

# THE NDB Research

## NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases January 2009

## Notes from the Director

Frederick Wolfe, MD

### HeadOn? Heads Up!

We want our treatments to be necessary, effective, affordable, and as free from side effects as possible.

If we are lucky we get drugs that fulfill these goals.

But too often some of the treatments that we use are not necessary, have limited effectiveness, cost more than they should, and have unacceptable side effects.

If you really want to find out more about this issue, I recommend a newly published book by Nortin M. Hadler M.D. called "Worried sick: a prescription for health in an overtreated America." There are a number of things I don't agree with in this book, but it contains a lot of wisdom and insight. It's well worth reading.

When our treatments don't meet the goals above there are a number of causes. One is simply deceptive advertising. About two years ago a now famous commercial debuted on cable and television networks in the US. The product was "HeadOn." The commercial

instructed, "HeadOn. Apply directly to the forehead."

HeadOn was touted to relieve headaches when you applied it to your forehead. What was astonishing about HeadOn was that it was utterly useless – it had no

active ingredients. It didn't work at all except perhaps by placebo effect. Yet, the catchy advertising led enough people to buy HeadOn that in 2007 sales amounted to \$6.5 million.

HeadOn escapes drug laws by calling itself a "dietary supplement." Otherwise it would fall under the regulation of the US Food and Drug Administration (FDA). Surprised? You should be. But "supplements" that lead you to believe that they are effective for medical problems can be promoted and sold as long as the packaging carefully avoids telling you to use it for a specific medical problem. There is a long list of expensive and inexpensive supplements and vitamin combinations that have limited or no value. Still, drugs that don't work at all are a small problem.

Most of them do no harm. If you want to buy one, that's your business. It's sort of like buying an additive for your gas tank to increase mileage.

But suppose we are enticed to use drugs that aren't necessary? In some

areas of medicine there are disputes about whether the symptoms that people have are illnesses or just people behaving differently. One of these disputable areas involves the diagnosis of childhood bipolar disorder.

On November 24th, the *New York Times* reported the following about a renowned Harvard psychiatrist and a

pharmaceutical company, "...e-mail messages and internal documents from Johnson & Johnson made public in a court filing reveal that Dr. Biederman pushed the

company to finance a research center at Massachusetts General Hospital, in Boston, with a goal to "move forward the commercial goals of J. & J." The documents also show that the company prepared a draft summary of a study that Dr. Biederman, of Harvard, was said to have written. Dr. Biederman's work helped to fuel a fortyfold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children."

There are a couple of points to pay attention to. The pharmaceutical company benefited by more children being diagnosed with bipolar disorder. The physician would benefit from a research center financed by the company. The company even prepared a draft summary that the physician was said to have written.



From HeadOn's TV advertisement

***"... We want our treatments to be necessary, effective, affordable, and as free from side effects as possible."***

## Notes from the Director (continued)

Here is another example. Three days earlier, the *New York Times* reported that “An influential psychiatrist who was the host of the popular public radio program [Dr. Frederick K. Goodwin] ‘The Infinite Mind’ earned

Doctors in practice do not think pharmaceutical companies influence them. But they do. Medical meetings are dominated by the presence of pharmaceutical companies. Pharmaceutical companies, not

and is effective in reducing heartburn and treating ulcers. When the patent on Prilosec expired a number of years ago, the manufacturer, AstraZeneca, released a drug called Nexium (esomeprezole) that is almost exactly the same in its effectiveness and potential side effects. You can get either drug today. But there is one big difference: Nexium costs three times as much as Prilosec. Why would anyone get a drug that costs three times as much but has no advantages over the less expensive drug? Yet, Nexium is widely sold.

**“...Why would anyone get a drug that costs three times as much but has no advantages over the less expensive drug?”**

at least \$1.3 million from 2000 to 2007 giving marketing lectures for drugmakers, income not mentioned on the program.”

Another report from the *Times* in 2005 illuminates the role of physicians with ties to industry in influencing the US Food and Drug Administration (FDA). Writing about drugs such as Vioxx, Bextra and Celebrex, they wrote:

*Ten of the 32 government drug advisers [at an FDA meeting] who last week endorsed continued marketing of the huge-selling pain pills Celebrex, Bextra and Vioxx have consulted in recent years for the drugs' makers, according to disclosures in medical journals and other public records. If the 10 advisers had not cast their votes, the committee would have voted 12 to 8 that Bextra should be withdrawn and 14 to 8 that Vioxx should not return to the market. The 10 advisers with company ties voted 9 to 1 to keep Bextra on the market and 9 to 1 for Vioxx's return. ...Eight of the 10 members said in interviews that their past relationships with the drug companies had not influenced their votes. The two others did not respond to phone or e-mail messages*

doctors, write many of the research studies presented at the American College of Rheumatology annual meeting. In Europe, attendance at the annual “EULAR” scientific rheumatology meeting is almost completely underwritten by pharmaceutical companies.

And the relation between doctors and pharmaceutical companies leads to high costs, too. Take a drug called Prilosec (omeprazole). Prilosec is what is called a proton pump inhibitor. It reduces or prevents acid formation in the stomach

The pharmaceutical industry has advanced the cause of science and led to many almost miraculous medications that were not available in the past. But the industry has two heads, the scientific humanitarian head that benefits us all, and a marketing head that undoes much of the good and causes considerable harm. The health care system needs good scientific information, not good marketing. Take a look at Dr. Hadler's book for more information.

### **For Women Only: Arthritis and reproduction**

There is very little known about how having a rheumatic disease (such as rheumatoid arthritis, lupus, osteoarthritis and others) changes a woman's reproductive life. Does it decrease your chances for having a healthy baby? Does it make you go through menopause earlier or later?

Should it change your family planning methods? These are questions that are important to many women diagnosed with a rheumatic disease, but doctors don't currently have good answers for them. Many of you indicated on a past questionnaire that you are willing to be sent a questionnaire on the effects of arthritis on reproductive function. This spring we will be sending some of you a special questionnaire that may help researchers find answers to these very important questions. We hope that you will be able to help us with this special project by completing and returning this special questionnaire.

# LATEST RESEARCH

## NDB Research Activities

The NDB regularly presents its research results at the annual meeting of the American College of Rheumatology (ACR) before publishing them in medical journals. This year we presented data in a number of areas.

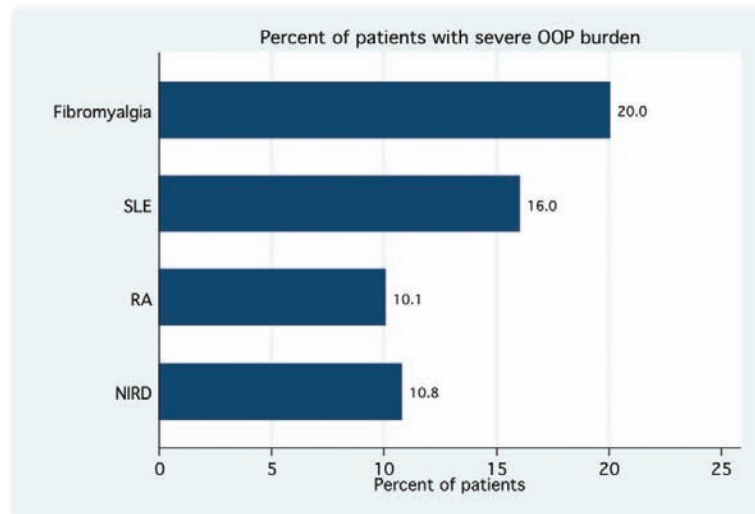
The NDB has been helping in the development of a self-reported Lupus Damage Index Questionnaire (LDIQ). Working with our colleagues at the University of Alabama and Harvard University, the NDB coordinated the worldwide testing of the LDIQ. The LDIQ allows researchers to measure the severity of lupus. Many of you with lupus completed the LDIQ. In the next few months, the NDB and the Boston and Alabama groups will submit their manuscripts for publication.

The NDB is also coordinating a new study of fibromyalgia criteria. Disease criteria are used to help doctors make a diagnosis. Sixty physicians in the US and Canada are investigating possible new criteria for fibromyalgia. More than 600 patients will participate. The NDB presented studies from its research to the ACR meeting that showed the basis for the development of the new criteria. We hope to have the study completed by July.

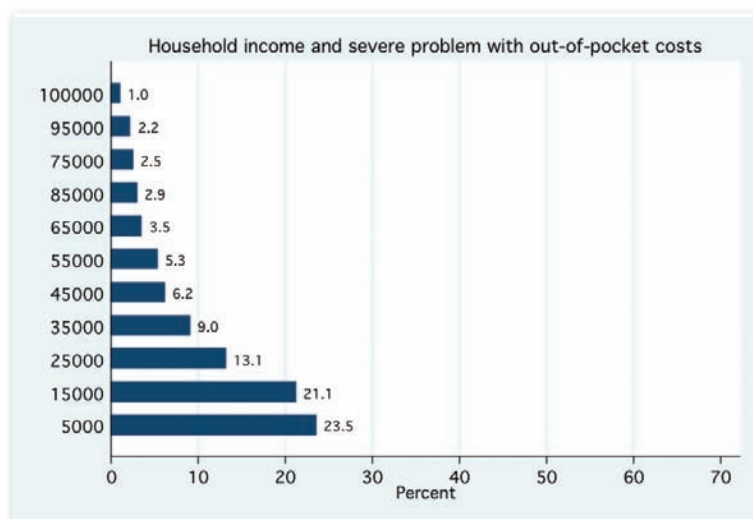
Those of you who ever have used the drug hydroxychloroquine (Plaquenil) may be interested to know that the NDB is working with physicians from the American Academy of Ophthalmology to determine just how safe (or toxic) hydroxychloroquine is. You probably remember our questions about Plaquenil and eye problems. This drug is widely used by people with lupus and rheumatoid arthritis, and also sometimes by people with osteoarthritis.

Last newsletter we told you something about the NDB's study of costs and affordability of medical care. We are about to submit that research for publication. We thought that you might be interested in two of the graphs from the future publication. The first graph shows the percentage of participants who have severe problems with out-of-pocket (OOP) costs. OOP costs are the costs you pay after your insurance company has paid. Severe financial burden means that you can't afford all of the medical care you need.

But on whom do these costs fall heaviest? It is those with the least income – usually older people or those whose severe arthritis has limited their ability to work.



Percent of patients with severe out-of-pocket (OOP) burden in fibromyalgia, SLE (lupus), RA (rheumatoid arthritis), and non-inflammatory rheumatic diseases (NIRD).



Percent of patients with a severe problem with out-of-pocket (OOP) costs shown by household income levels in US dollars.

The NDB is also reporting data on depression. The major cause of depression is pain. But you all know that. Surprisingly, many physicians do not. So, in a publication in process we will remind them again.

This is only some of the work the NDB has been doing. Please let us know where you think NDB should be going with its research. Thanks again.

## Meet the Participants

### Karen Subramanian

Twenty-nine years ago I was diagnosed with Rheumatoid Arthritis. We did not have a computer yet, so I went to our encyclopedia in order to find out about this disease, of which I had never heard. The article gave me the encouraging news that RA was “progressive and crippling!” The next 23 years were filled with trials of at least seven different medications, some of which worked and lasted better than others. My arthritis was aggressive, and I endured stiffness, pain, swollen joints, and profound fatigue. I also had several surgeries: shoulder replacement, surgery on each foot, and four surgeries on my right hand, the last one being a knuckle replacement. On the more productive side, I began teaching social work at the university level (I had a Masters in Social Work), obtained my Ph.D. from Madison,

Wisconsin, and was an Associate Professor of Social Work for 15 years at the University of Southern California. I also raised my daughter, who was eight when I was diagnosed. Both my husband and my daughter were of great support to me during those difficult years and are to this day.

Finally, in 1999, I was so exhausted that it took me two days to recover from teaching one three-hour class. I took the very difficult decision to retire. In retrospect, I should probably have retired years earlier but I had never looked at my arthritis as a reason not to work, only something I had to find a way around in order to do my job. When I had a good day, I believed it gone forever! By this time, I had severe joint deformities in both hands and could not get up and down from the ground without assistance.

The first two years at home, I spent a lot of time sleeping! My naps would be up to 3 hours in length, and then I would sleep well all night. In 2002, my physician recommended that I try one of the new biologic therapies. After researching it on the Internet, I became afraid of all the possible side effects and refused the treatment. Six months later, I woke up one morning and realized that since my body was deteriorating each day, the side effects of not going on the biologic therapy could be worse than if I were on it. I began the treatment, and a new chapter opened in my life. After only a few days, I felt more energy and less pain and stiffness. The good results lasted and increased, allowing me to begin to involve myself in the community around me through volunteer work and other activities. I felt as if I had been given a miracle...but more miracles were to come.

I had been in a gentle water aerobics class twice a week since I retired, and it helped me learn to become active for the first time since being diagnosed. About three years ago my massage therapist, who was also a yoga teacher, bought a yoga studio and included a class for seniors and persons

with special needs—she said that I was her inspiration for the class! I attend the class 2-3 times a week. The teacher is knowledgeable about the body and extremely caring, and she helps each person at his/her own level. In the beginning, she

needed to lift me up and down from the yoga mat since I couldn't do it myself. Because my hands do not lie flat on the floor and most of my toes do not bend, she had to invent modified poses for me. After the first year, I was strong enough to sit down and stand up from the floor by myself – the first

time in 25 years! After the second year, I could squat down for short periods, each time remembering the innumerable times my knees were swollen and had to have fluid removed and be injected with cortisone. People who knew me began to comment on how straight I was standing and how smoothly I was moving.

Now, in the third year, I am able to be in some yoga positions that would have seemed impossible before. I am truly humbled and astonished and thrilled to realize that I could regain the use of my body after so much damage and disuse. I had no expectations when I began the class, but now I realize that other wonders lie ahead of me if I continue on this path. I am now 64 and marvel that I feel better and am stronger and more flexible than I was at age 54.

Several years ago, my doctor asked me if I would join in the NDB research study. I was very happy to discover a way in which I could be of help to further research on rheumatic diseases. After my success in yoga class, I have been eager to find a way to let people with advanced arthritis know about the possibilities of regaining the use of their body even after so much pain and destruction. I wrote the NDB and asked if I could write an article in order to share my experiences, and I hope some of you on the new biological drugs will be inspired to find a suitable yoga class in your community. Please feel free to contact me at [karenrest@gmail.com](mailto:karenrest@gmail.com).

*(Editor's Note: The NDB does not endorse specific therapies.)*



Karen Subramanian

*“...I woke up one morning and realized that since my body was deteriorating each day, the side effects of not going on the biologic therapy could be worse than if I were on it.”*

# About the enclosed Arthritis Consumer Experts Newsletter

The NDB is excited to announce our support of Arthritis Consumer Experts (ACE). In this mailing we have enclosed the current newsletter from ACE. ACE does an important job in acting as an advocate for people with rheumatic diseases by helping them obtain reimbursement for medication, by providing information about arthritis and rheumatic diseases, by educating their physicians, and many other activities. We hope you will read their newsletter and give them your support.

The NDB does not promote or support pharmaceutical companies. Our goal is to study and supply information about rheumatic diseases so that all of you will be helped. Likewise, ACE does not promote any brand, product, or program on any of its materials or its website, or during any of its educational programs or activities. We are very happy that good, effective groups like ACE exist, and we fully support their mission.

If you've joined the NDB through ACE, thank you very much, and welcome!



## Welcome New Participants!

Everyone who works for the NDB and all of the doctors and researchers who benefit from our research are extremely grateful for the dedication of you, the participants, to helping this project. Many of you have been with us for several years or more. But every 6 months we are also glad to see many new people join us. Here is a quick primer on the NDB for the new and a refresher for the old timers.

The NDB is a non-profit organization that performs research in rheumatoid arthritis, osteoarthritis, fibromyalgia, lupus and other rheumatic diseases. The research is designed to improve the treatment and outcomes of these conditions.

The NDB is an independent organization that conducts its own research without influence from pharmaceutical, insurance, financial or other outside interests. Our research

is so well respected that we are often hired to provide independent drug safety verification to the government.

Your personal information will always remain private. We do not sell or share any identifying information about NDB participants. Before we work with researchers or collaborate with other research groups we remove any of your answers that could be used to identify you.

While the "N" in NDB stands for National, we have many participants from Canada, Puerto Rico, Mexico, Great Britain, and all over the world. Nearly all participants from outside the US participate using WebQuest, our online questionnaire. Nearly all of our research is available for you to read on our website.

We are glad to answer your general questions about rheumatic diseases

and treatments, but we are not able to give personal medical advice.

NDB research is different in an important way: Participants report on themselves; data is not collected by doctors or medical staff. With patient-reported data, researchers get a perspective that short, small clinical trials cannot provide. Our long-term study offers a much broader view of treatment and results. Clinical trials are good at identifying common side effects, but rare or subtle problems, or problems that take longer to develop, are better detected by studies like the NDB. The same is true of long-term effectiveness of a treatment.

So, welcome to the NDB, or thanks again for your continuing participation! If you ever have any questions or need help with your questionnaire, feel free to contact us.

## Helping the NDB in other ways

Achieving the NDB's goals of telling the rheumatology community about patient experience depends on a large group of participants. Here are a couple of ways you can help.

Now available for your support group or arthritis, fibromyalgia or lupus meetings...Our pamphlets explain what we do and how you can help. Each one has a postage-paid postcard to request more information or an enrollment form to join the project. The pamphlets and a small table-top stand are available free from the NDB. Just contact us at [info@arthritis-research.org](mailto:info@arthritis-research.org) or 800-323-5871 ext. 133 or 140. Thank you!



## Important Information about Email

For patients using WebQuest, email is our primary method of getting in touch with you. Even if you're not using WebQuest, we'd like to be able to send you important information by email.

We cannot emphasize enough how important it is for you to let us know whenever you change your email address. To update your email address go to our website and look in the participant's links, or call us.

Here's a VERY IMPORTANT step you can take to make sure our email gets to you: Add us to your email address book. Our address is [webquest@arthritis-research.org](mailto:webquest@arthritis-research.org). This will ensure that our mail makes it through the spam blockers. You will need to do this every time you change your email address. Thank you!

## WebQuest

WebQuest is the online version questionnaire. The questions are the same as what you get on the paper questionnaire. People who are comfortable using computers should find it easier than the paper version. If you would like to try it, follow the links from our home page, [www.arthritis-research.org](http://www.arthritis-research.org) and make the request, or send us an email at [webquest@arthritis-research.org](mailto:webquest@arthritis-research.org).

## Lottery Winners!

Return your research questionnaire within two weeks of receiving it and be eligible for one of three \$1,000 awards. The research data bank can best contribute to research when the questionnaires are completed and returned as soon as possible. Anyone who completes the questionnaire within two weeks of receiving it will be eligible for the award – given as a token of our gratitude in help with rheumatology research. The \$1,000 winners from the last questionnaire were James Sillik, Kingston, NY; Eldred Svoboda, Cedar Rapids, IA and David Elliot, Jackson, MS. Winning smaller amounts were Beverly Dawson, Clarence, IA; Phyllis Moore, Johnstown, OH; and Gale McIntire, Derby, KS. Other winners were not listed. Congratulations to all!

## Refer a Friend

Here's a really easy way to let a friend know about the NDB. Just give us your friend's email address and we'll send out an email invitation to join the study. Go to <http://www.arthritis-research.org/enrollfriend.htm>

### FOR MORE INFORMATION OR TO PARTICIPATE

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