



**Hubert H. Humphrey Building, Room800, 200 Independence Avenue, SW
 Washington, DC
 Wednesday, May 11, 2011 – 9:00 am to 4:30 pm**

Voting Membership

Name		Term
Chairman Christopher Snell, PhD	Stockton, CA	04/01/07 to 04/01/12
Dane B. Cook, PhD	Madison, WI	05/10/10 to 05/10/14
Jordan D. Dimitrakov, MD, PhD	Boston, MA	05/10/10 to 05/10/14
Eileen Holderman	Galveston, TX	05/10/10 to 05/10/14
Michael Houghton, PhD	Danville, CA	05/10/10 to 05/10/14
Leonard Jason, PhD	Chicago, IL	04/01/07 to 04/01/12
Steven P. Krafchick, MPH, JD	Seattle, WA	07/01/10 to 07/01/14
Nancy Klimas, MD	Miami, FL	04/01/07 to 04/01/12
Susan M. Levine, MD	New York, NY	05/10/10 to 05/10/14
Gailen Marshall Jr., MD, PhD	Jackson, MS	05/10/10 to 05/10/14

Ex officio Membership

Agency for Health Research and Quality

Christine Williams

Director of Strategic Partnerships

Marc W. Cavaille-Coll, M.D., Ph.D.

Medical Officer Team Leader
 Division of Special Pathogens and
 Immunologic Drug Products

Centers for Disease Control and Prevention

J. Michael Miller, Ph.D.

Associate Director for Science
 National Center for Zoonotic, Vector-borne,
 and Enteric Diseases

Health Resources and Services Administration

Deborah Willis-Fillinger, M.D.

Senior Medical Advisor Office of the
 Administrator, Center for Quality

Center for Medicare and Medicaid Services

Alaine Perry, M.P.H.

Senior Advisor for Disability and Special Need
 Population

CMS Center for Strategic Planning

National Institutes of Health

Food and Drug Administration

Primary

Dennis F. Mangan, Ph.D.

Senior Research Advisor
Chair, Trans-NIH ME/CFS Research Working Group
Office on Research on Women’s Health
Office of the Director

Alternate

Janine Austin Clayton, M.D.

Deputy Director Office of Research on Women’s Health
Office of the Director

Social Security Administration

Primary

Cheryl A. Williams

Director
Office of Medical Listings Improvement

Alternate

John Federline

Deputy Director
Office of Medical Listings Improvement

Designated Federal Official

Wanda K. Jones, Dr.P.H.

Agenda

9:00 a.m.	Call to Order Opening Remarks:	pg	Dr. Christopher Snell <i>Chair, CFSAC</i>
	Roll Call, Housekeeping:		Dr. Wanda Jones <i>Designated Federal Official</i>
9:15 a.m.	Welcome Statement from the Assistant Secretary for Health	pg	Dr. Howard K. Koh
9:30 a.m.	Social Security Administration: Presentation on Disability	pg	John Federline, SSA
10:00 a.m.	ERISA and Insurance Issues for CFS Patients	pg	Lisa Alexander Chief, Division of Coverage, Reporting and Disclosure Office of Regulations and Interpretations Employee Benefits Security Administration U.S. Department of Labor
11:00 a.m.	Break	pg	
11:15 a.m.	Committee Discussion	pg	Committee Members
12:00 p.m.	Subcommittee Lunch	pg	Subcommittee Members
1:00 p.m.	Public Comment	pg	Public
2:00 p.m.	Break	pg	

2:15 p.m.	Committee Discussion: Finalize Recommendations	pg	Committee Members
4:30 p.m.	Adjourn	pg	

Dr. Christopher Snell, Chair, was presiding.

CALL TO ORDER/OPENING REMARKS

Dr. Wanda Jones conducted the Roll Call:

ROLL CALL

Committee/Voting Members Present:

Dr. Christopher Snell, Chair
 Dr. Dane B. Cook
 Dr. Jordan D. Dimitrakov
 Ms. Eileen Holderman
 Dr. Michael Houghton
 Dr. Leonard Jason
 Dr. Steven P. Krafchick
 Dr. Nancy Klimas
 Dr. Susan M. Levine
 Dr. Gailen Marshall Jr.

Committee/Voting Members Absent:

Liaisons/*ex officios* Present:

Suzanne Adelman
 Lisa Alexander
 Dr. Marc W. Cavaille-Coll
 John Federline
 Elena Lynett
 Dr. Dennis F. Mangan
 Dr. J. Michael Miller
 Alaine Perry
 Christine Williams
 Deborah Willis-Fillinger

Liaisons/*ex officios* Absent:

Dr. Janine Austin Clayton
 Cheryl A. Williams

WELCOME STATEMENT FROM THE ASSISTANT SECRETARY FOR HEALTH

Dr. Howard Koh, Assistant Secretary for Health, U.S. Department of Health and Human Services

- Welcomed everyone to the committee and thanked Dr. Snell for his continued dedication and asked that everybody around the table introduce themselves.
- Stated that he remained committed to working as closely as he could with everyone on the committee to bring a unified approach to ME/CFS (Myalgic Encephalomyelitis/Chronic Fatigue Syndrome) and better resolve issues around research, education, treatment and quality of life. Acknowledged the work of Dr. Jones and asked for a round of applause.
- Stated that ME/CFS continued to be a major challenge for public health and noted that they needed the highest level of coordination and commitment to resolve the issues.
- Noted that in March they had a high-level leadership meeting with the Secretary on ME/CFS and they reviewed the status of research, clinical care, education. Discussed the status of the CFSAC (Chronic Fatigue Syndrome Advisory Committee) recommendations over the past years. Reported that the Secretary was engaged, receptive and supportive and expressed her appreciation to the group.
- Noted that the agency heads of the departments met several more times to share progress.
- Reported that the Secretary wrote a letter to support the State of the Knowledge Workshop.
- Reported that the Secretary provided her assurance that her department was working together with CFSAC and advocacy groups to develop inter-disciplinary initiatives that would address important aspects of the illness.
- Noted he was grateful to Dr. Francis Collins, the head of NIH (National Institutes of Health), who coordinated the meeting, appeared, spoke and expressed his commitment to try and gain a better understanding of CFS.
- Noted that the NIH was awaiting the results of two key studies that should come to a conclusion by the end of 2011.
- Noted that the *ex officio* members on the committee were at the meeting with the Secretary and would continue to assist them track and advance recommendations made by the CFSAC.
- Reported that they had a greater commitment to provide education on ME/CFS and noted that the committee had heard from the CDC (Centers for Disease Control and Prevention) and AHRQ (Agency for Healthcare Research and Quality) who had expressed an interest in updating and making more current provider education materials.
- Thanked Mr. John Federline from the Social Security Agency (SSA) for being there and conducting a presentation on disability. Noted that they would have colleagues from the DOL (Department of Labor) speaking about laws regulating disability plans in COBRA (Consolidated Omnibus Budget Reconciliation Act) for CFS patients. Stated that another key outreach effort was the Preexisting Condition Insurance Plan from the Affordable Care Act (ACA). Explained how

patients with preexisting conditions who had not been able to obtain insurance for six months could now go on to www.pcip.gov and see if they could obtain insurance coverage with limited screening online and obtain coverage and then care.

COMMITTEE DISCUSSION

Dr. Leonard Jason thanked Dr. Koh for addressing the group and for his meetings on a regular basis with the sub-committees, Chair and Dr. Jones. He referred to the RFA from 2003 that came out of the State of the Science Meeting. He wondered if he would comment on the possibility of a positive outcome for such an RFA taking into account the budget situation. Dr. Koh stated that the tradition for NIH was to have the conferences with the purpose of identifying the highest areas of potential scientific reward. Stated that this was why Drs. Dennis Mangan and Francis Collins conducted the workshop in April.

Dr. Koh stated that from that workshop there were conflicting results from studies about the etiology and cause and therefore conflicting suggestions about appropriate support and treatment. He noted that the issue of funding always came up. He stated that the research leads in the department wanted to go forward based on the best science with the best possible leads so confirmed that the latest strategy was to continue to review the results of the State of the Knowledge Workshop but also to await the results of the two studies.

Ms. Holderman asked about insurance issues. She stated that she was under the impression that preexisting conditions were not going to take effect until the year 2014. She asked if that was correct. Dr. Koh confirmed that preexisting conditions provisions for children were in effect immediately with the signing of the ACA and with adults it would come into effect in 2014. Until then, he urged them to investigate the bridge plan; the Preexisting Condition Insurance Plan (PCIP). He noted that it could help people. Ms. Holderman asked if that information could be put on the CFSAC website.

Dr. Michael Houghton stated that he hoped that funding decisions would not just be based on the role of XMRV (Xenotropic Murine Leukemia Virus-Related Virus) in the disease but other areas including biomarkers. Dr. Koh responded that the researchers were looking for the best possible scientific leads wherever they might be.

Dr. Nancy Klimas wanted to acknowledge and recognize the enthusiasm of the *ex officio* members. She noted the possibility of demonstration projects across a number of different HHS (Health and Human Services) areas that could be the answer when talking about centers in recommendations.

Dr. Snell noted that one of the ideas they had discussed was an inter-agency task force that could continue the work of CFSAC when the committee itself did not meet which would develop proposals using existing mechanisms. He asked if the Assistant Secretary would consider forming a task force with a mandate to look at ways of using existing mechanisms. Dr. Koh noted he was open to any suggestion for better coordination. Dr. Jones also gave a nod to the *ex officios* and noted that they met monthly and discussed recommendations and moved forward where possible. She agreed with the concept of the task force and stated that they needed that type of energy on an ongoing basis.

Dr. Susan Levine also noted the excellent work of the *ex officios* and particularly the CMS representative who spoke on the innovation program. She stressed that educating providers was essential, and that this was a major public health issue.

SOCIAL SECURITY ADMINISTRATION: PRESENTATION ON DISABILITY

Mr. John Federline, Social Security Administration, Office of Medical Listings Improvement, *Deputy Director*

- Gave information on his background in 1973 adjudicating social disability claims in Maryland and then supervising, managing, training and reviewing for quality review decisions made on claims. He then moved to the headquarters for SSA in Woodlawn, worked on international claims and moved into the policy arena where he currently worked.
- Stated that he was there today to talk about how SSA adjudicates claims and promotes consistency in adjudicating claims.
- Stated he would talk about the five ways that they promote consistency in claims for ME/CFS:
 - Sequential evaluation process
 - Social Security Ruling 99 – 2p
 - Adjudicator Training with those two areas
 - Provide operating instructions
 - Perform quality review
- Noted that each overlapped but it was important to ensure that a decision made in one state would be the same as any other.
- Explained the sequential evaluation process:
 - It is a uniform process to ensure that everyone knows what the steps are for adjudicating social security disability claims.
 - The process is codified in (20 CFR 404.1520, 416.920). Adjudicators are required to use this and the five steps.
- Explained the five steps as a process where they reviewed the claim to determine if and how much income the claimant was earning. Described sequential steps where they determined by specific means the degree of disability. Noted that any supporting documentation that the claimant supplied to the SSA greatly assisted the adjudicator. Noted that for CFS that they provided information about manifestations of CFS not just the CFS in order to establish the findings of facts and analysis of evidence to make an accurate decision.
- Explained further that if the impairment was found to be severe then they would move on to step three which was: does the claimant meet, (in medical listings) the criteria for one of those

listings or equal the severity of those listings. Gave chronic fatigue syndrome as an example and noted that there was no listing currently for CFS. Noted that for impairments not listed they consider whether there was a listing that establishes the severity similar to what CFS might be in its most severe stage? Explained that physicians at the SSA were also involved in assessments and considered the RFC (Residual Functional Capacity).

- Explained that they also considered the type of work that the claimant did. Noted that assessments in the earlier steps were easier but if the process continued to step four then the assessments were more complex involving work and medical evidence.

COMMITTEE DISCUSSION

Mr. Steven Krafchick asked whether it would not make more sense to just list CFS in their listings blue book rather than having adjudicators matching up various manifestations of the claimant's case to different areas. *Mr. Federline* stated that there were so many impairments that they tried to fit the ones in there where they thought appropriate.

Dr. Levine asked about the quality of the education of the adjudicators with respect to the specific knowledge of CFS. She asked was the knowledge the same nationally. *Mr. Federline* stated that he would discuss that in the part of his presentation dealing with the SSR (Social Security Ruling).

Dr. Snell asked whether disability could be substantiated using evidence that would be used to substantiate disability in another illness. *Mr. Federline* indicated that yes this would be acceptable. *Dr. Jason* asked if a recommendation was made by CFSAC, would this influence SSA to create a category. *Ms. Holderman* further asked if the SSA gave precise criteria for an illness to be included in the listings book. *Mr. Federline* responded that there were policy experts in the SSA that looked at the types of impairments and they considered many different advocacy groups, and if they could be accommodated in a category they did it where appropriate. He noted that having it listed did not necessarily mean that a claim would be successful only that it was more to the forefront.

Christine Williams asked what SSA could provide for those who could not work full time but could work part time. *Mr. Federline* explained that there was no such thing as partial disability in SSA. They might be able to say that they weren't engaged in substantial gainful activity.

Mr. John Federline

- Discussed the Social Security Ruling 99-2p. This section gave instructions to adjudicators that explained what was needed to establish ME/CFS as a medically-determinable impairment. Stated that this meant specific medical signs, symptoms and lab findings. Noted that information on the ruling was at the website:
http://www.ssa.gov/OP_Home/rulings/di/01/SSR99-02-di-01.html
- Noted that they train adjudicators and provide text resources including a Basic Disability Examiner Training Manual and a Medical/Psychological Consultant Handbook.

COMMITTEE DISCUSSION (CONTINUED)

Dr. Klimas asked about the inclusion of mental illness as part of the overall condition listed in SSA approval. She said when this was done they lost their private disability coverage after two years because of that inclusion. She noted that as a major problem. She asked if there was a way the patients could have anything to fall back on in what they received from SSA when they found out two years later that this inclusion had affected them. She asked if the ruling could be broken down by percentage. Despite their best intentions, this ended up being detrimental.

Mr. Federline responded there was no way of breaking this down, because the SSA looked at the whole person. He noted that if they were totally allowed on a primary impairment then the SSA would not have to enter a secondary impairment. Mr. Krafchick said what often happened was in the summary paragraph of a ruling it would indicate they had a mental health condition in addition to their physical conditions. If the disability policy said that it was caused or contributed to by a mental health condition, they lose their private policy, so this was a frequent problem. Dr. Klimas said this was all the more problematic since suffering from any chronic disease often leads to depression, but that in CFS cases, this led to losing insurance, whereas with other diseases, it did not.

Mr. Krafchick noted a solution might be listing CFS as an impairment in the blue book and then the adjudicators could stop there if they found that the CFS was disabling. They would be stopping at an earlier step. Mr. Federline responded that if some of their impairments contributed to it with CFS such as a mental impairment the whole person would have to be considered. Mr. Krafchick suggested that if fatigue alone was listed and that was the reason that they could not go to work then the adjudicators would stop there because they were looking at CFS.

Mr. John Federline

- Noted that they also have the Program Operations Manual System (POMS) for additional information.
- Discussed the quality review and noted that files had been converted to electronic folders. Explained that this meant they could have a virtual review in which reviewers from one part of the country could review claims in another part to ensure consistency.
- Explained they also use other sources for ME/CFS.
- Supplied fact sheets to treating sources to let them know what the SSA is looking for. Noted that they also have a question and answer area.

COMMITTEE DISCUSSION (CONTINUED)

Mr. Krafchick asked how the controlling weight for the physician works. Mr. Federline responded that if a source would give a medical opinion, for instance a functional opinion stating that the claimant could carry 20 pounds, it would be used and addressed by the adjudicator when they made the evaluation of the claim. He noted that if one source gave an opinion that differed from the treating source but all evidence in the file supported the treating source, the treating source was given controlling weight.

ERISA AND INSURANCE ISSUES FOR CFS PATIENTS

Ms. Lisa Alexander, Office of Regulations and Interpretations, Employee Benefits Security Administration, U.S. Department of Labor, Chief, Division of Coverage, Reporting and Disclosure

- Ms. Alexander stated that she was speaking in her individual capacity and was not expressing the views of the Department of Labor. The summary, below, of Ms. Alexander's comments has not been officially reviewed by the Department of Labor.
- Stated that she would be talking about several issues concerning the Employee Retirement Income Security Act (ERISA) of 1974. Stated this was the federal law governing private sector plans sponsored by private employers or sponsored by employee organizations, commonly referred to as unions.
- Stated that she would review the coverage provisions of ERISA, what types of plans were covered, some exceptions for plans, preemption provisions and disability claims under private disability plans. Noted that this also might concern COBRA. Noted she would also discuss disclosure provisions.
- Noted types of plans and exceptions:
 - Under ERISA an employee welfare benefit plan (which is commonly what the disability plans are) is a plan, fund or program established or maintained by an employer or an employee organization (often a union) for the purpose of providing certain benefits, including benefits in the event of a disability.
 - Individual disability policies purchased on the market are not ERISA covered plans.
 - There are exceptions from the ERISA coverage provisions such as payroll practice and this was elaborated on. Also included as an exception are plans maintained solely to comply with state provisions that might not be covered under ERISA.
- Commented on ERISA plans and preemption issues considering federal law and state law. Discussed two types of plans, self-funded or insured plans. Discussed the two plans in detail. Noted issues concerning the fact that some plans were covered under ERISA but the provisions under the insurance policy itself would fall under state laws.
- Discussed the disclosure and reporting regime under ERISA. Advisory Committee noted that the problem for CFS claimants was that they might not have the information or plan documents necessary to determine whether CFS was a covered benefit under the disability policy. Noted that ERISA did not mandate benefits so CFS might or might not be covered under the plan. Discussed disclosure and how the content should be current, comprehensible to the average person and accurately reflected the plan's contents. Noted that companies had to advise the participants and beneficiaries of any changes affecting benefits.

Dr. Klimas sought clarification, asking if someone had a condition, and a company decided to start excluding conditions, could they lose the coverage they had had for some time. Ms. Alexander said that this was the case, there could be an elimination of a benefit in a summary of material modifications.

- Noted the existence of the Office of Participant Assistance where there were several hundred staff who were tasked with assisting participants and beneficiaries and assisting claimants. Provided the telephone number for this: 1-866-444-EBSA (Employee Benefits Security Administration).
- Noted what needed to be included in the summary plan description with regard to claim procedure issues. Needed to include the procedures governing claims for benefits.
- Commented on ERISA's reporting regime concerning the DOL, IRS (Internal Revenue Service) and the Pension Benefit Guaranty Corporation.
- Commented that the DOL and the Department of Treasury, IRS share jurisdiction over COBRA. Discussed the disability extension under COBRA that might be available to individuals deemed disabled. Discussed the process.
- Discussed the ERISA claims regulation process in great detail. Noted there was a section entitled, "Frequently Asked Questions" on their website under Claims procedure.

BREAK

The Chronic Fatigue Syndrome Advisory Committee made a decision not to have an official break.

COMMITTEE DISCUSSION

Mr. Krafchick asked about whether the DOL would add the inclusion of the treating physician rule to their regulations. He noted that would make a huge difference to people. He also asked about time limits, and said that one thing they could be more specific about is if they could be required to disclose when the Statute of Limitations began to run. He also asked about the offset, where if a claimant was receiving an insurance benefit and social security, the social security benefit would be used as an offset. Ms. Alexander said she was aware of the treating physician rule but it was not part of the Department's claims procedure regulation. She replied that there was no statute of limitations relating to the claims in ERISA. She said regarding the offset issue it sounded like an issue regarding coordination of benefits. She indicated she had nothing further to add on that issue.

Dr. Klimas said that given that they were not going to be able to meet over lunch with the DOL as expected, could they invite them to take part in the subcommittee conference calls. Dr. Jones said that yes, if they were willing, given that they couldn't stay for lunch this would be valuable. Dr. Klimas underscored that this connection could be so useful, as it had been with SSA.

Dr. Klimas asked about class action lawsuits which were not allowed with disability plans in that you had to pursue lawsuits one at a time. She noted that the companies had documents that showed how they would systematically deny claims for CFS. She noted that patients had to hire attorneys and go after their benefits. She asked if they had any recourse if they saw other documents that showed a real intent to find a way not to pay. Ms. Alexander responded she did not know as she was not part of the litigation side of ERISA, but this was the point of the appeals process.

Dr. Klimas said that was an individual process, but what if they as an agency saw a pattern, where they attached the same reasoning to every CFS claim? Ms. Alexander stated they would have to look at it on a plan by plan basis as they did not have jurisdiction over the insurance companies. Ms. Alexander clarified that while they might all be plans with contracts from one insurance company, they were considered completely separate plans, and could not be looked at as a whole, this would be outside their (DOL) jurisdiction.

Suzanne Adelman from the Department of Labor gave some options on how this might be actionable with respect to fiduciaries, but again, DOL could not tell insurers what to do. Mr. Krafchick said that if ERISA fiduciaries, which may include insurance companies deciding claims, could be held to similar obligations as plan administrators, then this would be far more robust. Ms. Adelman said that the issue of insurance companies acting as fiduciaries in every instance is a complicated issue.

Dr. Levine asked if there was a way that they can ensure that the disability companies send the claims to someone knowledgeable. Ms. Alexander said the claims procedure regulation did stipulate it needed to be someone knowledgeable, but this could be a factual dispute. Dr. Levine asked whether they would be obligated to find a suitable specialist if the person evaluating the claim wasn't appropriate. Ms. Adelman said that this wasn't something their regulation spoke to.

Elena Lynett of the Department of Labor followed up and said the framework of laws that applies to group health plans is slightly different, they have the ability for group plans to be far more proactive if benefits aren't being covered as they should be indicated. The field offices start seeing a pattern and they react to this, but this is not for the disability plan context. Ms. Holderman also mentioned that the ACA (Affordable Care Act) had a provision which stipulated that material modifications required 60 days notice, and there has been some progress made here, though it hadn't been rolled out yet. Ms. Klimas remarked that even with a 60 day notice there would still be a 4 month window where someone would not be covered.

Ms. Holderman asked whether there was a hard copy of the presentation so that she could determine who she should best address her prepared questions to. Ms. Alexander said that she did not have a hard copy, but she would be happy to look at any questions she might have.

Dr. Jones reminded everyone that CFSAC had no jurisdiction over the DOL, and any participation was voluntary for the public good. She appreciated the opportunity for the dialogue. Ms. Adelman offered that the website had great information on COBRA, and that she could feel free to call her.

Dr. Klimas sought clarification about denial of related conditions to CFS, as these related conditions could include anything, as well as denials of conditions that are based on old definitions and literature. Ms. Holderman clarified that there are no particular mandates in ERISA related to this. She suggested that people in HHS working on guidance for essential health benefits under the ACA would be doing relevant work, and perhaps they need to loop into these discussions.

Dr. Jason asked if there were any other examples where insurance companies had denied benefits to people with other diseases and if so what happened, and how was it resolved. He noted perhaps they could learn from that situation and therefore help patients with CFS. Ms. Holderman said they had seen other types of problems such as with pre-existing conditions but not otherwise. She gave only an

example of limitations imposed on newborns and mothers. She thought that perhaps some of these issues could fall within mental health parity protections, and perhaps there was something there that was not being provided as required. Ms. Adelman said that all these specific provisions were congressional mandates that came about because the problem was considered big enough.

Ms. Holderman asked what government agency did they receive their literature from regarding CFS. Ms. Alexander stated she received the request to present but prior to that had not received any literature on CFS.

Ms. Adelman stated that if they got to a point where they get a claims procedure regulation, that's where CFSAC would come in to stipulate what medical requirements someone would need to make a reasonable claim evaluation. Mr. Krafchick clarified that they weren't looking for mandated coverage, just to limit the limitations placed on coverage.

Dr. Snell asked what the influence of SSA mandates were. Ms. Alexander indicated there was no requirement for coordination, they served different purposes.

Dr. Klimas again asked about comorbid psychological conditions, for instance someone who developed depression due to contracting AIDS. Dr. Klimas said the refusal of coverage after two years happens consistently, despite how she characterized her patient's problems. Ms. Alexander said this was beyond their scope, and Ms. Adelman repeated this, stating that they do not interpret plan documents or provisions. Mr. Krafchick said it would be of great assistance if they could preclude certain types of limitations, and they might be the only organization capable of providing redress.

Dr. Snell indicated that they would be preparing a letter addressed to the DOL noting that they were seeing a problem and recommending reviewing the regulations. They were concerned about the insurance companies' practice of excluding CFS medical claims if there was any indication, however limited, of mental issues such as depression.

Dr. Jason was struck by many questions regarding step three in the blue book and wanted to make a recommendation:

That ME/CFS be placed in the blue book and recognizing that there were probably many constituent groups that were making recommendations for the blue book and that they would be one of many.

It was seconded.

Dr. Snell said that a motion has been proposed and seconded. He asked if there was any discussion.

Dr. Marshall said that he did not want vague language if they were going to make a specific recommendation. Mr. Krafchick said he did not know how detailed the blue book descriptions were but the CFSAC could provide guidance in the process. Dr. Marshall said that the nature of a descriptor would become critical as they could use it to exclude. Mr. Krafchick said he would feel uncomfortable trying to draft a description as he had never seen the blue book. Dr. Jason asked Mr. Federline how to proceed, for example, when other groups have given input. He asked what was the best way? Was it to do a recommendation?

Mr. Federline advised some advocacy groups had approached them and the SSA advised them that they could not have all impairments in the blue book. Adjudicators had been trained to recognize similar impairments and make decisions based on that. He noted that adjudicators looked at the multiple impairments and applied them to medical evidence received. He noted that they were always looking at the SSR (Social Security Ruling) to update it.

Dr. Jason asked if it would be helpful if they made a recommendation showing that they at least had the examination started where the SSA would look at the criteria. Mr. Federline responded that he was not in a position to answer on behalf of those above him.

Dr. Levine asked if there were any laboratory requirements, at what point is a diagnosis excluded? Dr. Klimas said that they had had this discussion before, that they weren't essential, but they couldn't be used to exclude. Dr. Klimas indicated that it would certainly be worthwhile to update the literature. She echoed previous comments that having CFS in the blue book would simplify matters, as the analysis of disability if CFS was diagnosed, would come down to severity, in effect skipping steps.

Mr. Krafchick asked whether the inability to go to work regularly would be considered as evidence. Mr. Federline indicated that this was considered when they analyzed residual functional capacity. Dr. Klimas asked about how trial employments worked. Mr. Federline explained that someone would only receive social security disability if they weren't able to work for 12 continuous months. If someone fell into this category, trial employment could be tried without loss of benefit.

Dr. Snell proposed that the recommendation be discussed with Mr. Federline over lunch and then they would take it up from there. He noted after further discussion that it was decided that they would draft a statement as Dr. Jones noted that cooperation between committees was encouraged.

Dr. Marshall thanked Mr. Federline for taking the issue seriously and coming to the committee meeting.

LUNCH

The Chronic Fatigue Syndrome Advisory Committee recessed for lunch for one hour.

PUBLIC COMMENT

Sue Jackson

- Stated she has ME/CFS. Stated both of her sons 13 and 16 have it also and they had been sick for seven years.
- Stated her life had been dramatically affected by living with the illness but she wanted to concentrate on her sons as pediatric ME/CFS is a much larger problem.
- Stated they know seven other children in their area who have ME/CFS.
- Stated she writes a blog about living with CFS and stated that every week she receives e-mails from all over the country from parents whose children are completely disabled.

- Described the health problems with her son Jamie. Noted problems with his school and education and described special arrangements made so he could continue with his classes. Described the difficulties when he attended classes having to go home in between to rest.
- Described her younger son Craig's situation and stated he started to show symptoms when he was six years old. She stated after he missed 35 days of school in third grade they had him diagnosed.
- Described how with the help of Dr. David Bell and Dr. Peter Rowe working with their son's pediatrician, both of her sons returned to school.
- Noted that even with that improvement ME/CFS was still a significant part of their daily lives. Her elder son feels that the illness has ruined his life.
- Noted that she and her husband worry about their sons' ability to go to college and hold jobs as well as their medical costs.
- Noted that she became ill in 2002 and her sons became ill several years after that. Felt that their family is living proof that the disease has both genetic and infectious components.

Reverend Bernard Hillenbrand

- Stated he was a retired minister and was very popular with his congregation because of his short sermons.
- Stated that he was 86 and born in a real depression. Noted the big disease they were fighting then was polio. Stated that because of that the March of Dimes was organized and polio was cured.
- Stated he heard this morning that they were meeting at a time of a great budget crunch. Stated that after the depression they had a great war followed by massive debt. Stated that they did not worry about the debt and thought it was important to invest in people. Described how that investment paid off.
- Stated that they had to have hope as they had a great group of people there and a vibrant cause. Wanted to end it on a hopeful note and added if his generation could do it then this one could do it. Saluted the CFSAC.

Sophie Thorpe

- Stated that she is 15 years old. Stated she was diagnosed with CFS four years ago when 11.
- Stated that she had missed half of the sixth grade and almost all of seventh because she was always tired or sick to her stomach.
- Stated that it started in fifth grade when she had to stay home because she had mononucleosis.

- Described her life and her separation from friends. Noted that this sent her into a depression.
- Stated that when she was sent to boarding school for dyslexia in mid-state New York everything was different and difficult. Noted it was still a struggle to get out of bed in the morning. Stated that she is tired and aches all day and at the end of the day has an awful headache.
- Stated that living with CFS was affecting her now and her future too. Noted she had wanted to be a surgeon. Decided to try to become a marine biologist and she hopes to try for that.

Christina Gustavsson

- Stated that she was had CFS since she was nine years old.
- Stated she wrote a poem about her disease when she was 13 years old and read this:

"Though I am trapped in this prison my soul is free/Eyes that taught me with what I can't do/My soul is free/This mind that wants to explore hidden secrets but a body that can't follow/My soul is free/I can listen to the joy I want to encounter/ My soul is free/Pain that reminds me of this curse/My soul is free/ All I need is what is inside of me to know/Some day my mind, my heart, my body and my soul will all be free."
- Thanked the committee.

Amy Squires

- Stated that she came away from the State of the Knowledge Workshop very charged and excited.
- Stated CFSAC could coordinate CFS research in a way that had not been done before. Stated that the State of the Knowledge Workshop demonstrated that there were remarkable researchers across the critical disciplines dedicated to solving CFS.
- Urged inter and intra-departmental cooperation and alignment vital to positioning a range of inter-disciplinary studies.
- Discussed the work of Dr. Steve Munroe of the CDC (sic) at the State of the Knowledge Workshop and his research progress, notably the focus on reverse translational research, and systems biology.
- Discussed some of the problems with studies as mentioned by researchers at the workshop.
- Discussed a question raised at the meeting of how to maintain the momentum begun at the State of the Knowledge Workshop and gave some options.
- Recommended that they institute standardized definitions and operating procedures so the studies have meaning and would enhance the value of research.
- Agreed with the Reverend's comments and stated that she believed the problems could be solved with creative leadership.

Lori Chapo-Kroger

- Stated that she was the founder of CFS Solutions of West Michigan.
- Stated she would share the story of her three friends, Miley was a registered nurse who worked for the Michigan Department of Health. Her husband awoke one morning and found her dead in bed. Stated she died unexpectedly of ME/CFS. Stated that Everett was a social worker before he got sick with CFS. Noted that he spent the last years of his life bedbound before dying of complications from CFS. Stated that Jill took her own life last July because of pain, however noted she was not sure it was caused by the pain of ME/CFS or the emotional pain from the disbelief expressed by doctors, friends and family.
- Asked if their early deaths could have been avoided if they had received proper treatment? Probably. Asked if their lives could have been more bearable? Definitely.
- Stated she was an ICU nurse and had worked with the severely ill but it was nothing compared with the abuse and the suffering that CFS patients endured. Stated that they were the walking dead, some so close that it felt like they were lying in a grave already dug. Noted that each time a doctor said there was nothing they could do, a shovel of dirt was thrown upon them, disbelief another shovelful, told to exercise more, another shovelful.
- Stated that for medical authorities it felt like if your illness did not exist in the blue book then it didn't exist. Stated that if you say you have ME/CFS you are looked upon as if you're psychotic and a drug seeker and dismissed without treatment
- Noted that medical staff needed to be educated about ME/CFS by medical facilities and schools.
- Asked if the Medscape CME online course mentioned on the IACFS (International Association of CFS) website could be updated and activated so physicians had a place to learn about ME/CFS.
- Thanked the committee in memory of her three deceased friends.

Denise Lopez-Majano

- Thanked the committee and the audience for attending.
- Noted that she wanted to highlight young people with ME/CFS. Noted that she put out an informal request for information about early onset in CFS. Noted that she was deluged with information from about 90 people and a list was available with her written testimony.
- Reviewed some quotes she received as part of the comments. "I'm 12, I should be 18 but I've lost over six years of my life to ME/CFS." Matthew Lopez-Majano. "We're supposed to be out creating ourselves and meeting people and learning and working but we're not able to do any of that. It's as if our whole lives have been put on hold and all we can do is try anything and everything and wait." Erin Kressner.

- Noted that we, our government, its agencies and as a nation must increase awareness of the impediments ME/CFS imposes on learning as well as on earning, of the isolation created by ME/CFS and the way ME/CFS prevents people from having a normal, independent lives.
- Stated that we must require ongoing education for medical professionals about ME/CFS and its devastating impact on lives.
- Stated that we must promote a better understanding of ME/CFS and doing so would demonstrate the urgent need for increased research and increased funding for research that should be on par with the disease prevalence and severity to solve and treat ME/CFS.
- Read the emotional and moving comments of her young son.

Angel Mac (via telephone)

- Greeted members of the committee, Drs. Jones and Snell for giving her the opportunity to speak.
- Stated for 17 years she worked in a California hospital from which she thought she would retire. She was on the safety committee and had to attend all of the HIV AIDS conferences. Stated she had to quit her job due to the illness in 1985.
- Stated that now after 25 years of ME/CFS she was not able to get disability because it took so long to get a diagnosis. Asked the committee to discuss that.
- Stated that she lived alone and was 99 percent bedridden now and received no in-home help for anything. Stated that once every three to four months a friend would buy her groceries.
- Discussed the medical virus XMRV and her own case and research. Discussed the existence of the virus in families.
- Discussed the lack of funding given to this illness and asked for additional funding for this disease.

Mindy Kitei

- Stated she is a science reporter who had covered ME/CFS for 20 years.
- Noted that last June she began a blog CFS Central in honor of her friend Nancy Kaiser. Noted that she met Nancy in 1994 while working on an investigative piece for a magazine, called "The AIDS Drug No One Can Have" about the experimental HIV and ME/CFS drug ampligen. Noted that Nancy had a severe case of ME and had multiple seizures every day. Described her condition in detail and stated that she tried many experimental treatments. Stated she died on June 15, 2008.
- Noted that three other patients she interviewed in 1994 had also died.

- Gave her opinion that although there was ample evidence that ME was an infectious disease that the government did not treat it seriously. Criticized studies done by the NIH and the CDC.
- Said to the NIH and the CDC scientists who have been doing this research for three decades and sweeping a worldwide human catastrophe of 17 million people under the carpet, "Have you no sense of decency at long last?"
- Discussed the lack of helpful drugs and asked where were the drug trials to be able to develop proper medication for people suffering with this disease. Asked that ME/CFS patients have the same freedom to try new drugs as was given to AIDS patients in the early days.
- Stated after 30 years of neglect ME/CFS needed research parity with HIV, there needs to be an ME/CFS care act. She asked Dr. Jones whether she would assist, Dr. Jones said she could not commit to the schedule but would be following up.

Kathleen Rogalla

- Stated she has three sons with ME/CFS, Miles, Albert and Bill.
- Said every morning when she wakes up her son, he says mom I'm in pain. This motivated her to go to bring word of this devastating disease to life, to put a face on the disease and to have the voices of the afflicted heard.
- Stated that Miles was 18 and had been sick since age ten. Stated that he did not go to school. He was socially isolated and had no friends. Stated he was in pain every day and received no compassion because the public did not understand or know anything about the disease.
- Stated that her adult son Albert was 26 years old and had been sick since he was 17. Noted he was able to finish high school and some college but was in constant pain. Noted that his sleep was poor and he was unable to sustain employment all due to ME/CFS.
- Stated her oldest son Bill was 28 years and had been dealing with ME/CFS since he was 15. Bill struggled through high school and college with little help from the administrations. Noted he also is in pain every day but had managed to blend into society. Noted that he had been fortunate to be married, working and starting a family.
- Asked for support from the government to raise awareness and help find a cure. Noted that they must support effective treatments to improve the quality of life for thousands in need.
- Noted that basic research was needed. Asked that researchers and physicians need to listen to their patients and what the disease is telling them.

Faith Newton (via telephone)

- Stated that her 9th grade son had CFS and he was diagnosed in early 6th grade.

- Noted that her comments were more directed to what could be done to help educators with children who have CFS. Noted that public schools, teachers and administrators needed to be more educated on how the illness affected kids and what they could do to teach children who had CFS especially if they were there only half-days or not there at all. Thought that educators needed to make those accommodations and look at different ways to teach those students.
- Noted that she was an education professional and was fortunate in that her charter school was very helpful and the teachers had bent over backwards to give him resources and make it work. Stated that she also advocated for other students but did not see that in all places.

Suzanne Vernon

- Stated that in 1988 the CDC named a disease that for the past 100 years had been called a variety of things and listed some of them. Stated that the name could not be agreed upon and the disease defied definition.
- Noted that there were many groups who experienced different symptoms that included pain and fatigue. Noted that today fatigue still had no objective markers.
- Stated that a disease that was described by non-specific symptoms should not be defined by those same ill-defined terms.
- The six month requirement for sickness as defined by the 1994 or the Canadian Consensus creates a diagnostic lag which causes problems.
- Advocated use of the NIH-sponsored REDcap (Research Electronic Data Capture), which is a free way of jumpstarting research networks for CFS.
- Discussed patient standards of care and health insurance issues. While awards are limited, they have been useful, and they must keep up momentum.
- Thanked Dr. Jones for her leadership, and hoped the federal agencies followed her lead.

BREAK

The Chronic Fatigue Syndrome Advisory Committee recessed for a break.

COMMITTEE DISCUSSION: FINALIZE RECOMMENDATIONS

Dr. Jones stated that there were some housekeeping issues:

- Noted that at the beginning of the meeting that they had extensions granted to three members, Dr. Snell, Dr. Jason and Dr. Klimas. Stated that their terms would expire April 1, 2012, so they would attend for one more meeting. Stated that that would mean they would have another call for nominations during the summer. Asked members to add that to their to-do list and noted they would see the solicitations for nominations for vacancies on the website or in the Federal Register.

- Stated that for nominations to a federal advisory committee they would be required to address several things such as geographic distribution , racial, ethnic and gender and age-diversity in their representatives.
- Advised that they would look at the web-streaming for the committee to ensure it occurred in a reliable fashion. Noted that some of the problems were capacity issues with service providers.
- Noted that it was a time of transition and some of the ex-officios were retiring. Noted that she had introduced Dr. Nancy Lee who six weeks ago took over as the newly-named director of the Office on Women's Health and the Deputy Assistant Secretary for Women's Health.
- Stated that Dr. Lee would take over as the designated federal official for the committee, and the transition would take place over the summer. Commented that Dr. Lee was bringing a strong commitment to public health.
- Acknowledged many staff members from the OWH (Office on Women's Health) had stepped up to make the meeting very positive.
- Thanked the NIH video-cast team and their contractors, Granicus and Web Tech the audio team for their support and for making the committee meeting so successful.

Dr. Snell

- Noted that some of the ex-officios would be leaving after today's meeting including Dr. Miller from the CDC and Christine Williams from AHRQ. Stated it was a breath of fresh air when Dr. Miller began with the committee. Stated that there was now an open line of communication, discussion and debate between the committee and the CDC. Felt that ultimately there were some good decisions made and they had the basis for a productive relationship with the CDC. Noted that Christine Williams had not been with them as long but had made an impressive impact. Stated they would both be sorely missed.
- Stated that they would allow the outgoing *ex officios* to give farewell remarks as was the tradition.

Christine Williams

- Stated that she appreciated the opportunity to sit on the committee.
- Explained that when she became ill she found the committee to be an important outlet in terms of bringing her own experience with the illness and her experience in health policy and health services research to the group.

Dr. Miller

- Stated that CFSAC was one of the most critically important committees that he had ever served on and interaction on both the adult and children's side had been very valuable to him.
- Tried to make it an action post as opposed to a listening post. Hoped that the CDC could respond to the committee and hoped they had begun that process.

- Urged the committee to take on "winnable battles" a concept offered by a colleague at the CDC. Recommended that there were some things that the committee could commit to, to think through that might be winnable in the short term without neglecting other important issues.
- Gave his opinion that recommendations to the Secretary should be science and evidence-based and would therefore more likely get done.
- Stated he was proud to be with the CDC and associated with their CFS program.

Dr. Snell

- Wanted to say a few words about Dr. Jones as he had only recently learned it was her last meeting. Stated that the committee and government were working well together and there was no feeling of being on different sides. Felt that this was a testament to her tact, diplomacy and advocacy beyond the scope of the meetings. Expressed the view of committee members that Dr. Jones would be sorely missed and that they owed her a great deal.
- Stated that the committee wanted to have a more considered process for electing the next Chair. Indicated that the new Chair would take over officially in the spring of 2012.
- Asked that they spend a brief time discussing how the committee members wanted to set up the mechanism for deciding upon and approving a recommendation for the next Chair of CFSAC.

Dr. Marshall asked him how his responsibilities as Chair differed from when he was just a member.

Dr. Snell responded that he took part in both the research sub-committee and quality of life sub-committee and telephone conferences that happened every month. He stated that the Chairs of those sub-committees had a third meeting with Dr. Jones and if possible, with Dr. Koh. He stated that there was e-mail correspondence and approval of the agenda. He stated that keeping track of time and keeping the meetings running smoothly was challenging. Dr. Jason stated that the advanced preparation for meeting agendas under Dr. Snell allowed more time for interaction and thinking about recommendations.

There was discussion of term lengths, and Dr. Snell indicated their terms were extended for a year to preserve continuity due to the people who were leaving. Dr. Jones confirmed that the committee was chartered for 11 voting members. Other non voting members could be brought in as expert consultants as resources allowed. Dr. Jones explained the swearing in process for the absent incoming member Dr. Ann Vincent, who was from the Mayo clinic. She stated that it was up to incoming members what subcommittees they felt better suited for, and said that she felt that the subcommittees were in good hands. Dr. Jason suggested that Dr. Jordan Dimitrakov communicate with Dr. Vincent regarding which subcommittee she would be involved in so that they would be evenly distributed.

Dr. Snell gave his thoughts on the process for a new Chair. He stated that nominations of other people or self nominations would be forwarded to him. He would put a ballot together and circulate to everyone by e-mail. Then he would receive all the votes from committee members. He said if they wanted a process where people would be available for questioning then they could not do that before the next meeting. Dr. Marshall outlined how a process could proceed which was not onerous for the nominee.

Dr. Jason moved that the following would be the process.

An individual who would be willing to serve would just prepare a statement of why they would be willing to serve and what they felt like they would bring to the leadership position.

Dr. Marshall seconded the motion.

Dr. Snell asked for a vote. He stated that the motion carried. He put a two-week timeline on nominations so he asked for e-mail nominations to him by June 1.

Dr. Klimas discussed the work of the quality of life sub-committee, and stated they had a need for academics if people wanted to shuffle over. She mentioned there was also a bit of a gender split. Dr. Marshall discussed how a balance would be useful. Dr. Jones indicated that people could work on both sub-committees if they were willing to take on the work.

Dr. Jason called for prepared statements that could be read in advance so that more of the meeting could be dedicated to interaction. Dr. Jones indicated that they do try to get both public comment and presentations in advance, but it was difficult and submissions were not forthcoming. Dr. Jason indicated that time limits on presentations would be useful along the same lines as the rules for public comment. Dr. Levine called for better organization of assignments, and for a more task oriented process.

Dr. Klimas discussed the work of her subcommittee. She stated that from CMS they had an interesting proposition to use the innovation mechanism to come up with a consortium of people dealing with illnesses that could provide a model to Medicare for a better and more cost-effective care. Ms. Perry confirmed that their innovation center had a public process for submitting proposals and it was on the website, a web portal. It would involve a proposal being selected out of many. Dr. Jones asked if there was a timeframe. Ms. Perry said she would check for the details but it was her understanding that they had funding for ten years. She did not know of any deadlines but would confirm. Dr. Jones indicated they could use the CFSAC website to drive traffic to this innovation center site, and perhaps encourage proposals.

Dr. Klimas indicated she was excited about the opportunity to come up with ways of improving healthcare access, and along these lines Project ECHO (Extension for Community Healthcare Outcomes) was also an exciting prospect for a training program. She pointed to how networking and methodical effort on the front end would benefit reverse translational research.

Dr. Marshall said that they should advocate for the structure that would allow insertion of data and would drive funding, investigation and ultimately meaningful intervention. This would need to tabulate data, like ages, lengths of time they have had fatigue, gender etc. This needed to be emphasized by both subcommittees if they wanted to capitalize on an opportunity to get more funding via reverse translational research.

Mr. Krafchick emphasized the importance of the set dataset on the form; what was on the form in the beginning was very important. Dr. Marshall agreed and mentioned there should be discussion about that with clinicians and the CFS community to ensure the form was complete with all relevant questions, and they would be getting the most for the time spent filling out the form

Dr. Levine asked whether there was a mechanism for finding out information about pediatric CFS patients. Dr. Klimas said that the move to EMR (electronic medical records) was the time to act to develop a system to come up with a network. Dr. Klimas proposed that they put together a working group to initiate the clinical network that they keep discussing. She stated that there were a number of them in emergence.

She suggested the possibility of using the REDCap system that had been suggested, and let it be their framework and get the four or five main assessment tools that they all agreed to as reasonable. She stated if they all started using the same framework they would be a network. They could just start doing it, and she would be happy to lead the effort, once some people began doing it, they could demonstrate how easy it was to others, but she didn't want them just to be talking about it in another six months time. Once this system was in place, they could then leverage it to get funding.

Dr. Willis-Fillinger noted that project ECHO leveraged expertise so that a small number of experts could demonstrate use of the assessment tools to direct primary care. They would then telemedicine to direct the training. She noted that there should be flexibility for the data fields as new questions and issues would arise with investigations. Dr. Marshall said that this whole process was a circle, a feedback loop and Dr. Willis-Fillinger agreed.

Dr. Dimitrakov agreed with the use of REDCap and the usefulness of setting up a network, but in connection with the discussion on data mentioned the use of electronic diaries for patients where they would track their symptoms over the course of time and suggested this could be very useful. He also mentioned the issue of pediatric patients falling through the cracks, and said that taking DNA samples would be of great assistance for this.

Dr. Snell indicated that the Americans with Disabilities Act (ADA) was involved in instances where individualized education plans were required, so this was one way of finding these patients, and gaining epidemiological data, although some parents opted for homeschooling in these circumstances. Mr. Krafchick noted that patient groups could be used to identify this pediatric group.

Dr. Klimas discussed that the quality of life subcommittee had a window of opportunity to make progress on the issue of pediatric ME/CFS. They had discussed presenting on the ADA national conference. She asked for any suggestions on what they could be working on in advance of the next meeting.

Ms. Holderman indicated that this was the most productive meeting she had attended. She called for a PSA for ME/CFS, there should be government support for this, and the time was right for this. They needed to get the message out, not just preach to the choir. She mentioned on behalf of Marly Silverman that both WPI and CFIDS Association have advanced to round two of the Chase Community Giving Challenge, and encouraged people to vote.

Dr. Klimas noted that they were working on using their new connection with the DOL to work on ERISA-related health insurance and disability policy issues. She reiterated that they needed CFS to be included in the blue book listing. Dr. Jones indicated understanding was that the committee would draft a statement offering consultation and support for strengthening and increasing visibility for CFS.

Dr. Jones indicated they may not be able to get into the blue book, but Dr. Klimas said they were keen to actually have it listed, and the subcommittee could bring someone in who was knowledgeable about social security to flesh this out. Dr. Levine suggested they needed to look at the blue book to see the phrasing. Mr. Krafchick said that given there was already a regulation specifically dealing with CFS, they were not starting at a blank slate, but that the actual criteria were very important. Dr. Snell indicated a listing would help in legitimize testing for insurance companies.

Dr. Willis-Fillinger returned to the idea of bringing together an expert group to agree on unified guidelines, was there a place for this sort of committee. Dr. Klimas indicated that the IACFS had treatment guidelines underway and were almost at a final draft. Disability assessment in CFS was lagging behind and this required scrutiny. She was eager to have a workgroup that leads to an end product, so that patients could determine they had had an appropriate evaluation which would lead to a successful application. They could look at other diseases and correspond the criteria to CFS symptoms, and this would greatly assist with disability assessment. It would be really helpful to know where the cut points are and correspond these. Dr. Snell agreed with this.

Dr. Klimas proposed a motion:

That HHS sponsor a workshop to review disability measures that would apply to chronic fatigue syndrome.

She suggested this could be done as a virtual half day seminar given the lack of funds. Dr. Willis-Fillinger asked whether this product would inform providers on the ground of how to assess and evaluate. Dr. Klimas confirmed that this would be so, and it would include disability assessment as well as clinical assessment.

Mr. Krafchick seconded the motion.

Dr. Snell opened it for discussion. Ms. Holderman asked about the issue of measurement of fatigue with respect to good or bad days, how would they guard against this assessment hurting patients? Dr. Snell said that they use post-exertion malaise, they basically make sure that the next day is a bad day, and while this was hard on patients, it was necessary due to bias against the disease. Mr. Krafchick indicated that travel alone often produced impairment, so this addressed this concern. Dr. Klimas indicated that the point of the workshop would be to address these very concerns. Dr. Marshall indicated that this intentional prompting of an abnormality for testing purposes was used for other diseases as standard practice for instance chronic obstructive lung disease. Dr. Dimitrakov echoed that patients were well aware of their triggers, and Dr. Marshall said that patients have a huge number of things that produce measurable abnormalities, so it isn't that difficult. Dr. Snell said that all testing did have to deal with accusations of deconditioning and malingering, and this complicated the process.

Dr. Snell took a vote and the motion was carried.

Dr. Jason announced that he had received an e-mail from a patient representative and they had asked that the committee give Dr. Jones a standing ovation for her excellent contribution to the CFSAC. The committee happily did that.

Dr. Jason mentioned that some good work had been done with the research subcommittee. He repeated the concept of concentrating on smaller things and getting them accomplished. He thought that after speaking with the editor of an academic journal at the workshop that they consider providing some guidelines for authors writing about ME/CFS. These guidelines would say these are some standards and this is what you need to report. He felt it would help the scientific field. He asked if he could propose to the research sub-committee that they think about the possibility of crafting that.

Dr. Snell thought instead the idea was that they had been given a contact of a person working on a journal that had been tasked specifically with publishing those sorts of things, and that they were given an invitation to contact this person, and that they could provide an idea of the things they would like to see in articles. Dr. Jason said the question was would the task be a good idea, and then they could find an audience for it.

Dr. Snell indicated that they would be finishing the meeting early due to missed breaks and travel arrangements. Mr. Krafchick indicated that the meeting had been very rewarding and he appreciated in particular the involvement of the DOL. Dr. Jones singled out Dr. Marian Mehegan for her assistance in monitoring the video cast, as well as Mahak Nayyar who with Marian worked on dealing with the CFSAC mailbox. She stated she was humbled by the commitment of these people, and all the day to day work they do. Dr. Snell also mentioned Linda who works on all the travel arrangements.

ADJOURNMENT

The Chronic Fatigue Syndrome Advisory Committee adjourned for the day at 4:30 p.m.