement, language development, more complex sentences. We have a database on my website for the LDN list. It has about 1500 families in it now, autism_LDN@yahoogroups.com. I have hundreds of reports in there that anyone can get on the list and see all of the things that happen and the transitions that happen with the children. I would estimate 75-80% have positive reactions. Some of the ones that have had bad reactions have been children who have gone off the diet or have a lot of infractions with the diet. Some people don't want to change, so they stop the LDN because to them, going back on a restrictive diet is just too hard for them for various reasons—not always something that they can help.

A difficult case is where a couple is divorced or separated and one of the parents does not believe in the diet, so every time the child is with the other parent they get all kinds of wheat and milk and pizza and ice cream; in those kinds of cases, LDN would continue to possibly give that child negative reactions, aggressive reactions, hyperactive reactions to the opioids in their systems. If the child is either through the early phase, and the gut inflammation is down so that they're not putting out peptides into the brain or they're on a strict diet, children very seldom have any negative reaction. Some of the smaller children do need to go to smaller doses.

Dr. Bihari, who still does work on AIDS patients and many other patients with autoimmune diseases like Crohn's Disease and multiple sclerosis and other autoimmune diseases, says to push on through to the full dose. I have stopped starting with a small dose and slowly building up, waiting to see how it works; I've tried to push through very quickly to the full dose because that's where we feel the optimum work will start on the immune system. Still, all children just cannot handle the full dose and parents insist they do very well with smaller doses, and that has to be all right, as there is still a lot we do not yet know about this medication.

You mean the full dose of low-dose?

Yes, the full dose of low-dose, which is 3 mg for children below 100 pounds, 4 mg for 100 to 120 pounds, and 4.5 mg for adults or any children over 120 pounds.

Now Dr. McCandless, does that dose depend upon whether it's transdermal versus oral? If the child's taking it in a capsule, would it be a different dose than if the child is receiving it transdermally?

No. It makes absolutely no difference. And we have many kids who are big enough to swallow capsules and go to bed after 9 o'clock. I don't want it to be given before 9 o'clock. But if kids are old enough to swallow capsules, they get exactly the same benefit from the 4.5 mg and we use the same doses for the transdermal as we do the oral.

At the same time of night?

Yes, between 9 p.m. and 2 a.m.

Well I didn't know if the capsule is absorbed at the same rate as the transdermal cream.

Yes, it's the same.

A couple of questions I'm curious about. I've spoken to a mom who said the only time her son seems fully recovered—and he's doing very well otherwise—but he seems fully recovered when he has a high fever.

Yes, I know cases like that. The fever is one of the body's mechanisms for heightening the immune system and killing off pathogens because a lot of pathogens can't stand the high heat. That's why I encourage parents not to do anything about fevers until they get to 102°F and then just put them in tepid bath water. Don't give them medicine to try to get the fever down because the fever is the body's way to help the immune system.

Then why does the child seem not recovered after their fever is gone? I mean, you'd hope that it would have killed off some things.

Well, you would. But the pathogens are everywhere. We never get really rid of pathogens. All we do is cut down their population. So as soon as the fever's over, the pathogens start growing again. That's true with viruses. We never eradicate viruses. All of us have viruses. All we can do is cut down the replication a bit so that they stop growing and then a normal immune system will hold them in check. Then if there's any kind of dips in the immune system for any kind of reason, like getting a toxic injection or being exposed to or getting some kind of big infection, the immune system takes a hit and the viruses are opportunistic and they grow again.

So we get a period of replication where the viruses are increasing and increasing. So the main thing is to stay healthy enough so that the immune system can handle them – we all have viruses and we never can fully eradicate them. Anything that would eradicate viruses would kill us first. All we can do is cut down their power to replicate and so we keep the population down.

You mentioned some effects I won't call them side effects because they're just effects of children who are taking LDN if they are not on strict gluten-free, casein-free diet. You mentioned some acting-out behaviors, but what I want to know is if it still going to help their immune system? Is there some sort of a—I'll say cost-benefit analysis here between—"can I deal with this acting out"—if the parents can't maintain a strict gluten-free, casein-free diet. Say one parent's not on board or the child's able to sneak some of it at school or something, is it still beneficial to the immune system to use LDN even if they end up with some acting out behaviors? Is there still balance?

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Yes, I think it does, but I'm not positive, and no studies have been done yet to help us find that out, but most parents won't put up with it for too long. But, yes, I think it would help the immune system.

Right, because it was helping the immune system of the addicts, correct?

Yes. Most people will not put up with hyperactive children that are hostile or that are acting out. And what parents really can't handle are children who don't sleep at night. So we don't have too many children that continue on it unless the parents are willing to cut down the dose and start having a better diet to see if that will help.

This is really a tangential question, but it's something that you brought to mind when speaking about the diet and you also mentioned enzymes. There are some people who may not do the diet, but they give enzymes and they think that enzymes will take the place of the gluten-free, casein-free diet. What's your opinion on this?

Studies show that the diet helps 75%—it helps block 75% of the peptides, and then the combination of the diet and really good enzymes will take care of most of the other 25%. Whereas, if people just take enzymes, the tests have shown that they really are only 50% covered. So it's really hard unless your child is already pretty healthy and has reached a place where he or she does not have the gut inflammation and they're not putting out the reactions, it's very hard for children to be free of the large peptides on enzymes alone. What's best for all the children is a combination of dietary restriction and enzymes.

Those are the children over and over in my practice that have gotten well. The parents that are really strict about the diet and will give enzymes also, those are the children that just really do constantly improve. Because if the gut is not inflamed, they're able to absorb the nutrients they need to nourish the brain and that's the best of all scenarios.

All right. You mentioned about 75-80% of the children showing positive benefits; correct me if I did not remember that right. But how many children with autism are now taking LDN approximately?

I called Dr. Tyrus Smith at Coastal Compounding this morning to get some information on this. This year so far he has given out 1800 prescriptions for the transdermal only and probably that many more of the capsules, which some children use capsules too if they're big enough to swallow them. But the capsules are mainly for adults. And he has given his formula (which I broadcast on my net that he will give it to any qualified pharmacist) to at least 50 pharmacists all over the country and in Israel, Scotland, Hong Kong, all the places that I've taught where the compounding pharmacists want the formula.

So we talked about it and estimate that at least between 3,000 and 4,000 autistic children are on LDN at this point.

And you think that, including those children outside your research study, 75-80% of these children are showing benefits?

It's very hard to know for sure. However, I just completed a study and I'm still compiling the results, but I do have the results of the 20 children in my study. One child had an overall negative response; one child had a zero score—which means no change from the beginning to the end of the study, which lasted 16 weeks. All the other 18 of the 20 were reported by the parents to have an overall positive response by the end of the study.

So that's 90%?

Yes, of the ones who finished. Some kids dropped out, and I generally assume it was because they were not having a good response, though there were actually many other reasons for dropping out also. So I would still say between 75-80% show a positive response. In the adults (mostly parents of ASD children) it was a little bit different. I believe the children do better on it because most of them are on the diet. *Some* people from the adult LDN list who are mostly multiple sclerosis patients and various other autoimmune diseases have been visiting my list and finding out that some of the reasons why some of them are having bad effects to the LDN is that they probably have an intolerance to wheat and milk; some when changing their diet started having better response.

Right.

And an MS person on the group who was helped by the diet has really been trying to get others to read my protocols and try the diet, take care of their candida, common in all immunocompromised groups, and some of them are showing positive results.

She just asked me to speak at the next LDN annual conference and she really wants me to stress how important the diet is. I have learned that celiac (an allergy to gluten) is not an all or nothing affair; actually, 30% of people have some degree of wheat intolerance and do not know it. They don't even know what it feels like to feel good. They always have stomach aches, bowel problems, various kinds of constipation, whatever, and they don't know that they have a wheat intolerance.

When some people who had a bad reaction to LDN are willing to consider that diet could be the reason and stop eating wheat and milk, not only do they feel better, but then they can have a better response to the LDN, too. The LDN in these cases becomes a diagnostic marker for an intolerance to the large peptides that are in wheat and milk primarily, and also soy and, to some extent, corn. We can never get rid of all of them, but if you take those three foods out, casein, gluten, and soy, you will cut down the opioids in the brain if you are someone whose immune system is unable to tolerate these foods.

Soy, wheat, milk—by wheat do you mean all gluten or just wheat?

Yes, all gluten. But the celiac is just the gluten in wheat which is the thing to which they're mainly intolerant. But 30% of us are walking around with some degree of celiac intolerance, and so many people would feel better if they did remove wheat, yet it's such a staple in our diet.

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I wanted to tell you the difference of what happened with the 38 adults that I had in the study. On the adult list I had three participants with negative scores and one participant with a zero score. But the rest of them—of the 38—that means 34 of them showed an overall positive response to LDN.

Okay. This is in your study.

Yes, the 38 adults... parents of autistic children. Anyway, the primary benefit for the parents was energy. And the second positive was sleep quality. Third was overall mood, and the fourth was digestion. But in terms of the kids, the main thing that they showed first was overall health. For many kids, their allergies were much less severe, however, not all. Some allergies disappeared completely. Improvement in overall mood was the second. Cognition was the third and sociability was fourth, whereas sociability was the tenth for the adults, it was fourth for the children.

And energy, which was first for the adults, was only sixth for the kids. So there are very different patterns and I think the difference in the patterns is that most of our children are on restricted diets so they had a different pattern of reaction to LDN.

Okay.

But the cognition and sociability has been the thing that the parents appreciate most – they all want their kids to have better immune systems, but what they're delighted about is that the kids are happier and they speak longer sentences. They have more understanding of nuances.

And the main thing is the delight that people have that their kids are social and they're playing with their brothers and sisters and they're relating to their fathers for the first time. So this is what you'll get the parents talking about the most.

I've worked in Israel twice now with the doctors there, and they just got their Jerusalem Institute for Child Development to approve a trial of LDN with children and they're primarily interested in the social and the cognitive aspects of this. They are not even drawing blood to do the immune testing in their study. They're only observing them through one-way mirrors and getting reports from teachers and parents, and they're primarily interested in the social, cognitive benefits of the LDN. Whereas I was primarily interested in what happens to the immune system and took these big panels of blood tests—36 different tests—on the immune system.

Still, what parents are the happiest about are the cognitive and the social benefits, which naturally make their kids easier to live with; they're happier when they wake up in the morning, and they're playing with their brothers and sisters. The parents are obviously so delighted with this. And then the bonus is that all this time their immune system's getting better.

And I do feel that they need to be on it for four to six months to get the immune system to its optimum state. And some of them say that when they take them off after six months or nine months or whatever, the kids get kind of glum again. They don't have the mood elevation and the happiness and they're not quite as social. Not all of them though; for many the benefits are retained. After people go off it, and they go off it after awhile, many of them say I'll never go off of it. This is too wonderful because it's easy just to put some cream on their kids every night when they go to bed.

And it's no big deal after you've been on it for a couple of months to miss a night once in awhile either. In fact, a lot of the early investigators 10 years ago were doing it every other day. But I encourage people to do it everyday in the beginning because the immune system seems very, very quickly responsive.

If they miss a dose, they might get a cold or some kind of manifestation so quickly. It has really astounded me. And no one else has done any studies for this to be really clarified as to how this can happen so fast.

But in the early beginning, I do ask people not to miss any doses at least for the first two months to let the immune system get stabilized into a new way of functioning.

And what I'm hoping that my tests are going to show definitively, is that there is more of a shift to the T-1, or innate form of functioning, away from the T-2, or the more allergy autoimmune kind of adaptive immune system.

Now talking about one of the specific aspects of the immune system, what does the term CD4+ mean and how is it a measure of the function of the immune system?

CD4+ is also called T-helper, immune helper, and it's one of the most important cells in the immune system. It tells other cells what to do. Dr. Bihari's work with HIV+ patients was what got me interested in CD4+ particularly. Even though the autistic kids did not have HIV+, still, 15 out of 20 of the autistic children raised their CD4+ level in only 16 weeks.

Of the adults, out of the 38, 25 adults raised their CD4+ level. The importance of the CD4+ level is that this is the cell level that is measured to determine the progression of HIV+ to full-blown AIDS. When people get infected with the virus, they have a period of usually 3 to 5 years or more where their CD4+ level stays within normal range, and then it starts dropping.

When it gets to be at 200 cu. mm, when there's only 200 cells per cubic millimeter of cells, they are then considered to be in category C, which is full-blown AIDS. And what Dr. Bihari found was that if he can get these people to stay above 200 of CD4+ cells, the LDN will prevent them from ever going on into full-blown AIDS.

At first, all of them were staying without going into full-blown AIDS. Now, 15 years later, Dr. Bihari says 4% of people who take LDN who are infected with HIV+, only 4% go on to full-blown AIDS and this is better than any other AIDS medication on the market; even the triplicates, the three-in-one, all of them.

So they're infected with HIV+ and - they're all infected with HIV - only 4% go on to full-blown AIDS?

Yes, if they stay on LDN.

I see.

They do not develop resistance to it like they do to many of the HAART drugs commonly used now. To these, many people get resistant and have to keep changing kinds of medication.

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Also, these medications usually have to be taken three times a day, some with food, some without food. Very complex medical direction and supervision is necessary on the HAART drugs. Whereas, with LDN, it's simple and easy; they just take a capsule every night when they go to bed. And most of his—Dr. Bihari's—patients have only been on LDN. Some of them were already on HAART drugs so LDN was added. The combination of the HAART and the LDN is excellent and people do not go on to full-blown AIDS.

What is a HAART drug?

It stands for Highly Active Anti-Retroviral Therapy. Most people familiar with the AIDS scene know that the HAART drugs are the anti-retroviral and the viral inhibitor drugs that are commonly being used against AIDS now.

And do people need to take the LDN with the HAART drugs or can they take the LDN alone?

Most of Dr. Bihari's patients have refused to go on the HAART drugs. For one thing, they're extremely toxic; terrible side effects. They build up fat in strange places in the body in a condition called lipodystrophy. Many who know about it refuse to take these drugs and they're only on LDN. Most of his patients that he's had for years now – he has 350 AIDS patients with HIV positive or in various stages of AIDS – and they're continuing, the majority of them, with only LDN.

And is the LDN more cost-efficient as well as being more humane?

Absolutely. Basically the LDN probably costs between $20 and $25 a month; whereas the HAART drugs are $240 a dose three times a day. One has to have help, and most Americans are enabled to get these medications. The new three-in-one is $14,000 a year. Some Americans can afford that, but I wonder how many Africans are going to get that drug? Probably none of them.

All right. Well that leads us into your prospective study. So please tell us about the next study that you hope to do with LDN. What will you be treating?

Having been participating in training at least 400 doctors in autism—and there are many brilliant people now handling the autism scene—I want to move on and I want to take LDN to Africa. Dr. Bihari has been trying to do this for years, having already set up a protocol for the country of Mali. I had met with the Health Minister of Liberia who was desirous for me to do a study there, but they have so many problems with continuing war and chaos in that country, that I decided to work on the protocol that Dr. Bihari had already set up for Mali. They have a university there and a hospital where they're all set to do this study. So I have joined the medical consultancy of this board and am now the coordinator. At the present time, I am trying to get a fiscal sponsor so that it can be a 501(C)3 so people can donate money to this and it will be tax deductible. We need $300,000 which is not a lot of money to many of these big organizations that are now helping Africa.

We're going to do a study for 48 weeks on three groups of people. One we're only going to give the HAART drugs. One we're going to give the HAART drugs and LDN. And the third group will only get LDN.

We are quite confident that the LDN will stabilize the CD4+ level. And once that gets published and gets out there, we believe that all the countries in Africa will want to get this because it is so non-toxic, so simple, so inexpensive, so effective, that there is no reason why it couldn't save millions of lives in a relatively short time.

At the present time, they estimate that there are 15 million orphans in Sub-Saharan Africa. And half of those, at least seven million, are born HIV+ because the reason they're orphans is that their parents died of AIDS. More married women have AIDS than any other group; tragically there are many villages where there's not a woman left between 20 and 40 years of age.

Oh no.

Much of Africa has a polygamous and promiscuous society where women have few or no rights. It is a very gender hierarchical society where women can't insist that their men use condoms. They can't refuse sex. Women are very subjugated there. Dr. Stephen Lewis, the U.N. envoy for AIDS says that until there's more equality between men and women, the country is being decimated and the women are being destroyed. So I'm very desirous of getting it to young women, to getting LDN to young women, and to these orphans.

The orphans – AIDS goes much faster in little children and most of them have a horrible death by the age of two and all of the medicines that they have now are too toxic for children. Very few of them can be used on children. And they need incredible medical supervision and constant testing. I'm actually going to Mali in December with my husband and we're going to meet all the doctors and the principals on the health team there, where they are all set up to do this important study. Mali is very desirous of having this study done there. We have a lineup of doctors and technicians, many of them trained in the U.S. We have the lab set up. Everything is ready for this study. All we need is the funds. These countries do not have money; Mali is the poorest African country. They're extremely cooperative; the HAART drugs are going to be provided for our study by the Malian government. And a pharmacy in New York has volunteered to give us the LDN for free, so we are all set to go. The health team there are the hands-on people who will do the study, and they are the only ones getting very modest salaries for their work on the study. The patients must have lab testing every eight weeks during the 48 week study to make sure they are not descending into active AIDS. If anyone starts to do that, their protocol will be changed if they are not already in the group with the HAART drugs, now the commonly used therapy for AIDS.

The objective of this study is to compare LDN to the regularly used HAART drugs, and we are quite positive and optimistic that if we can get this study done, it could change the face of AIDS in Africa.

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Yes. I think this has enormously positive implications. So you're saying what you need is a non-profit umbrella under which you can accept the donations and you need $300,000 in donations to fund the study.

Exactly. That is exactly what we need. We have several people we are considering, but I'm hoping for one of the bigger AIDS/HIV+ organizations, because then they would have more possibilities of reaching groups who have money so that they could fund this study. It's really not a very expensive study when you come down to it. I haven't even asked anyone for money yet because I haven't had a fiscal sponsor so that it can be tax deductible.

Right.What do you mean by a bigger group?

Well, I was hoping to get one of those big HIV+/AIDS groups that have Hollywood stars or some connection with Bill Gates or Bill Clinton. Their grant agencies will not accept applications from individuals, so I need to be part of a group to apply.

Oh, I see. Well the study does have enormously positive potential implications. It's really a marvelous study; a marvelous idea.

Well, what's exciting is that I got there through my study with autistic children.

And I wonder, does the AIDS community realize that there's this similarity?

No, I don't think so. Dr. Bihari, he's a medical genius, but he's been very ill for many years. He's had rheumatoid arthritis for years. He took a lot of steroids and his bones are not good. And he broke his neck and his hip and he's been in a rehab facility for two years now. And so he has limited ability and energy and enthusiasm to go out and continue to push this as I have. And it's amazing how so few people are interested. When you hear about this you think "how could this have possibly not been grabbed up long ago?"

Does it have anything to do with the fact that LDN is relatively non-profitable in a fiscal sense?

Of course. Right, you hit the nail on the head. No pharmaceutical company has the slightest interest in a drug that they can't own so as to increase their corporate profits. And because it's a cheap, generic drug, you can get a barrel of this powder for very little. If we can have it manufactured there in Mali, it would cost less than $25 a year to keep these people alive; $25 dollars a year. And no pharmaceutical company is at all interested.

It's wonderful that you're doing this, but now it's no secret.

Right, because things are moving very fast and I think that probably we'll have the study undergoing by the beginning of the year is my guess.

Well it's wonderful that you're doing this. And I want to thank you for your wonderful book and your work with DAN!, for studying this fascinating intervention, and for your caring about the women and orphans in Africa who are prey to HIV/AIDS and trying to provide a safer, more humane, more accessible treatment.

Well, it's very, very gratifying to be able to do this and to think that I can help. And I've always been incredibly interested in women's rights. So this is the underlying cultural thing that I want to try to do some work on, too. But first we have to stop the dying and then we can work on the cultural underpinnings of this inequity that is allowing so many orphans to be born and so many women to be dying. So anyway, first thing's first.

Well if there are any groups listening such as representatives from women's groups, AIDS groups, autism groups, multiple sclerosis, or just any humanitarians who are listening to this who would like to become involved and help with this worthwhile project, how would they contact you?

I have an email address that's all over the autism internet; it's JMcCandless@prodigy.net and I welcome any correspondence or enquiries about this topic.

I really appreciate, Teri, your letting me talk about this and letting parents know about the whole dietary thing in conjunction with LDN—to help some parents understand that if their children did have a reaction and they quit too soon, they might be missing a chance to actually help their child's autism in important ways in addition to the LDN in terms of the importance of the diet to gut healing.

We're a strong community and I love the community. It's extremely helpful. And I've never seen parents who love their kids more than the parents of autistic children. They'll do anything for them. Even the parents who have bad effects and they won't stop their diet, they will at least put their kids on the diet because they love their kids so much. I love parents for doing that.

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