HIV -1 Isolation - 1982

Political Influence on Scientific Research and the Impact it has on us ALL

MANY DEATHS BEFORE ESTABLISHMENT BELIEVED IN RETROVIRAL CAUSE

November 7, 1991
Introduction – In 2006, the human retrovirus XMRV (xenotropic murine leukemia virus-related virus) was identified and reported to be associated with certain cases of prostate cancer. Although the public health implications of this finding were not immediately clear, a series of presentations at the most recent Cold Spring Harbor Laboratory meeting on Retroviruses provided additional support for this linkage and suggested that the number of individuals infected with XMRV is significant enough to be a cause for public concern. In view of these developments, it was deemed appropriate for NCI to convene a small group of intramural and extramural scientists and clinicians with expertise in this area to provide the NCI leadership with recommendations on future directions. The following summarizes the scientific presentations and resulting round-table discussion among workshop participants.

Organizers
Stuart Le Grice, Ph.D.
CEHCV
John Coffin, Ph.D.
CCR

HIV Drug Resistance Program & Head,
Tufts University & Office of the Director,

Participants
Carlos Cordon-Cardo, M.D., Ph.D.
Stephen Goff, Ph.D.
Eric Klein, M.D.
Robert Silverman, Ph.D.
A. Dusty Miller, Ph.D.
Ila Singh, M.D., Ph.D.
Judy Mikovits, Ph.D.
Nevada

Columbia University
Columbia University
Cleveland Clinic
Cleveland Clinic
Fred Hutchinson Cancer Research Center
University of Utah
Whittemore Peterson Institute, University of Nevada

Stephen Hughes, Ph.D.
Vineet KewalRamani, Ph.D.
Douglas Lowy, M.D.
John Schiller, Ph.D.
Chris Buck, Ph.D.
William Dahut, M.D.
James Gulley, M.D., Ph.D.
Biology, NCI
Jeffrey Schlom, Ph.D.
Biology, NCI
W. Marston Linehan, M.D.
Charles Rabkin, M.D.
Genetics, NCI

HIV Drug Resistance Program, NCI
HIV Drug Resistance Program, NCI
Laboratory of Cellular Oncology, NCI
Laboratory of Cellular Oncology, NCI
Laboratory of Cellular Oncology, NCI
Medical Oncology Branch, NCI
Laboratory of Tumor Immunology and
Laboratory of Tumor Immunology and
Urologic Oncology Branch, NCI
Division of Cancer Epidemiology &
The Center of Excellence for HIV/AIDS and Cancer Virus Research proposed to the National Cancer Institute a program for XMRV reagent development with a budget for over $800,000.

It is important to note that only a link to prostate tumor patients had then been published.

When the link of XMRV to prostate cancer and CFS was not reproducible, the expenditure of this funds had to be explained so the Science concerning CFS research and not prostate cancer research whose poor science started it was attacked. Why?
November 17, 2009

Dr. Frank Ruscetti
Head, Leukocyte Biology Section
Senior Investigator
The National Cancer Institute
Laboratory of Experimental Immunology
The National Cancer Institute
Building 567, Room 251
Frederick, Maryland 21702

Dear Dr. Ruscetti:

Thank you for taking the time out of your busy schedule to meet with me recently.

I appreciated the opportunity to learn more about the Whitemore-Peterson Institute’s breakthrough discovery. I look forward to continuing to work with you to ensure that work is being done at a federal level to support the advancement of this important discovery.

If I can be of any assistance to you in the future, please do not hesitate to contact me.

You have my best wishes.

Sincerely,

[Signature]

Harry Reid
United States Senator
Assured by Senate majority leader’s support Whittemores remove Ruscetti/NCI as an inventor on patent of variant strains of XMRV

From: Harney, Dennis J. <dennis.harney@anrdenhton.com>
Date: Tue, Apr 5, 2011 at 8:57 PM
Subject: Revised draft Variant application due April 6 (Whitt Variant/NPA ; SNR 40000377-0022)

To: Vinnie <vclombardi@gmail.com>, Judy Mikovits <jimikovits@gmail.com>
Cc: Carl West Kinne <ckinne@wpinstitute.org>, "Nemeth, Brenda K." <brenda.nemeth@anrdenhton.com>, "Bock, Joel N." <jbock@anrdenhton.com>, "Filatov, Diane" <diane.filatov@anrdenhton.com>, Annette Whittemore <annette.whittemore@wpinstitute.org>, Harvey Whittemore <hwh1956@aol.com>, "Matthews, Stafford" <stafford.matthews@anrdenhton.com>

Vinnie and Judy,

Attached is a revised draft of the Variant application we propose filing tomorrow as a US and PCT application. All feedback you provided earlier today has been entered into the document. Further subject matter was added to the specification and claims. For your convenience, also attached is a redline comparison showing all changes made compared to the last version you reviewed.

We will file after about 3PM CT tomorrow April 6, 2011. Please provide any additional feedback in advance of this time.

Thank you for all your assistance in preparation of this Application.

Regards,

Dennis

Dennis J. Harney, Ph. D.
SNR Denton US LLP
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Suzanne Vernon: "Agency heads are scared to death...if XMRV works out"
Discussion in 'Action Alerts and Advocacy' started by CBS, Feb 23, 2011.

“I've been struggling with what I ought to do with this for almost six months. Suzanne Vernon said this during a conversation she was having with me and Cort. She just sort of interjected it. No real need nor was there much of a segue. She said that it should not be repeated. Yet I wondered why I earth she would say something like that to someone she had just met.

I was troubled by Dr. Vernon's words. I wished I had not heard it. I discussed the comment at length with my wife. I've asked Cort about it on a couple of occasions. He responded that he does not recall having heard her say it. And so I approached Jennie Spotila and I asked her what Dr. Vernon might have meant. That conversation took place on December 10, 2010. Jennie said she would check with Dr. Vernon and get back to me. I haven't heard back from Jennie on this topic and so I'm assuming that there won't be a reply. Why can't this be shared with the patient community? Who am I protecting and who is being harmed? I have not felt that it was right to keep this from the patient community.

I was reading Hillary Johnson's recent post about "FRENEMIES". Hillary stated "Whatever these two [Suzanne Vernon and Kim McCleary] tell you they're doing, you can assume it's about one-twentieth of what they're doing behind the scenes and, given the lessons of history, you can bet it's not on your behalf." I was reminded of Dr. Vernon's comments.
Dr Busch tells Whittemores that they should reimburse patients for test
In order to save the institute, all grant money, they need a scapegoat

From: "Busch, Dr. Michael" <mbusch@bloodsystems.org>
To: "Ruscetti, Francis (NIH/NCI) [E]"<uscettf@mail.nih.gov>
CC: "jamikovits@gmail.com" <jamikovits@gmail.com>
Date: Sat, 8 Oct 2011 21:05:00 -0400
Subject: RE: VIPdx response

Frank and Judy,

As I mentioned to Judy last week Annette sent me the email below and attached letter shortly after my visit to WPI, during which she and Harvey were clearly trying to discriminate the testing you performed on the BWG panel from the XMRV testing performed in their reference lab run by Vince. I was under-impressed with Vince to say the least, and what I saw and understood in terms validation and QC of the XMRV assays in the reference lab was disturbing.

I replied with the email copied below, and never heard further from Annette. If they have stopped offering XMRV testing as stated in the blogs and I understand on the web site, then the issue is how to inform/counsel the 1/3 of patients who they reported to be XMRV infected interpret their results and should they be reimbursed for invalid testing. What do you recommend we do to address these issues, and particularly to assure that future XMRV/HGRV testing by the WPI reference lab does not occur without proper oversight, validation and QC?

Please keep this exchange, including the letter from Annette, confidential.

Judy - what is the status of you participating in the Lipkin study, either performing testing at WPI or elsewhere?

Frank - did you ever get sequence data on the positive cultures detected on samples from the BWG panel? If so we would like to receive the sequences and compare them with other XMRV and MLV sequences to see if the positive results were due to contamination, as you seem to have suspected given the further experiments re cross contamination you described in the supplemental on line content for the Science paper.

Mike
That's impossible. I have IRB protected data that I cannot even access until the 6th. I told that to Graham yesterday and he indicated that was fine. Given the complexities and limitations of this study, many of which were not recognized at the time the (flawed) experimental design was agreed upon, to have one day to agree upon a manuscript, a holiday at that, is totally unacceptable. This is NOT good science or the appropriate process. What is the rush?

Afraid the truth?? how many of these viruses were introduced into the human population and are now threatening a lot more than the blood supply ??!! because a few declared it "impossible" 40 years ago and JC himself was the most vociferous!

How many XMRVs??

I am sending this to only Simone and Frank because I will make this a public relations nightmare for the entire US govt.

I have integration data and variants of many new strains!! Did those arrogant SOBs introduce these into humans and now are trying to cover it up??

And then pedigree the negatives with a test with a cutoff so high it would not find a willing roman in a whore house??

Wonder if anyone will listen to a press conference from me?? Asking how many new recombinants from Vaccines? From lab workers?? doctors? The first ever contagious Human retrovirus?? Spread like mycoplasma?? Are you kidding me??

It happened once!!! How many xenograft cell lines were created? How many vaccines contained mouse tissue??
These sick people lost their entire lives and this travesty of justice will not be carried out at their expense. Not again. If we have to write and publish online a dissenting opinion, we will and I will not coauthor any paper that misrepresents our findings. Not will our data be included. You can simply say we all found nothing. Totally expected ANC, we’ll prove them all wrong. Our assays may not be sensitive or reproducible given the complexity and lack of knowledge of reservoirs etc. Nothing about these data say anything about Lombardi et al of Lo et al. Except that their are likely many strains of XMRVs and only God knows the impact on chronic disease but nothing about this study says anything about our original discoveries. And if this is rushed to print without a fair and balanced discussion of its limitations, I will spend every minute of my life exposing the fraud that has been perpetrated against this patient population.

Judy Mikovits
Scientific Fraud: Blood working group charged with assay development to detect XMRVs
Failure to Confirm XMRV/MLVs in the Blood of Patients with Chronic Fatigue Syndrome: A Multi-Laboratory Study

Graham Simmons,1 Simone A. Glynn,2 Anthony L. Komaroff,3 Judy A. Mikovits,4 Leslie H. Tobler,1 John Hackett Jr.,5 Ning Tang,3 William M. Switzer,6 Walid Heneine,6 Indira K. Hewlett,7 Jiangqin Zhao,7 Shyh-Ching Lo,8 Harvey J. Alter,9 Jeffrey M. Linnen,10 Kui Gao,10 John M. Coffin,11 Mary F. Kearney,12 Francis W. Ruscetti,12 Max A. Pfost,4 James Bethel,13 Steven Kleinman,14 Jerry A. Holmberg,15 Michael P. Busch,14 for the Blood XMRV Scientific Research Working Group (SRWG)†

12 September 2011; accepted 20 September 2011
Published online 22 September 2011;

Mikovits said she hopes to have full sequences of her new viruses “in a couple of weeks.”

–JON COHEN

VIROLOGY
The Waning Conflict Over XMRV And Chronic Fatigue Syndrome

OTTAWA, CANADA—Less than a day after a new study dealt what many consider a lethal blow to the controversial theory that a newly detected virus, XMRV, is linked to chronic fatigue syndrome (CFS), proponents and skeptics of the theory squared off in a meeting here.

In one corner was Judy Mikovits, research director at the Whittemore Peterson Institute for Neuro-Immune Disease (WPI) in Reno, Nevada, and the main champion of the idea that XMRV and its relatives play a role in CFS. Her opponent, an erstwhile supporter, was heavyweight virologist John Coffin of the Tufts University Sackler School of Graduate Biomedical Sciences in Boston. When Mikovits and Coffin took the stage at the meeting, which was organized by IACFS/ME (an international association devoted to the disease) and attracted 460 researchers and patients, they sat on opposite sides of the lectern. During their introductions, Coffin clasped his hands in front of his mouth, looking like a man in prayer who wished this would all stop. Neither addressed the contamination of laboratories and reagents (table S6) – which stands for xenotropic murine leukemia virus (MLV), a newly identified group of viruses whose nearest relative is the LAV from AIDS patients, and the theory that XMRV and its relatives are the cause of a mysterious and incurable disease called chronic fatigue syndrome (CFS) in some countries:

For both XMRV and MLVs, he said. “To claim that XMRV and its relatives play a role in CFS, Mikovits and co-workers had used geneticist at Cornell University in New York. A second study, led by De Meirleir in Brussels, had WPI run its testing was performed fully blinded so as to reduce contamination of laboratories and reagents. bob (table S6)

Two others offered evidence that XMRV and infection of fresh cells, Mikovits revealed only partial viral sequences that she had asserted—explained the XMRV DNA it found in some patient samples. But Mikovits and Coffin disagreed about the results of the first study. Mikovits said her team had analyzed samples from 15 patients, and had detected virus, XMRV, in all of them. Coffin said the XMRV sequences may be foreign to the community finds voting. Instead, she offered new evidence that people with CFS (known as myalgic encephalomyelitis in some countries) had a virus “highly related” to XMRV. Unlike the original study that appeared in Science that showed entire sequences of XMRV and infection of fresh cells, Mikovits revealed only partial viral sequences that she
Ian Lipkin, 03:37 PM 11/21/2011, Re: Replication study

On Nov 15, 2011, at 12:03 PM, Judy A Mikovits wrote:

> Dear Ian
> Thank you for giving me the opportunity to do the replication study in Frank Ruscetti's lab at the NCI. I understand that no money can be given for these studies but that you can provide resources, reagents such as PCR and culture supplies and sequencing or other services (contracted through a third party). Frank will need to get permission for me to work as a special volunteer from Drs Fauci and Varmus in order for me to work in his lab. I will provide a budget for the resources needed today.
> As originally designed, I will do the replication by PBMC culture followed by Western and/or PCR as well as sequencing of PCR products and appropriate contamination assays, Serology by Flow with Western confirmation.
> Kind regards,
> Judy A Mikovits, PhD

Dear Harold,

Frank Ruscetti and I just spoke. He also spoke to JM.
1. JM is eager to complete the study via a strategy whereby the work is done in Frank's lab.
2. FR and JM understand that JM cannot enter the NCI campus and that security will ensure that she abides by this proscription.
3. I will cover the costs described in previous transmissions.
4. JM and FR will visit Columbia on 16 Dec. JM will arrive NYC on 15 Dec, spend the 16th at Columbia with our staff discussing logistics, consulting agreements, and protocols for experiments. I'm scheduled for a lecture and university senate meeting that day but will see them at the beginning and close of their visit to ensure we are on track to meet milestones. This is the only day I can do meet with them in NYC before 2012. Judy will return to CA on Sat 17 Dec.

Tony-
Cathy Laughlin has been terrific during these negotiations.

All the best,

Ian
Apparently, stopping at Dulles Airport to visit one’s mother, ruins the Integrity of NCI studies!

On Dec 2, 2011, at 12:53 PM, "Allison M. Kanas" <amk2203@columbia.edu> wrote:

Dear Judy,

In order to maintain this study's integrity, we are unable to support an itinerary that includes a stop in DC. I am happy to book you a direct flight from LAX to NYC. If you will be stopping in Washington DC unfortunately we will not be able to host you at Columbia.

Regards,

Allison M. Kanas
Project Manager
Center for Infection & Immunity
Mailman School of Public Health
Columbia University
amk2203@columbia.edu
Direct: 212-304-5689 Main: 212-342-9031
Fax: 212-342-9044
www.cii.columbia.edu
Varmus was in charge of the implementation of xenotransplantation (to include xenografts). Varmus set up a subcommittee and appointed John Coffin.

Many infectious diseases of animals can be transmitted to humans via routine exposure to or consumption of animals (e.g., rabies). Viruses that are not pathogenic in their natural host reservoirs may, in some cases, be highly pathogenic when transmitted to a new host species. Several zoonotic viruses have produced significant outbreaks when introduced into human hosts under normal circumstances of exposure (e.g., Ebola, Hanta Virus, Influenza).

Consequently, the recipient of a xenotransplant is potentially at risk for infection with infectious agents already known to be transmissible from animals to humans as well as with infectious agents, which may become transmissible only through xenotransplantation and which may not be readily identified with current diagnostic tools. Infected xenograft recipients could then potentially transmit these infectious agents to their contacts and subsequently to the public at large.