CFS PHOENIX

'The Phoenix is A Mythical Bird That Rises From the Ashes of it's Own Destruction'

PHOENIX RISING: A CFS/FMS NEWSLETTER by Cort Johnson	**March/April 2007 Special Edition**
Advocacy Edition: Letter From Lobby Day and the CFSAC Meeting Plus the Neuroimmune RFA Pt. IV: Conclusions!	**Subscribe to PHOENIX RISING!**

NEWS

Rich Carson Talks- Rich Carson, CFS patient, the founder of ProHealth (ImmuneSupport) and CFS advocate talks about his increasingly better health, how he's achieved that, and his ongoing efforts involving the name change.

Dr. Klimas featured in a beautifully produced full color feature article available online from the University of Miami. Don't miss this one featuring one of most innovative researchers and effective advocates.

Turn Water Into Wine? Learning Life Lesson's From CFS? A CFS project by Justin Chernow - Check out this interesting project by Justin Chernow. Every difficult situation is an opportunity for insight and growth and we all know how difficult CFS can be. Can it be an opportunity for growth as well? Justin thinks it can be.

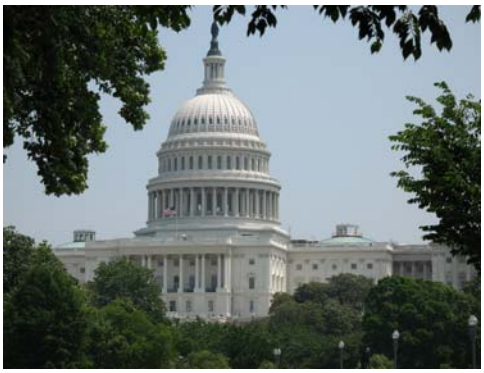
"My name is Justin Chernow, and I am diagnosed with Chronic Fatigue Syndrome (CFS). I still struggle with my symptoms on a daily basis. Yet in looking back to where and who I was before CFS — I am also able to perceive positive changes stemming from my process of coping with, adjusting to, and seeking meaning from CFS. Some might call these changes growth, but I think of them as transformation.

*Currently, as part of my dissertation research at the Institute of Transpersonal Psychology in Palo Alto, CA, I am looking for other adults with CFS who believe they have experienced personal, spiritual, and/or religious growth or transformation from CFS. If you might be interested in sharing your story of positive change from CFS through a brief interview (by phone or in-person), I invite you to contact me at growth.from.cfs@gmail.com. Please note that all inquiries are confidential By sharing your story and perspective, you may benefit from the opportunity t*o":

- See your life in a new way by reflecting on your own experience;
- Help others with CFS, and the people who live and work with them.
- Consider the positive aspects or perceived benefits of CFS; and

For more information, please visit www.GrowthFromCFS.com. Many thanks and all the best, Justin Chernow, Ph.D. Candidate/650- 224-7472 /growth.from.cfs@gmail.com

SPECIAL ADVOCACY EDITION



Letter From LOBBY DAY

Lobby Day! I'd been skeptical about Lobby Day for years. How, I thought, could one day possibly make any difference? It was probably more of an attempt to pump up the participants, or appease the natives, so to speak, than to actually achieve anything. Look, the CFIDS Association of America, could say, we did a Lobby Day – we're really trying.

My questions about the efficacy of Lobby Days evaporated, however, just minutes before I got to my first one. As I was on my way to the hotel, my nose in a map, someone in the crowd took mercy. After pointing me in the opposite direction we walked on together and I asked him what he did. He said he assisted non-profit health groups in getting legislation passed up on the hill (!). I said I was on my way to a Lobby Day for Chronic Fatigue Syndrome and I asked him if lobby days were really effective. He said he did them for groups all the time and that they could be very effective.

Not an Easy Undertaking: It was pretty clear early on that putting on a Lobby Day takes a lot of effort. Everyone received a substantial packet in advance of the event (plus a shirt and nice Spark! Bag); the CAA brought several staffers to the event; they apparently worked well into the night juggling schedules; the letter we to deliver was still being tweaked the day before the event; Tom Sheridan and his associates were there on both the training and Lobby Day. The CAA obviously devotes considerable resources to bring these off events.

The Purpose: The purpose of this Lobby Day was to get senators and congressmen to sign a letter urging Dr. Zerhouni to give priority to CFS as he carries out the 'Roadmap Initiative' at the NIH. The Roadmap Initiative focuses on multi-systemic processes and diseases that the Institutes, with their emphasis on separate areas of the body, have ignored. If it succeeds, it will very likely undercut the power of the Institutes - something it appears that CFS, after 20 years of struggling with them, very badly needs to happen for help to materialize at the NIH.

Because CFS is a multi-systemic disease par excellence, the Roadmap Initiative provides a big opportunity for us to get 'in' on a major initiative at the NIH. The CFS research program at the NIH has declined markedly since the Cooperative Research Centers were shut down in 2001. The problem is that multi-systemic processes are at play in many, if not most diseases. The money for the Roadmap will, one way or another, have to come out of the Institutes and the already 'big diseases' with their entrenched programs will fight furiously to retain their share of funding. One could easily see CFS with its miniscule research program (1 employee!) being pushed to the side again.

That is why we needed political support. Dr. Zerhouni, the director of the NIH, has not thus far been a friend of CFS. Tom Sheridan described Senator Reid dragging him into his office because he had been so tardy in getting our (small) Neuroimmune RFA underway. If we could get the support of significant numbers of senators and congressmen, we could perhaps force Dr. Zerhouni to do what it appears he does not care to do – give some attention to CFS.

Finding a Champion and Staying in the Game: Two unstated purposes are always present at Lobby Day; find a champion and stay in the game. CFS had a champion, John Porter, who was able to assist us in tripling research funding from 1990-1995. We have not had a leader like John Porter since he retired. John Porter's contribution came out of one contact. The next person a CFS advocate meets could become another John Porter. Another goal is to be sure we have an on-going presence on the Hill.

Our High Cards: We had two high cards to play in this game. Harry Reid's signature on the letter and the bi-partisan support it has gathered. Harry Reid is from Nevada and he has been a friend of CFS since his early days on the Hill when the outbreak in Incline Village, Nevada, erupted. Now that he's the Senate Majority Leader, his word obviously carries a lot of weight. Senator Reid does not normally sign this kind of letters – he does not want his position to influence others – but he did so this time.

Training Day: The afternoon before Lobby Day, we met at the Washington Plaza Hotel to hear talks by Tom Sheridan, his dynamic aid Kevin Mathis and Kim McCleary about the day ahead. We watched Tom, Kevin and Kim perform several skits – one of which involved a hilarious send up by Kim of a befuddled congressional aide. Then one group did a trial run and off we went.

The Plan: A 'Ground and Air' Attack - The plan was for the advocates on the ground to hit the legislators with the letter in face-to-face meetings and for the virtual lobbyists to hit them with it with their e-mails. Kim McCleary visited one staffer who'd been on the job for only two days and didn't know anything about CFS but said she'd just received 30 e-mails on it. Not only did the virtual lobbyists contact the many politicians the advocates couldn't get to, they also supported the advocates who were visiting them.

THE DAY

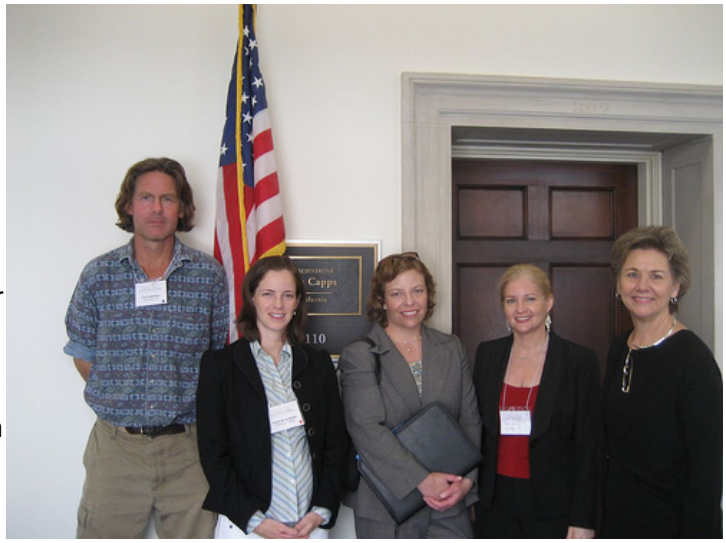
Lobby Day involved about 70 persons, a significant number who did not have CFS themselves but who but had a relative or friend who did. The most experienced Lobby Day participant was a father from Texas who was on his ninth. We went in groups of 3-6 according to state. New Jersey, Texas, California and others had sizeable contingents but, surprisingly, New York, which was almost within spitting distance, had only a single participant. (!)

The California Group: Everyone in our group had, amazingly, been something of an athlete prior to getting CFS; we had a tri-athlete, a martial artist, a runner, a ski instructor. Terri, the tri-athlete, was at the top of her game when she got ill. She owned a house at 27 and had just returned from a vacation in Spain when it all fell apart. She spent 7 years in bed. Jen had watched her mother fall apart with this disease and then came down with it herself as a teenager. Ann had been a martial artist and had dreams of traveling the world as an opera singer when she fell

apart while in school and spent two years in bed. Anna was pregnant and had a husband in medical school. We were also lucky to have with us Amy whose best friend had had CFS for 12 years and now was almost completely disabled, and Anna's mother and father.

Who Did We See? Although some groups apparently met with Senators or Congressmen our group met with staffers. The meetings were arranged in advance and we knew who we were going to meet. My brother, Cass, who runs a Textile Lobbying firm, said that meetings with actual politicians were fairly rare. He also said that at times it is agonizingly apparent that a staffer has little or no interest in meeting with him. That fortunately did not occur to us. We did, however, get stuck with a lowly 'fellow' at one appointment, a medical student on an internship – not a sign we were getting much priority there. Most of the staffers, however, seemed both competent and interested.

Degree of Difficulty – Not as high as one might expect. I was quite nervous at the beginning (apparently the only one in our group) but settled down as the day went on. We had one person give a short introduction to CFS, another give their 'sob story' – and in my groups they always did end up sobbing – and one present the letter and attempt to close the deal.



The Response: No one agreed to sign the letter on the spot but, with the exception of two Texas House members, all see med receptive to it.

The Aftermath: Those who were still mobile met at Tom Sheridan's house for a catered reception with Tom Sheridan's staff, Dr. Bateman and Dr. Klimas and Kim McCleary. We drank our beverage of choice, nibbled on finger foods and talked about the day and related matters (Tom Sheridan's horses acupuncture treatments) for a couple of hours. The CAA and the Sheridan group will analyze the politician's responses and Dr. Zerhouni's response to them and take it from there. If this effort is successful they will build on it next year.

Parting Thoughts: These are small steps. It is very frustrating that after 20 years we're still trying to find a home at the NIH. When the CFS research program was based in the Institute of

Allergy and Infectious Diseases (NIAID) it was run by Stephen Straus – not a friend to CFS. Now the CFS research program is in friendly hands at the ORWH but the ORWH itself has been undercut in its attempts to run the program and in some important ways things are actually much worse.

The ORWH has an excellent focus, and is currently funding some excellent studies – among the most complex and innovative we've ever had --but funding in real terms has tanked. Now that the payback funds at the CDC have been exhausted, funding for CFS appears to sinking back to its abysmally low levels. The innovative research Dr. Reeves engaged in with the payback funds has not yet been rewarded with increased funding.

At one point I commiserated with my brother Cass about how slowly it all was all going. We weren't trying to get an increase in CFS funding; we were simply trying to get a letter signed that would ask the director of the NIH, Dr. Zerhouni, to give CFS more priority. (Lawmakers decided some time ago to let researchers determine research priorities at the NIH. Its extremely difficult to get earmarks for specific diseases. You can build a hundred million dollar road to nowhere but you can't tell the NIH to spend X amount on CFS – go figure). This was definitely a small step. Cass said, however, that everything in Washington is set up to impede motion. He said many of his clients had no idea just how difficult it was to get anything done.

It doesn't help of course that these are budgetarily very difficult times. The $300 million dollars a day the US spends in Iraq is cramping budgets everywhere. The flip side of this work is that if you do get something done on this level it can make a huge difference; the potential pot of gold sitting at the NIH's table simply dwarfs anything private sources could ever hope to raise. Even at its pitifully low levels, federal funding for CFS research in 2005 was about 30 times what the CFIDS Association could contribute.

TAKING STOCK: THE GOOD NEWS - One of the things Lobby Day opened my eyes to was the progress that we <u>have made</u>. There are a lot of negatives, and we tend to dwell on them, but some very positive things have happened. That's what I left with and that's what I'll end this letter with.

Building a Foundation: CFS has actually made a quite a splash for such a controversial, poorly respected, poorly funded disease. Tom Sheridan, the CAA's lobbyist, obviously has some stake in this matter but he was emphatic in stating that no disease with such little support from the power structure has made as big a splash as CFS. While we've been watching funding levels decline, we've actually made considerable progress in other areas. In fact some of the cornerstones or foundation blocks needed for CFS to succeed have recently been laid. Some of them are listed below.

The CDC Scandal: In some ways the high water mark of CFS advocacy was the CDC funding scandal. That scandal really rocked the CDC's world; nothing of that sort had ever happened to that respected institution before. By the time it was over the director had resigned and the CFS research program was put under oversight and CFS got an enormous amount of publicity. The scandal wasn't all good news; it apparently generated a lot of bad blood. Some people there will never forgive Reeves for the embarrassment his testimony caused. But it was a remarkable achievement.

Ironically one could make the argument that shenanigans of the late 1990s helped CFS more than they hurt it. They got CFS into the news in a big way, we got all the money back that was taken from us, and the program was put under the direction of a vigorous researcher who took advantage of technology not available during the late 1990s. Dr. Reeves may or may not be right in his approach – only time will tell - and he definitely ruffles feathers from time to time, but he is undoubtedly engaged and interested in the subject – something we did not have

before. One could also argue that the media campaign would never have taken place without it.

Social Security Ruling: The CDC scandal was the most exciting achievement but other, less obvious but still important, ones have occurred. In 1999 the Social Security Administration produced a special ruling on the requirements for CFS disability. This ruling spells out what the SSA is looking for with regards to CFS and it gives CFS patients a legal document they can use to dispute their rulings if necessary. It is a very important document. This was, again apparently a fairly unusual matter; special rulings on specific diseases are not an everyday occurrence.

CFSAC Committee: The creation of the Chronic Fatigue Syndrome Advisory Committee (CFSAC) to advise the Secretary of Health is another resource most diseases do not have. While one can certainly question the effectiveness of the CFSAC this committee does give CFS advocates a potential 'in' that most diseases do not have and that 'in' could pay great dividends at some point. It gives CFS professionals and advocates the ability to publicly comment and advise the government on a wide variety of governmental programs pertaining to CFS including CFS research at the NIH and CDC, Social Security, educational efforts, the FDA and so on. Even if its potential is not currently being met it is important that it continue. The goal of the last Lobby Day was to ensure that the CFSAC committee was reauthorized.

The CAA/CDC Media Campaign: The media campaign is not just unusual, it's actually precedent-setting. The CDC has <u>never</u> done a media campaign for any disease before. I asked Kim how it all got started: did they come to her or did she go to them and if so how did she sell the CDC on something they'd never done before? She said she went to them and, using a study indicating that earlier diagnosis improved outcomes in CFS, she argued that the CDC should run a media campaign as a kind of public service message. The understated factor was, of course, a feeling that the CDC really owed the CFS community something for its past behavior.

So kudos to the CAA for its innovative approach in this area. The media campaign has been successful enough that the CDC now has a new problem – other diseases want their own media campaigns. The media campaign's next stop, by the way, is a two week stint at one of the busiest buildings in the U.S. - Union Station – with 80,000 passers-by a day.

Gaining Legitmacy. If you look at the big picture, we have almost everything we need to get very substantial increases in funding. We have population studies that show CFS strikes a lot of people, that it often leaves them very disabled and that CFS costs the country an enormous amount of money every year (at least 25 billion dollars). These are real accomplishments; it's surprising how many diseases do not have this kind of strong prevalence and economic data.

Despite these studies, the upper levels of the NIH still don't 'get it' about CFS. They appear to get it at the program level; Drs. Pinn and Hanna are well versed in CFS research and have produced an innovative research plan. But the NIH as a whole is still acting as though CFS were a minor disease worth nothing more than pocket change: the kind of money people might give to beggars on the street. CFS, for instance, has almost double the indirect economic costs of asthma but receives about $1/80^{th}$ of the funding (about 4 million/year versus about 300 million dollars a year).

The only way officials with any sense of integrity can allow something like that to happen is for them to tell themselves that CFS isn't really real. The good news is that it is getting and harder for them to do that. Gaining legitimization is one area we have made great strides in. Five years ago it was not that hard for someone working at the NIH to dismiss CFS; today it is pretty hard to do so; hopefully tomorrow it will be impossible.

CFS has been struggling for legitimacy for about 20 years. The word at this Lobby Day was that that struggle is just about over. Tom Sheridan, the CAA's lobbyist came in and basically said, "This is about closing the door on that issue and moving on". The fact is that the opinion makers in the medical world have shifted their stance on CFS. They include public acknowledgments by high ranking officials, official websites that legitimize the disease and support by respected medical organizations. The big stakeholders are beginning to support CFS.

The CDC/CAA Press Conference that jumpstarted the CFS media campaign may turn out to be a watershed moment in the history of CFS. There can't be many more impactful ways for CFS to gain legitimacy than having the director of the CDC and the Asst. Secretary of Health stand up and announce to the world that CFS is a real and serious disease. The fact that this came just five or six years after the CDC was taken to the mat by Congress for lying about its misuse of CFS funds only helped matters; to go from chief skeptic to promoter in this amount of time is little short of amazing.

The short report on CFS by Research America was another foundation stone. CFS is only the 14th disease this highly respected organization has produced a fact sheet on. Another brick was laid by the American College of Physicians (with their 120,000 members) in their detailed overview of CFS including Dr. Bateman, Dr. Komaroff and others. Another rock was pushed into place with the Mayo Clinic's report on CFS on its website. This report isn't all we would want but it presents CFS as a legitimate disease. Mayo Clinic, which is often mentioned in the same breath as the NIH and the CDC, is an important arbiter of medical opinion.

Several encounters I had over the week suggested CFS was indeed being viewed differently. During a break at the CFSAC meeting I asked Dr. Fennell if her peers have reacted differently to CFS over time. She said there'd been a remarkable change in the past five years or so. Most people in her field (behavioral sciences) used to think that people were traumatized and **that** was causing CFS, now they think something **in CFS** is causing people to be 'traumatized'. That shift – from a psychological orientation to a physiological one – is a major one.

The husband of one of our group members had recently encountered a short class in medical school in which CFS was treated as a nothing more than a puzzling but entirely legitimate disease. The fact that CFS both a) made it into a class in medical school and b) was treated fairly is somewhat astonishing. The Vermont CFIDS organization was recently able to get a bill passed to educate physicians about CFS in part because it was able to point to the CDC's website to show lawmakers that CFS was, indeed, a legitimate disease. An earlier effort failed because they didn't have a respected source they could utilize.

It is clear that the foundations for the widespread legitimization of CFS are being laid. Most of the physicians on the ground and many researchers haven't gotten the news about CFS yet but it appears that the major stakeholders and opinion makers in the medical field have. It will take time for 'the message' to filter up or down but eventually it will.

There is a sense that we're starting to get a bit of a tailwind behind us. If we keep speaking out and supporting our local and national organizations and keep getting involved, we may be able to translate these results into meaningful activity at the research level.

At some point, CFS patients will be diagnosed quickly, treated compassionately and effectively and CFS will have a strong research base and (a decent sounding name), etc. CFS will become a mainstream disorder that has 'made it' in the medical world and will be able, like other mainstream diseases, to reap the very considerable benefits of having done that.

THE CFSAC MEETING

The meeting of the committee to advise the Department of Health and Human Services (DHHS) on matters pertaining to CFS met two days after Lobby Day. It looks a strong committee comprised of Dr. Jason, Dr. Klimas, Dr. Bateman and others. Our patient representative is Rebecca Artmann who has been closely associated with PANDORA in southern Florida. The committee typically hears from representatives from the CDC and NIH (Dr. Reeves, Dr. Hanna), the FDA, and others, as well as members of the government as well as people they request to testify. This year Dr. Fennell testified.

I wasn't able to attend the CFSAC meetings so all I can relate is my own experience testifying. I got there at lunch and sat with Kim McCleary, Marly Silverman and a few other people. I was not in particularly good shape but I did get to watch Marly Silverman in full gear networking furiously with Kim McCleary – which was quite a sight.

The meeting room was a medium-sized conference room with tables for the committee and speakers arranged in a square. Behind that were enough seats for about fifty people – about a third of which were filled. Marly Silverman had placed photos on the chair backs of several rows to represent CFS patients who couldn't be there.

Of course I was extremely nervous. I always am in these situations. It didn't help that I had been working on something else all week and had little time to prepare. Of course I was the last to go. I was too rattled to catch more than bits and pieces of what the other CFS patients were saying, although I did notice they all seemed quite comfortable.

At one point it seemed that I would escape my fate. After five people had testified Dr. Oleske rose and began to thank everyone for coming. Just as I was celebrating my escape, I glimpsed, with some horror, Kim McCleary rising to the left of me. She said 'We actually have one more person to go'. God knows how she knew I had signed up to testify while the committee didn't. Given the lateness of the day I very obligingly told the committee it would be fine with me if I just submitted my remarks in paper form but I was informed that we actually had five more minutes left! My goose was cooked and up I went to table. I didn't do as poorly as I'd feared or as well as I had hoped. All in all it was quite a stimulating experience. You can read my testimony at http://phoenix-cfs.org/CFSAC%20Testimony%20May%2007.htm

The NEUROIMMUNE RFA GRANTS FOR CFS: *Making the Difference or More of the Sa*

Part IV: Conclusion - Assessing the Grants by Cort Johnson

This is an abbreviated version of the complete paper.

As an introduction to a series of papers exploring the state of CFS funding at the NIH I focused my attention on the NIH's big effort in this regard; the $4,000,000 set aside for grants into Neuroimmune Mechanisms in CFS. While $4,000,000 doesn't go all that far in medical research this was a significant endeavor; the RFA had the potential to double NIH funding for CFS research.

Three years, one conference and - according to Dr. Hanna, the leader of the CFS research program at the NIH - a lot of hard work later, this effort culminated in these 7 grants. The NIH

RFA is a good test case for the NIH; it is the first major initiative by the Office For Research into Women's Health (ORWH) to implement its new multidisciplinary approach to CFS and it was widely trumpeted as proof that the ORWH and the NIH are serious about re-invigorating CFS research. Given the decline in NIH funding for CFS - now reduced to early 1990's levels - the RFA couldn't have come at a better time. Given the kinds of studies the NIH likes to fund - complex, innovative, expensive, multi-systemic studies – a fully funded RFA would be a considerable breakthrough for CFS research.

In this four part series we have charted the positives (the purely biological approach, a focus on some important issues) and the negatives (the possibility of non-CFS grants being funded, the few CFS researchers at the conference or on the review committee, the inclusion of some peripheral issues in both, etc.). (See Part I: The Neuroimmune Mechanisms Conference of 2003; Part II: Reading the Grant; Part III: Reviewing the Reviewers).

Now, we ask, how did the NIH do? Was the RFA a success? Did the NIH pick good grants? Did they include CFS patients? Did they use CFS researchers? ITs been suggested these grants are an exciting development. Are they? Let's find out.

Researcher Interest - One purpose of the RFA was to spark investigator interest. Officials at the NIH have repeatedly said that one reason CFS has not been better funded has been a lack of researcher interest. The research community responded well to the RFA; at least 29 grant applications – enough for the NIH, even with a high rejection rate, to fund 10 or so grants. The response was good enough, in fact, for Dr. Hanna to state at one point that $4,000,000 was the floor, not the ceiling, and speculate that the funding level could increase if the Institutes found more projects they wished to fund.

First the individual grants and then the entire grant package are reviewed.

Analysing the Grants - Each grant gets scored on its applicability to CFS pathophysiology. The type of grant it was funded and the Institute funded it are noted. The scores are

- 0 points – topic not directly related to CFS research, no CFS patients involved
- 0.5 points – some relevance to CFS research
- 1.0 – relevant, important research

Plus the type of grant is noted. This RFA involved two different kinds of grants

- **RO1 grants** – large scale, long term (4 year) grants

  .

- **R21 grants** – smaller scale, shorter term (2-year) grants of an experimental nature.

The Funder -.The CFS research program is in an unusual position in the NIH; most diseases have a base within one of the 28 Institutes and Centers that make up the NIH, but the CFS research program does not. CFS is based in the Office for the Research into Women's Health (ORWH), an organization with little funding ability itself which must therefore lobby Institute representatives to get the funds for its CFS research program. Identifying which Institutes stepped up to the plate at this RFA may give us some insight into which Institutes are willing to support CFS.

Click here to see an analysis of each grant

ANALYSIS - The 2006 NEUROIMMUNE GRANT PACKAGE

Overall Grant Package - Seven grants totaling $2,032,372, or half the projected total, were funded. Four grants were focused on CFS pathophysiology, one was on a process (HPA axis hyperfunction) not found in CFS, one was on FM and one was on cognitive behavior therapy with a neuro-immune component.

Two of the four 'good grants' were R21's – short 2-year studies. Two of the three 'losers' on the other hand, were RO1's, costly 4-year grants. Instead of $2 million the NIH actually ended spending $1,116,937 on studies of CFS pathophysiology. Only about a quarter of the projected $4,000,000 was spent on studies directly focused on CFS pathophysiology, a rather stunning disappointment given the good response from the CFS research community. Unfortunately this is what one has come to expect from the NIH; in the last couple of years, only about half the funds they attributed to CFS research actually went to CFS projects.

The NIH has stated that they need new researchers to revitalize their program and it was hoped that the RFA would begin this process but the RFA did not bring new researchers into the fold. All the CFS researchers awarded with grants (Fletcher, Baraniuk, Biaggioni, Light and Antoni) were past NIH awardees. Instead of bringing in new researchers this RFA ended up rewarding researchers who were already accomplished at negotiating the grant review process at the NIH.

Individual Grants - The final grant score was 4 out of 7 points; a C. There are some excellent projects here; the Biaggioni, Fletcher and Baraniuk and half of the Light study, are all excellent studies and they are a cause for celebration. It was very welcome to see several studies emphasize the sympathetic nervous system; an important subject that was mostly ignored in the Neuroimmune Conference and RFA. This suggested the review committee had the flexibility to look outside the guidelines of the RFA.

Still if one considers that the Baraniuk grant was probably already a 'given', a close examination of the grants indicates that this long process actually yielded only three grants the CFS community might not otherwise have seen.

How did a project that appeared poised to succeed falter so badly at the end? This is not an easy question to answer. Dr. Hoffeld, the administrator of the CFS SEP that reviews CFS grant proposals has described the NIH grant process as a kind of 'black hole'. NIH rules preclude us from learning much about the rejected grants; we can't learn who submitted them or find out how they were scored or what comments they were given. Indeed it can be difficult even to determine how many grants are submitted. (This was a rare occasion when it was publicly announced.) A recent court case indicated it is possible to learn the titles of the grants submitted.

A review of the grant process suggests some possible culprits.

Lack of Agency Support - The success of any grant process in CFS is dependent upon the willingness of the 14 Institutes that make up the Chronic Fatigue Syndrome Working Group (CFSWG) to fund CFS projects. These Institutes fund a wide variety of medical research topics involving the immune system, cardiovascular and nervous systems and others. Some Institutes (NIAID - immune, NINDS – nervous system) have close ties to CFS research subjects but most of the other Institutes (e.g. NIAAA, NIEHS, NINR) on the CFSWG have only tenuous connections to CFS. In order for CFS research at the NIH to be successful, the Institutes with mandates to study the kind of subjects CFS researchers are engaged in exploring, such as the NIAID, NINDS

and NHLBI (immune, nervous and cardiovascular) research, need to support CFS research projects.

In this case, the NINDS did fund several of the grants in this package, but the others did not. Most surprising was the inability of the NIAID to fund a single CFS grant despite its close connection to the topic at hand. Instead, two Institutes that between them have funded only a single CFS grant over the past 15 years, the National Institute of Alcohol Abuse and Alcoholism (NIAAA) and the National Institute of Environmental Health and Sciences (NIEHS) stepped up to fund almost half the grants in this package. This suggests the ORWH had trouble getting the NIAID on board for at least the first year of this grant package.

Another warning sign concerns the amount of time the ORWH needed to find the funds for this relatively small RFA. Dr. Pinn, the director of the ORWH acknowledged she took 'some heat' over the two years it took her to get the Institutes 'on board'. Yet the RFA was published during a time when the Institutes were in relative terms funding less CFS research than they had for at least a decade. During a time when the NIH budget was undergoing unprecedented increases, almost doubling in five years, funding for CFS research dropped dramatically with the closing of the Cooperative Research Centers (CRC's).

Dr. Hanna recently stated that the CFS research program has two options; it can either have a research grant program or have a Centers of Excellence program – the Institutes would not support both. Six years ago, however, they were supporting both. This suggests that institute support of CFS has declined dramatically in the last six years.

Lack of Researcher Support – It's possible that the CFS research community simply did not rise to the occasion. NIH officials have long said that most CFS research grants have lacked innovation. Did the rejected grants not meet the test of innovation? This is impossible to tell but at least one researchers experience suggests not.

Dr. Andrew Lloyd has an extensive resume; over the past 10 years he has co-authored approximately 40 papers on CFS, hepatitis C, fatigue states in cancer, HIV and others. He is the leader of the groundbreaking Dubbo project examining the physiological changes occurring as people come down with CFS following infection. His results to date have suggested that immune and nervous system abnormalities play a key role in the disease process in CFS.

The Dubbo project's next course was to be an examination of the neuro-immune interface in CFS. Despite Dr. Lloyd's resume, the success of the past Dubbo projects, the innovative nature of these projects, and the fact that they fit the parameters of the Neuroimmune RFA, neither of two grants he submitted were funded. That these projects by this researcher could not pass muster suggests something is very wrong in the grant approval process at the NIH.

A Failed Process - Unfortunately we don't know where in the process the Lloyd (or other) grants failed. Poor scores by the initial reviewers could have sealed their fate. The grant review panel has been a point of contention almost since a special panel was formed to review CFS, FM and TMD grant proposals. The CFIDS Association appealed in vain for an administrator other than Dr. Hofford to overview the review process. While the RFA panel Dr. Hofford assembled was a step up from others before it, it did not include many CFS researchers and had a number of poorly qualified reviewers (**click here).**

Alternatively the grants could have been scored well but were simply not funded by the institutes.

A worst case scenario - Let us suppose the Lloyd grant proposals were an absolute mess, a highly unlikely proposition given Dr. Lloyd's extensive research experience but nevertheless, lets assume they were sloppily done. Special grant mechanisms like RFA's give NIH officials a justification for overlooking poor review scores and funding studies they believe have value. Dr. Hofford has, in fact, stated that Institutes regularly pass over more highly scored grants and fund less well scoring grants they have more interest in. If NIH officials were really committed to increasing CFS funding they could easily have found a way to do so. After all they regularly acknowledge the woeful underfunding of the CFS research program and regularly state they are committed to increasing it.

Given the Dubbo project's record of success, its innovative nature (something NIH officials say again and again they do not see from CFS researchers), the NIH should have found a way to fund these projects.

It is difficult to know why these grant proposals failed. What we do know is that several grants by an experienced researcher that fit the ORWH's criteria of subject matter and innovation ended up being left on the table in an RFA that ended up being significantly underfunded.

Conclusions: Given the opaqueness of the NIH grant process, it is impossible at this point to know why this RFA sputtered so badly at the end. If we go back to the beginning, however - the Neuroimmune Conference in 2003 - plenty of warning signs are evident. The few CFS presenters, the lack of discussion on CFS, the presentations on other diseases, the focus on ancillary subjects such as antidepressants: all these factor suggest that the NIH has difficulty focusing on CFS. The RFA was strong - it emphasized CFS pathophysiology and provided many opportunities for CFS researchers; but it had loopholes that allowed for projects on other diseases. The choice of Dr. Hofford – someone the CAA actively lobbied against – as the review panel administrator was not encouraging. The long lag time between RFA's announcement and its actual funding date suggested the ORWH had trouble getting the Institutes on board. The fact that the ORWH had to take funds out of other programs to pay for the RFA suggested a lack of support for the CFS research program at the Office of the Director. These warning flags suggest the CFS research program at the ORWH faces many hurdles that impair it from mounting a strong effort.

The NIH is a very, very important part of the CFS research effort. It is one of the few institutions that can fund the kind of expensive, multi-dimensional studies that CFS desperately needs. They NIH has and is doing vital work in CFS; many of the brain studies, most of the cardiovascular studies, the natural killer cell studies and most of the twin studies came out of the NIH. Even when the NIH fails it can succeed in ways other funders cannot; few institutions are able to fund studies as complex and expensive as the Biaggioni or Baraniuk ones.

Making the Difference or More of the Same? Some of the grants are quite exciting but the grant package underperformed severely given its potential. In the end this RFA was a mix of bad and good; several grants have the potential to make a difference but in several ways the process appeared to exemplify a more-of-the-same approach. The inability of an experienced CFS researcher to be awarded grants for an ongoing project aimed squarely at the focus of the RFA is inexplicable and alarming. The approach the ORWH has taken to fund CFS research is not workable and needs to be replaced.