

COMMITTEE ON AGRICULTURE

SUBCOMMITTEE ON
DEPARTMENT OPERATIONS, OVERSIGHT,
NUTRITION AND FORESTRY

SUBCOMMITTEE ON
GENERAL FARM COMMODITIES AND RISK
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FINANCE AND TAX

SUBCOMMITTEE ON
CONTRACTING AND TECHNOLOGY

COMMITTEE ON THE BUDGET



The 111th Congress
U.S. House of Representatives
Washington, DC 20515

KURT SCHRADER
FIFTH DISTRICT, OREGON

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March 9, 2011

Mr. Kenneth Boorum
2685 South West Dearmond Drive
Corvallis, OR 97333-1441

Dear Mr. Boorum:

I am writing regarding your concerns with the National Institutes of Health.

Please find enclosed a copy of correspondence I have forwarded to the National Institutes of Health on your behalf. Please be assured I will continue to provide you with information as I receive it.

In the meantime, should you have any questions or concerns, please contact Alison Craig in my Oregon City district office by calling (503) 557-7257.

It is a privilege to serve you in the United States Congress.

Sincerely,

A handwritten signature in black ink, appearing to read "Kurt Schrader".

Kurt Schrader
Member of Congress

P.S. You can sign up for my e-newsletter by visiting my website at schrader.house.gov

KS/ac

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March 9, 2011

Francis Patrick "Pat" White
Associate Director, Office of Legislative Policy and Analysis
National Institutes of Health
U.S. Department of Health and Human Services
Building One, Room 244
Center Drive
Bethesda, MD 20892

Dear Mr. White:

I am writing on behalf of my constituent, Kenneth Boorum of Corvallis, Oregon.

Please find enclosed a copy of correspondence from Mr. Boorum regarding his concerns about Blastocystis. He has corresponded previously with NIAID and has some follow-up questions regarding the process used to determine whether an organism is considered a pathogen. Please consider his/her concerns in accordance with all applicable laws and regulations.

Correspondence in this matter may be directed to Alison Craig in my Oregon City district office at 621 High Street, Oregon City, OR 97045. Ms. Craig may be reached by phone at (503) 557-7257, by facsimile at (503) 557-1981 or by email at alison.craig@mail.house.gov.

Thank you in advance for your attention to this matter.

Sincerely,

Kurt Schrader
Member of Congress

KS/ac

Hi Trevor,

We enjoyed meeting you this morning in our conference with Representative Schrader.

It would be great to follow-up on of the things we discussed, especially asking the NIH about how they intend to decide whether they will consider Blastocystis to be a pathogen.

Some background is below, and attached, and a few points that might be of help in the NIH letter are below.

Thanks again for your help on this.

Best Wishes,

Ken

NIAID Letter

* The NIAID has previously indicated it will not issue a funding opportunity announcement specifically to address deficiencies in the diagnosis and treatment of Blastocystis because the NIAID has "questions" concerning whether the organism causes disease (see letter - 2008_05_28_REPLY_FAUCI.pdf)

* Question #1: As the NIAID has not funded a single grant into Blastocystis for the last 15 years, no reliable diagnostics or treatments are available in the US. Research in Oregon suggests that there is a substantial population of patients who have chronic illness due to the lack of diagnostics and treatments. If the NIAID determines Blastocystis has been causing disease, would it, for example, issue a Funding Opportunity Announcement specifically to help redress the NIAID's previous inactivity in this area?

* Question #2: Please communicate to Congress the process the NIAID uses to determine whether an organism is to be considered a cause of disease in the United States. Is that process being used for Blastocystis infection? Is this a transparent process, or an internal process which is not disclosed to outside groups? Does the process consist of a review? Is so, how often is that review repeated? Are notes or summary statements made during that review? Can those notes be provided to Congress? Does the process depend on personal opinions of specific staff members or researchers, or is it contingent on objectively verifiable criteria? If it depends on personal opinions, whose opinions are used? How does the NIAID ensure the opinion holders do not have a conflict of interest?

* If the NIAID is unable to define a process, would they consider funding a study with the Institute of Medicine (IOM) to perform the assessment. I've attached communications from the Institute of Medicine on this (see e-mail - Dr. Choffnes). If not, does the NIAID wish Congress to develop the process for them?

Other:

* As I mentioned, Blastocystis is now Oregon's #1 GI protozoa, and doctors don't have any information from US researchers about what to do when they find it in patients. I've attached an e-mail from the Oregon Public Health lab showing, for example, in 2004 they had over 100 positives, or about 11% of the patients. Based on what's been published since then, most of those patients will be sick 5 years later.

* Rep. Schrader asked if anyone overseas were doing work, so I've attached a letter listing major infectious disease groups in countries overseas, and the number of studies published in the last several years from those groups. BRF also maintains a map showing where studies are being published world-wide, and categorized lists of those studies:
http://www.bhomcenter.org/online_lab/research_collections.htm All these pages point into the NIH's Pubmed

BACKGROUND:

Attached - A February 2008 letter from Representative Neal (D-Mass) to the NIH and CDC, on behalf of his constituents who were sick with this. He asked them to add Blastocystis to the pathogen list and issue a FOA (Funding Opportunity Announcement) for clinical research into better diagnostics and treatments. We also sent the NIH a petition (not shown).

Attached - A 5/28/2008 response from Dr. Auchinchloss is attached as well, where he says they will not issue an FOA because "questions remain" about whether it causes disease.

Attached - Representative Kurt Schrader sent a letter on 11/25/2009 with a follow-up question about how they will decide if it is a pathogen, but I believe that didn't get a clear response.

NIH funding history for GI protozoa - they ended research in 1995 and have not approved one grant. Physicians have no idea what to do about the illness (source: NIH REPORTer web site)

Gazette-Times Article on Family in Corvallis:
http://gazettetimes.com/news/local/article_f0d84d6d-6e91-5caf-ad73-103871d3494e.html

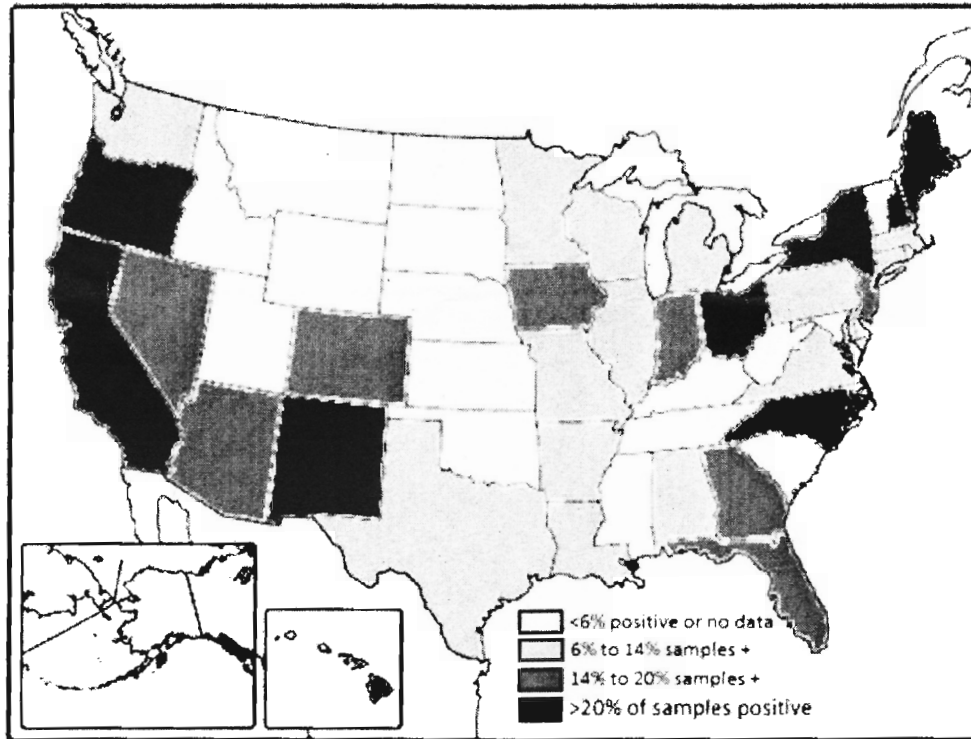
Paper Attached: Association of Blastocystis subtypes 3 and 1 with chronic gastrointestinal illness in an Oregon Community

Link to testimony given in Oregon House on Blastocystis infection, 2007:
http://bhomcenter.org/journalist/transcript_2007_03_salem.htm

Petitions signed by physicians in Corvallis identifying Blastocystis as a problem infection:
http://bhomcenter.org/pdfs/BOOROM_2007_PETITIONS_AND_TESTIMONY_FOR_STATE_OF_OREGON.PDF

List of studies performed at the NIH before 1995, most of which identified Blastocystis as disease causing:

[http://www.ncbi.nlm.nih.gov/pubmed?term=%28Zierdt\[Author\]+AND+Blastocystis\[ALL+Fields\]|%29](http://www.ncbi.nlm.nih.gov/pubmed?term=%28Zierdt[Author]+AND+Blastocystis[ALL+Fields]|%29)



Blastocystis Infection Rates in the United States

Source: Amin, O. Epidemiology of Blastocystis in the United States. Research Journal of Parasitology, 2005:1-10

Blastocystis Research Foundation
5060 SW Philomath Blvd, #202
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Web Site: <http://www.bhomcenter.org>

Phone: 815-572-9701

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email: director@bhomcenter.org



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

May 28, 2008

Mr. Ken Boorom
Director, Blastocystis Research Foundation
5060 SW Philomath Blvd., #202
Corvallis, OR 97333-1044

Dear Mr. Boorom:

Thank you for your letter of May 12, 2008, to Dr. Anthony S. Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), concerning funding for the development of diagnostics and treatments for *Blastocystis hominis* infection. Thank you also for your note transmitting a copy of the letter to Dr. Elias Zerhouni, Director of the NIH. As the Principal Deputy Director of NIAID, I am pleased to respond to your letter.

NIAID is committed to funding innovative basic research, as well as the development and clinical testing of vaccines, diagnostics, and therapeutics for a wide variety of infectious and immunologic diseases, including diseases caused by parasites and protozoans. Because many questions remain regarding the ability of *B. hominis* to cause disease, more basic research needs to be done before the research that you suggest would be feasible. Although NIAID currently is not funding research directly related to *B. hominis*, should a researcher submit a grant application to NIH regarding *B. hominis*, it would be reviewed, like all grant applications, through the NIH peer review process, which is designed to evaluate and rate the scientific and technical merit of research applications for possible consideration for funding. More detailed information on the NIH peer review process can be found at the following Web site: <http://grants1.nih.gov/grants/peer/peer.htm>.

Thank you for your interest in NIAID research on *B. hominis*, and for your leadership and advocacy on behalf of other patients. I hope that this information is helpful to you. Please do not hesitate to contact me if I can be of further assistance.

Sincerely,

Hugh Auchincloss, M.D.
Principal Deputy Director
National Institute of Allergy and
Infectious Diseases

Ken Boorom

From: Choffnes, Eileen [EChoffnes@nas.edu]
Sent: Tuesday, December 07, 2010 11:52 AM
To: 'Ken Boorom'
Subject: RE: Dr. Choffnes - question on how topic selection for the IOM's Board of Global Health

Dear Mr. Boorom:

When the IOM is formally asked for advice, it convenes a highly standardized, multidisciplinary consensus committee process supported by several staff. The appointed committee members are chosen after the solicitation of nominations from a wide range of sources. For a simple question, we may ask six or seven experts to serve; more complex studies can involve as many as 20 committee members. Appointed members are carefully screened for biases and conflicts of interest. In the course of their work, a literature review may be completed as well as other approaches deemed necessary to gathering sufficient information to answer the charge to the committee. Typically a public workshop would be one of these other approaches. The committee's deliberative process typically extends over a period of months and includes several face-to-face meetings. When a draft report is completed, it is reviewed by a formally appointed peer review group. The authoring committee is held to respond sufficiently to the peer critiques before a report can be released in the name of the Institute of Medicine. The costs of this comprehensive, multi-disciplinary approach are substantial. The average IOM study takes about 17 months and currently costs about \$1.2 million. The most simple consensus studies can be typically carried out in 7 or 8 months and cost an estimated \$600,000. Given the costs and time involved with the IOM committee process, the IOM generally only undertakes studies that other organizations are not well-positioned to carry out.

Hope this helps clarify an often opaque process.

Eileen

Rediscover the IOM at our new website. www.iom.edu

From: Ken Boorom [mailto:kboorom@bhomcenter.org]
Sent: Tuesday, December 07, 2010 2:46 PM
To: Choffnes, Eileen
Subject: RE: Dr. Choffnes - question on how topic selection for the IOM's Board of Global Health

Dear Dr. Choffnes,

Many thanks for the quick response. Would you have an idea of what kind of grant amounts have been used in the past to conduct a literature review and answer a specific question, like "Is Blastocystis a pathogen in humans, in the sense that Giardia and E. histolytica are considered pathogens?"

If it helps, we organized a group to look at this question and published a review in 2008. We downloaded abstracts for all Blastocystis studies on the NIH's pubmed server and categorized them by study type, researcher conclusion, etc. The data from that effort is still available, and we could also get the same group to update it. The scientists from the group at the time were at the US Center for Disease Control, China's CDC, the Pasteur Institute, a WHO Coordinating Center for the Molecular Epidemiology of Parasitological Infections, the US Air Force, and some other groups.

Thanks again for your help.

Best Wishes,

Ken

From: Choffnes, Eileen [mailto:EChoffnes@nas.edu]
Sent: Thursday, December 02, 2010 1:03 PM
To: 'kboorom@bhomcenter.org'
Cc: director@bhomcenter.org
Subject: RE: Dr. Choffnes - question on how topic selection for the IOM's Board of Global Health

Dear Mr. Boorom:

Many thanks for your inquiry about the process that the IOM uses for the initiation of a study. The Institute of Medicine consensus advisory studies come about in a variety of ways. Most of the studies are either directed by Congress through specific legislative language or initiated as a result of a formal request by an agency within the Executive Branch such as the CDC or the NIH. Though the experts who serve on IOM consensus committees serve without compensation for their time, the process of conducting an advisory study involves a significant expense which is usually provided for through a contract with the requesting government agency. Sometimes foundations also award grants to the IOM to conduct studies in which they have an interest. States, foreign governments, and even international organizations have also commissioned advice from the IOM. So, in deciding to undertake a formal advisory study, it is important for us to have a clear scientific question, a sufficient scientific evidentiary base to examine, and a committed financial sponsor(s).

I hope that this background information helps you as you decide how you would like to proceed on a study of Blastocystis.

All the best,

Eileen Choffnes, Director, Forum on Microbial Threats
 Rediscover the IOM at our new website, www.iom.edu.

From: kboorom@bhomcenter.org [mailto:kboorom@bhomcenter.org]
Sent: Thursday, December 02, 2010 12:59 PM
To: Choffnes, Eileen
Cc: director@bhomcenter.org
Subject: Dr. Choffnes - question on how topic selection for the IOM's Board of Global Health

Dear Dr. Choffnes,

Many thanks for the work you have done on the IOM's Board of Global Health.

Could you tell me how our group might work toward getting the Board of Global Health to address a specific topic concerning the pathogenicity of a microbe?

The specific question is, "Based on currently available peer reviewed medical literature, should Blastocystis (a single-celled enteric protozoan) be considered as a cause for abdominal pain and diarrhea in immunocompetent adults? "

We've had several Congressional representatives contact the NIH and CDC asking them to address the infection. Both agencies have indicated they are taking no action because "experts disagree"

on the question. There is a large body of published medical literature that can be reviewed - pubmed shows about 850 studies on the organism. Their are clinical studies from major hospitals and medical centers in about a dozen countries. There are also about 10 microbiology labs publishing on an ongoing basis (animal studies, in vitro, etc.)

Does the IOM's Board of Global Health need a full committee to address a question, or would it be able to act on requests from two or three Congressional Representatives?

Would the IOM act on a request from a State legislature or a governor?

Would the IOM act on a petition from several hundred scientists and physicians?

Thanks again for your fine work.

Best Wishes,

Ken Boorom
Director, Blastocystis Research Foundation

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