From: Health Referrals
To: s22
Subject: MC16-021765 - FW: PARLEC D resp: s22 .....HPV [SEC=UNCLASSIFIED]
Date: Wednesday, 25 May 2016 2:27:00 PM
Attachments: Gardasil no benefit for us-2.2016.pdf
Fw s22 HPV SECNo Protective Marking.msg
Fw s22 HPV GARDASIL....Fw Articles of s22 SECNo Protective Marking.msg

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MC16-021765

D Response – 20 Days – SL – OHP
Please link to MC16-001385

From: Minister Ley
Sent: Wednesday, 25 May 2016 1:28 PM
To: Health Referrals
Subject: D resp: s22 .....HPV [SEC=UNCLASSIFIED]

She has called the Office twice now. I'm not sure why her earlier emails weren't received
Can we please get a D response to her

Thanks
s22

From: s22 mailto:s22 @smartchat.net.au]
Sent: Wednesday, 25 May 2016 1:25 PM
To: Minister Ley
Subject: Fw: s22 .....HPV [SEC=No Protective Marking]

From: s22
Sent: Thursday, May 12, 2016 12:41 PM
To: Sussan.Ley.MP@aph.gov.au
Subject: Fw: s22 .....HPV

Sussan Ley,

My daughter had a serious side effect to the HPV Gardasil in s22 after her s22 vaccination three days later. It was confirmed by our local GP and Chiropractor.

I was lead to believe I was protecting my daughter from cervical cancer and after she became seriously ill I researched and was desperate for an answer. I was totally shocked at what I found. I said to my GP it is making some girls sterile he said no that's not true. I came back on the next visit and provided him with Dr s22 findings please see attachments in separate e-mail.. I think he was quiet surprised. I have continued to provide many peer reviewed articles to my GP. I strongly feel I wasn't fully informed enough on

the side effects and the true scientific facts which I believe should be included on the card that is received at school regarding the HPV.

The HPV Gardasil is a GLOBAL problem causing serious side effects and many families are searching ways to heal their daughters and sons for some families their children have died and more recently a young girl in the UK just days ago sadly yet to be confirmed by autopsy. Please visit the web site www.sanevax.org. Countries are questioning its value and Japanese government doesn't recommend it as too many serious side effects. In Ireland a politician s22 has stood up recently and is questioning its value. The R.E.G.R.E.T Group have formed and is a group of mothers wanting answers and help for their sick children.

My s22 children have had every vaccine on the list and my other s22 children won't be receiving this particular vaccine and I'm very frightened about giving any vaccine.

I believe you as the Health Minister needs to look at the damage this vaccine is causing to many young Australian girls and boys and look at what it is also doing globally. I would appreciate if there was a discussion on the safety of this vaccine. I am sick of hearing how safe it is as I have experienced first-hand how it isn't along with many other families in Australia.

Within my local community other girls have become damaged after my daughter was affected and others with minor side effects. I am very vocal on this matter. I have also encouraged these people to write in letters. I continue to bring awareness to the school my daughter once attended (s22) s22 however I will not stop and I have written to the s22 and the Catholic Education Department which I have enclosed these letters.

s22

s22 . It has been an emotional draining, financially distressing and extremely hard to see my once very healthy active daughter now living with constant pain and I feel her youth has be taken away. I'm a very determined mother to get her well and back attending school and enjoying the hobbies she once did s22 s22 .

I am extremely determined to bring awareness to others to get fully informed before giving this vaccine. I would appreciate you taking a good look at the website above that has many peer reviewed articles in particular the HPV vaccine and Dr Lee's findings.

I have a huge amount of medical records regarding s22 Health.

I have also included my story on the events of what happened to my once vibrant happy fun loving girl and the aftermath of what HPV Gardasil vaccine done to us. My biggest ever regret and worst decision I have ever made for my child.

I also would like the Health professionals to acknowledge this is real vaccine injures are very real and deaths there are other families suffering and demand the help they so desperately need.

I'm extremely alarmed at this recent information of allegations of scientific misconduct by GACVS/WHO/CDC representatives' et al. and could you please read through.

I would appreciate you thoroughly reading what I have provided and look forward to hearing from you.

I will forward more information in separate e-mails.

Thanking-you

s22 [redacted]@smartchat.net.au

From: s22
To: Sussan.ley.mp@aph.gov.au
Subject: Jenny Scott HPV
Date: Thursday, 12 May 2016 12:42:02 PM
Attachments: Allegations of Scientific Misconduct by GACVS (1).pdf

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As per previous e-mail...

Please read through and I look forward to your response and I'd also like to send you Dr s22 findings in another e-mail sorry I can't send all in the one email.

s22 @smartchat.net.au

Allegations of Scientific Misconduct by GACVS/WHO/CDC Representatives et al

An open-letter of complaint to the Director-General of the World Health Organization, Dr. Margaret Chan chanm@who.int

Cc: The Ministry of Health, Labour and Welfare, Japan, www-admin@nhlw.go.jp
Minister of Health, Labour and Welfare, Japan, shiozaki@y-shiozaki.or.jp
Thomas Frieden, Director CDC, tomfrieden@cdc.gov
Vice-Chancellor, Professor Stuart McCutcheon, The University of Auckland, s.mccutcheon@auckland,ac.nz

From: Sin Hang Lee, MD shlee01@snet.net

Date: January 14, 2016

Dear Dr. Chan:

As a medical doctor and scientist, I write to present grave concerns regarding the conduct of certain members of the Global Advisory Committee on Vaccine Safety (GACVS), the World Health Organization, the CDC and other scientific/health professionals during the time shortly before the public hearing on HPV Vaccine Safety which was held in Tokyo, Japan on February 26, 2014. I have come into possession of documentation which leads me to believe multiple individuals and organizations deliberately set out to mislead Japanese authorities regarding the safety of the human papillomavirus (HPV) vaccines, Gardasil® and Cervarix®, which were being promoted at that time.

I am sure you are well aware of the controversy currently surrounding these vaccines on a global level. I am also sure you are aware of the fact that public confidence in national and international health authorities is at an all time low throughout the world.

Should the information in this letter prove to be accurate, nothing short of an immediate independent investigation resulting in appropriate disciplinary actions for those involved will be able to restore the public trust. Therefore, I implore you to act quickly and decisively regarding this critical public health issue.

FOI Request and Significant Related Communications

A series of emails recently uncovered via a Freedom of Information request submitted in New Zealand revealed evidence that Dr. Robert Pless, the chairperson of the Global Advisory Committee on Vaccine Safety (GACVS), Dr. Nabae Koji of the Ministry of Health of Japan, Dr. Melinda Wharton of the CDC, Dr. Helen Petousis-Harris of Auckland University, New Zealand, and others (including WHO officials) may have been actively involved in a scheme to deliberately mislead the Japanese Expert Inquiry on human papillomavirus (HPV) vaccine safety before, during and after the February 26, 2014 public hearing in Tokyo. I believe the information supplied by this group led directly to the issuance of the GAVCS statement on the continued safety of HPV vaccination on March 12, 2014 which contains the following paragraph:

> *"Several papers have also been published pertaining to the finding of HPV L1 gene DNA fragments in clinical specimens following HPV vaccination [13, 14]. These papers claimed an association with clinical events of an inflammatory nature, including cerebral vasculitis. While the GACVS has not formally reviewed this work, both the finding of DNA fragments in the HPV vaccine and their postulated relationship to clinical symptoms, have been reviewed by panels of experts. First, the presence of HPV DNA fragments has been addressed by vaccine regulatory authorities who have clearly outlined it as an expected finding given the manufacturing process, and not a safety concern [15]. Second, the case reports [13] of adverse events hypothesized to represent a causal association between the HPV L1 gene DNA fragments and death were flawed in both clinical and laboratory methodology [16]. The paper described 2 fatal cases of sudden death in young women following HPV vaccine, one after 10 days and one after 6 months, with no autopsy findings to support death as result of cerebral vasculitis or an inflammatory syndrome. Thus the hypotheses raised in these papers are not supported by what is understood about the residual DNA fragments left over following vaccine production [17]: given the extremely small quantities of residual HPV DNA in the vaccine, and no evidence of inflammation on autopsy, ascribing a diagnosis of cerebral vasculitis and suggesting it may have caused death is unfounded." (the references 13-17 quoted were those listed in the GACVS Statement)*

I believe this paragraph to be deceitful based on the following analysis:

The first sentence, "*Several papers have also been published pertaining to the finding of HPV L1 gene DNA fragments in clinical specimens following HPV vaccination [13, 14]"* was apparently constructed for dissembling and designed to mislead. The study in reference 13 [Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceut Reg Affairs 2012, S12:001] was about HPV L1 VLPs. The authors of reference 13 never mentioned HPV L1 gene DNA fragments at all. Dr. Pless knew the difference between HPV L1 VLPs and HPV L1 gene DNA fragments because in his February 18, 2014 email addressed to Dr. Helen Petousis-Harris and the others involved in this scheme, Dr. Pless specifically asked Dr. Petousis-Harris to address her "*statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects*." (see copy of February 18, 2014 email attached- It was not about HPV L1 VLPs). One cannot help but conclude that Dr. Pless intentionally put these two unrelated articles together and claimed that both articles studied HPV L1 gene DNA fragments in order to mislead the non-scientific readers and vaccination policy makers.

The second sentence, *"These papers claimed an association with clinical events of an inflammatory nature, including cerebral vasculitis"* is not true because the author in reference 14 (Lee, SH. Detection of human papillomavirus L1 gene DNA fragments in postmortem blood and spleen after Gardasil® vaccination—A case report. Advances in Bioscience and Biotechnology, 2012, 3, 1214-1224) never claimed clinical events of an inflammatory nature, including cerebral vasculitis. Dr. Pless in fact mis-states the author's words in this document apparently to create a target to attack.

When the facts don't fit – simply change them?

The purpose of Dr. Pless intentionally combining two unrelated studies and two unrelated chemicals shows up in the following sentence: "*the finding of DNA fragments in the HPV vaccine and their postulated relationship to clinical symptoms, have been reviewed by panels of experts".* Who were these panels of experts? Dr. Pless presented none of their names.

The sentence *"Second, the case reports [13] of adverse events hypothesized to represent a causal association between the HPV L1 gene DNA fragments and death were flawed in both clinical and laboratory methodology [16],"* is a blatant misrepresentation of the facts. The authors quoted in Reference #13 never presented any data on HPV L1 gene DNA fragments. Reference #16 never reviewed the potential harm of HPV L1 gene DNA fragments in the HPV vaccines when injected into humans.

A plea for help – and anyone will do?

The fact that Dr. Pless could not find any scientific reviews on the HPV L1 gene DNA fragments in HPV vaccines was illustrated in the email he sent to Dr. Helen Petousis-Harris on February 18, 2014 with the following plea for help:

> *"We are seeking your advice on someone who may be able to address the more detailed questions around HPV DNA - specifically the hypotheses you have address in your statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects. While the issue of whether the fragments constitute "contamination" has been dealt with, your statement was the only one to address the more obscure alleged consequences of the presence of those fragments. The GACVS has not yet had a chance to delve into the DNA question."*

The FDA declaration confirming HPV DNA fragments in Gardasil® as an expected finding (Ref. 15), but providing no safety data on these HPV DNA fragments after being injected into animals or humans, obviously does not represent a review by panels of experts because it does not refer to any animal or human experimental data on *"aluminum binding to DNA fragments and subsequent effects,"* which was supposed to be Dr. Pless' major concern.

It is worth noting Dr. Helen Petousis-Harris demonstrated to Dr. Pless that she had experience using similar tactics in her *February 18, 2014* email which stated:

> *"To the best of my knowledge the rebuttal on our website is the only attempt to address this particular issue which Shaw and Lee presented at a coronal enquiry here. Placing the rebuttal in the public domain was the only means of providing the information to the crown representatives involved in that process at the 11th hour."*

Apparently under pressure to issue a statement within a week or two after the public hearing, Dr. Pless needed to find a panel of experts to declare the safety of aluminum bound to DNA fragments after injection into humans. The only publication remotely related to the subject he could use was Reference #16, a Clinical Immunization Safety Assessment (CISA) Network Technical Report titled "Review of a

published report of cerebral vasculitis after vaccination with the Human Papillomavirus (HPV) Vaccine" dated November 9, 2012.

However, in this CDC technical report, the unnamed author(s) of the document only questioned the data on HPV-16 L1 particles, never HPV L1 gene DNA fragments because the Lee paper reporting the finding of HPV L1 gene DNA fragments (Lee, SH. Detection of human papillomavirus L1 gene DNA fragments in postmortem blood and spleen after Gardasil® vaccination—A case report. Advances in Bioscience and Biotechnology, 2012, 3, 1214-1224) was not published until December 27, 2012, one and a half months after the CISA Network Technical Report was issued.

For the record, the quoted CISA report (Reference #16) began with the following paragraph:

> *"Recently there was discussion on a federally-sponsored vaccine safety listserv of a report in the literature of cerebral vasculitis after vaccination with the Human Papillomavirus Vaccine (HPV) (*Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceutical Regulatory Affairs: Open Access 2012,S12:001*). To address questions about the findings and conclusions reported in this manuscript, CDC convened a CDC-Clinical Immunization Safety Assessment (CISA) working group. Researchers from Vanderbilt Medical Center, Johns Hopkins University, Columbia University, Duke Clinical Research Institute (Duke University), CDC and FDA participated in the call."*

Lack of Peer-Review Credibility

According to: http://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/publications.html, this is the ONLY Technical Report issued in the last 12 years of records that has never been published in peer- reviewed journals. The Disclaimer at the end of this report states:

> *"The information and conclusions in this report are those of the work group participants addressing this issue and do not necessarily represent the official position of CDC."*

In other words, the CDC's "Technical Report" (Ref #16 of the GACVS Statement) was written by unnamed ghost writer(s) based on phone conversations.

Apparently Dr. Pless had no choice but to misbrand two unrelated articles and two unrelated chemicals in the vaccine Gardasil® so that he could use the CISA Network Technical Report on HPV-16 L1 particles to support his declaration on safety of HPV L1 gene DNA fragments after injection into humans. But first, he had to make policy makers believe "HPV-16 L1 particles" were synonymous to "HPV L1 gene DNA fragments" in chemistry. Once that was done, he apparently thought he could use the opinion on HPV-16 L1 particles to uphold the safety of HPV L1 gene DNA fragments bound to aluminum adjuvant.

Unable to find a scientific report published in a peer reviewed journal on this issue of concern, Dr. Pless had to knowingly misquote the CISA report on HPV-16 L1 particles as evidence to support Dr. Helen Petousis-Harris' blog published in the social media as he wrote in the GACVS statement:

> *"Thus the hypotheses raised in these papers are not supported by what is understood about the residual DNA fragments left over following vaccine production [17]".*

Acknowledgement of Residual HPV DNA in Gardasil®

Dr. Helen Petousis-Harris, the author of Ref. 17, was the only writer brave enough to publicly claim "*extremely small quantities of residual HPV DNA in the vaccine*" to be harmless without any supportive data.

Who is Dr. Helen Petousis-Harris? Her qualification was disclosed in Dr. Pless' email dated February 18, 2014 as he wrote:

> *"A meeting has recently been organized in Tokyo for February 26th, where Dr. Lee will present his findings…*
>
> *…We are seeking your advice on someone who may be able to address the more detailed questions around HPV DNA - specifically the hypotheses you have address in your statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects. While the issue of whether the fragments constitute "contamination" has been dealt with, your statement was the only one to address the more obscure alleged consequences of the presence of those fragments. The GACVS has not yet had a chance to delve into the DNA question."*

Accepting the assignment, Dr. Helen Petousis-Harris wrote back immediately on February 18, 2014 as follows:

> *From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz] Sent: Tuesday, February 18, 2014 5:19 AM To: 'Robert Pless' Cc: Robert Pless (Robert.Pless@phac-aspc.gc.ca); 難波江 功二(nabae-koji); ZUBER, Patrick Louis F.; Wharton, Melinda (CDC/OID/NCIRD) Subject: RE: URGENT: Regarding the posted commentary on the coronial inquiry expert witness testimony*
>
> *Dear Rob Oh dear! I am so saddened to hear how extensive the impact of Lee, Shaw and Tomljenovic's activities has become. I will certainly do anything I can to assist. To the best of my knowledge the rebuttal on our website is the only attempt to address this particular issue which Shaw and Lee presented at a coronal enquiry here. Placing the rebuttal in the public domain was the only means of providing the information to the crown representatives involved in that process at the 11th hour. Prof David Gorsky has written prolifically on some of the experiments in his science blog over the past few years so I assume he has also given the material some thought.*
>
> *I do not know if I am expert on this but certainly have some experience in considering aluminium in vaccines and its role in inflammatory responses and local AEFI as part*

> *of my PhD some years ago. I assume you are referring to the VLP tightly bound to the adjuvant and the Shaw and Tomljenovic 'hypothesis' that it somehow finds its way to the brain carried by macrophage?"*

Lack of Qualification/Credibility of Expert Witness Dr. Helen Petousis-Harris

Based on the above correspondence, Dr. Helen Petousis-Harris had no clue what Dr. Pless wanted her to address at the February 26, 2014 public hearing. She mistakenly assumed she was being asked to comment on "the VLP tightly bound to the adjuvant." She did not even know that VLP is a protein, and cannot be tightly bound to the aluminum adjuvant as the DNA molecules can.

Evidently, her only qualification was she had written a social media blog much like Professor David Gorski, a well-known online character assassin masquerading as a science defender whom she also recommended to the group saying:

> *"Prof David Gorsky has written prolifically on some of the experiments in his science blog over the past few years so I assume he has also given the material some thought."*

I find it incredible that the WHO GACVS had to depend on online science blog writings as evidence to **dismiss the potential risk** of HPV DNA fragments in Gardasil®. As evidenced in the email above, on February 18, 2014, Dr. Pless knew very well that the CISA Network Technical Report dated November 2012 did not address the presence of HPV L1 gene DNA fragments in the vaccine Gardasil® because he wrote to Dr. Helen Petousis-Harris:

> *"…We are seeking your advice on someone who may be able to address the more detailed questions around HPV DNA - specifically the hypotheses you have address in your statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects. While the issue of whether the fragments constitute "contamination" has been dealt with, your statement was the only one to address the more obscure alleged consequences of the presence of those fragments. …"*

So, as of February 18, 2014 Dr. Pless and those whose names are listed on his email knew Dr. Helen Petousis-Harris and Professor David Gorski were the only two writers who had addressed the issue of HPV L1 gene DNA fragments in the HPV vaccine, but in social media blogs only, and not in peer-reviewed scientific journals. Dr. Pless needed to find someone to put a veneer of science over these online blogs. He found Dr. Helen Petousis-Harris for that.

Government Counter-Actions to Evidence of Harmful Effects of HPV Vaccination

The following emails showed the actions taken by the bureaucrats of the Ministry of Health, Labour and Welfare of Japan, the chair of the public hearing session, Dr. Pless and Dr. Melinda Wharton of the CDC to counter the plausible consequences of the presence of the HPV DNA fragments in the Gardasil® vaccines.

From: 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>
Sent: Friday, 21 February 2014 11:05 p.m.
To: Robert Pless; Helen Petousis-Harris; ZUBER, Patrick Louis F.; jbeytout@chu-clermontferrand.fr; Wharton, Melinda (CDC/OID/NCIRD); Koji Nabae (k-nabae-@nifty.com); 阿部 圭史(abe-keishi); Robert Pless
Subject: RE: (FYI) HPV vaccine international sympo on 25 Feb in Tokyo
Attachments: GACVS Statement HPV Feb 2014 discussion draft.docx; Annotated Agenda 26 Feb 2014.docx; Participants List.docx

Dear Rob,

Thank you so much for the excellent work you and your colleagues have done.
It sounds very strong. It is indeed very helpful.

I made minor comments on the attached file.

===

For the conference call today, there will be 4 participants from Japan.

Koji Nabae (Ministry of Health, Labour and Welfare (MHLW)) Keishi Abe (MHLW) Ichiro Kurane (Chair of the public hearing session, Deputy Director General of National Institute of Infectious Diseases(NIID)) Dr Hiroshi Yoshikura (Former DG of NIID)

In case you wish to discuss GACVS statement only among GACVS members, please let me know so that we will join you later.

==

Attached please find the draft annotated agenda and participant list of the public heating meeting.

I look forward to talking to you soon.

Warm regards,

Koji
Deputy Director
Division of Tuberculosis and Infectious Disease Control Ministry of Health, Labour & Welfare Government of Japan-
Tel: [redacted]
Fax: +81-3-3581-6251
email: nabae-koji@mhlw.go.jp

-----Original Message-----
From: Robert Pless [mailto:rpless2@gmail.com]
Sent: Friday, February 21, 2014 4:19 PM
To: Helen Petousis-Harris; 難波江 功二(nabae-koji); ZUBER, Patrick Louis F.; jbeytout@chu-clermontferrand.fr; Wharton, Melinda (CDC/OID/NCIRD); Koji Nabae (k-nabae-@nifty.com); 阿部 圭史(abe-keishi); Robert Pless
Subject: Re: (FYI) HPV vaccine international sympo on 25 Feb in Tokyo

Dear all,

Attached please find a draft GACVS statement for review. We can discuss it tomorrow (actually in a few hours) and then it would go through vetting by the committee if the feeling remains that it should be posted in advance of the events of next week.

I propose the following topics for discussion on our call:

1. Introductions
2. Current situation in Japan with respect to the signal 3. Origins of the 2 meetings being held next week and potential outcomes 4. Planned and likely topics that may arise by the speakers (MMF, HPV DNA, ...other) 5. Responses during the meeting on the 26th (invited experts, Ministry, Expert advisory group) 6. Format and timing of responses outside the meetings (GACVS statement, follow up statements?) 7. Other interventions?
8. Other issues

Please feel free to add/alter
Looking forward to getting together on the phone, Rob

Based on the emails copied above, Dr Pless and those listed in these emails already drafted a GACVS statement before the public hearing. However, after having discussed to his boss, Dr. Nabae Koji wrote to the group on February 23, 2014 the following email:

From: 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>
Sent: Sunday, 23 February 2014 6:01 p.m.
To: SAHINOVIC, Isabelle; rpless2@gmail.com; Robert.Pless@phac-aspc.gc.ca; Helen Petousis-Harris; mew2@cdc.gov; ZUBER, Patrick Louis F.; jbeytout@chu-clermontferrand.fr
Cc: 阿部 圭史(abe-keishi); 難波江 功二(nabae-koji)
Subject: HPV vaccine conf call Follow-up

Dear all,

Thank you so much for your time and commitment. The conference call was very useful for us.

I talked to my boss and we agree that it is better not to have WHO GACVS presence during the public hearing session [redacted] and there is no need to hurry for a statement. We are hoping the statement to come out a week or two weeks later so that our expert committee can refer to it when they finalize the report in March (or a bit later) (if things go smoothely).

Thank you so much for your help.

I look forward to meeting and talking to you later.

Warm regards,

Koji Nabae

In plain language, it appears that Dr. Nabae was instructing the WHO GACVS not to present any information formally in order to avoid cross-examination and scrutiny at the February 26, 2014 Public Hearing. Information provided after the public inquiry would provide a means for decision makers to be duly influenced by informal and cherry-picked 'expert' opinions.

I believe this maneuver was orchestrated by the Chairperson of the WHO GACVS and others as nothing more than a very cunning means of avoiding having to supply scientific evidence to decision makers. Actions like this corrupt the entire concept of science-based medicine.

Dr. Helen Petousis-Harris was finally selected as spokesperson for the February 26, 2014 Tokyo public hearing. But according to the emails uncovered, Dr. Petousis-Harris' Powerpoint slides had to be reviewed by the group before presentation at the public hearing to ensure she put forth the proper message.

I found it astonishing to read the February 25, 2014 email sent by Dr.Nabae Koji to Dr. Helen Petousis-Harris, their designated spokesperson. Dr. Nabae was concerned about Dr. Helen Petousis-Harris' Powerpoint slide which stated *"immune activation on uptake of HPV vaccine does not include an increase in inflammatory factors (incl TNF) even in vaccinees with large injection site reactions at time of local inflammation"* because such claim contradicted the data presented by another expert at their previous meeting which in fact confirmed that cytokines following vaccines increased particularly at injection site after Cervarix® compared to other vaccines (including tumor necrosis factor- TNF).

It is of interest to note that Dr. Nabae Koji also deleted some questionable "*Japanese Wildcard*" data from Dr. Helen Petousis-Harris' Powerpoint slides to be presented at the February 26, 2014 public hearing because he, Dr. Nabae, could not "*explain it well*".

GACVS Suppresses Vital Information and Manipulates Data to Support Claim of Vaccine Safety in the Face of Valid Contradictory Evidence

I find this to be yet another blatant example of suppression of information this group found to be potentially contradictory to and/or not totally compatible with their pre-determined GACVS "party line" statement on continued safety of HPV vaccination. Dr. Pless and the WHO officials seemed to have simply written a script for Dr. Helen Petousis-Harris to regurgitate at the public hearing and then proceeded to put forth the same presentation as an independent research reference to support their pre-determined GACVS statement. What an insult to the intelligence of the citizens of the world!

The Powerpoint slides Dr. Helen Petousis-Harris presented at the public hearing claimed Dr Lee's case report had no controls to prove that unvaccinated New Zealand teenage girls do not have HPV DNA in non-B conformations in their blood, therefore the findings are not scientifically valid. She said, "*There are no controls used (unvaccinated). This is a vital part of the scientific process*." [original emphasis.]

Dr. Helen Petousis-Harris evidently does not understand the difference between a case report and a clinical trial; nor does she seem to know how hard it is for pathologists to find any HPV DNA in blood samples of patients, even those known to have HPV infections, let alone HPV DNA in non-B conformations. This shows how little, if any, experience she has in laboratory medicine.

I find Dr Petousis-Harris blog[1] which was quoted as Ref. 17 by Dr Pless in the GACVS statement in support of the declaration of HPV vaccination safety, to be more concerned with character assassination than in disputing the science of HPV L1 gene DNA fragments in Gardasil® or in postmortem materials.

The very important email exchange between Dr. Nabae and Dr. Helen Petousis-Harris on February 25, 2014, one day before the Tokyo public hearing, is copied in this correspondence so you can judge for yourself whether these people manipulated the scientific data and process in order to mislead the Japanese Expert Inquiry, and vaccination policy makers worldwide.

First, please note Dr. Dr. Nabae's concern about Dr. Helen Petousis-Harris' claim of no cytokine increases in HPV vaccinees, as expressed in the email dated February 25, 2014 shown below, which was apparently written after he had an opportunity to review her proposed powerpoint presentation.

[1] http://www.nzdoctor.co.nz/media/2003295/response_to_theories_by_lee_and_shaw_final_180912.pdf

From: 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>
Sent: Tuesday, 25 February 2014 1:56 p.m.
To: Helen Petousis-Harris
Subject: RE: Doc and Video Conf
Attachments: NZ Public hearing session on HPV safety.pptx

Fantastic!! Very strong and convincing. Many many thanks!
It think there is no need for further explanation since your slides tell all the story.

One thing I came up to my mind,

- In addition, the immune activation on uptake of HPV vaccine does not include an increase in inflammatory factors (incl TNF) even in vaccinees with large injection site reactions at time of local inflammation.

In our previous meeting, one expert presented his studies on mice,
http://www.mhlw.go.jp/file/05-Shingikai-10601000-Daijinkanboukouseikagakuka-Kouseikagakuka/0000033876.pdf

In page 21 and 22, cytokines following vaccines increased particularly at injection site after Cervarix compared by other vaccines (incl TNF) but not in serum. I am just concerned that this finding may contradict with your statement.

I also deleted Japanese Wildcard (since I cannot explain it well!!) and found one typo in page 2.

Grateful for your confirmation!!

Best regards,

Koji

From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz]
Sent: Tuesday, February 25, 2014 8:03 AM
To: 難波江 功二(nabae-koji)
Subject: RE: Doc and Video Conf

Dear Koji

Phew!

Here you are.

I have put some credentials on the first slide, please adjust to what you think would be most useful
Also, I have used the Japanese translation for the word Wildcard (according to Google) but if this doesn't work please remove it from Slide 3.

Later in the morning apparently after a video conference Dr. Helen Petoussis Harris replied, asserting her scientific authority to comment as follows:

From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz]
Sent: Tuesday, February 25, 2014 10:02 AM
To: 難波江 功二(nabae-koji)
Subject: RE: Doc and Video Conf

Great!

Actually that is my own work, We have conducted a clinical trial using Gardasil vaccine. We specifically examined the reactogenicity of the vaccine and associations with 27 cytokines inlc TNF and IL1, all the main players. There was no elevation of any cytokine associated with reactogencity. I have it on a list to publish and it had been peer reviewed in a PhD thesis which is available in the University Library and the data is available for scrutiny.

So Dr. Helen Petousis-Harris used her PhD thesis[2] as authoritative research to support her theory of "*No elevation of any cytokine associated with reactogenicity*"?

In fact, her PhD thesis has not been published in a peer-reviewed scientific journal because not only the experimental design and methodology used were highly questionable, as demonstrated in over 500 pages of Official Information documents and emails, but also in section 8.2 on limitations of this thesis, where Dr. Petousis-Harris states:

> "Timing and lack of baseline cytokine measures: Only a single blood sample was taken. The absence of a baseline measure precludes any within-individual changes. It cannot be determined if there were any changes in cytokine levels as a result of the administration of the vaccine or if these were base-line levels. In addition, blood samples were taken on day two, the day following vaccine administration, as it was thought local reactions would peak on this day. Injection site reactogenicity is not reported in a way that clarifies the peak time of reactions therefore this was an educated guess. Reactions actually peaked on the day of vaccination. It is possible that any elevations in cytokine levels may have waned by day two. Also, as many cytokines have localised activity it is possible that increased activity is not captured systemically. The fact that atopic score was associated with a range of cytokines supported that the assays were conducted successfully."

In Dr Helen Petousis-Harris' own words, "*as many cytokines have localised activity it is possible that increased activity is not captured systemically.*" Nevertheless, Dr. Helen Petousis-Harris managed to satisfy Dr. Nabae that she only measured the cytokines in the serum and found no increase of cytokines after HPV vaccination and her data did not really contradict the findings presented by their

[2] https://researchspace.auckland.ac.nz/handle/2292/10600

expert which confirmed increases in cytokines at the site of HPV vaccine injection. So both Dr. Nabae and Dr. Petousis-Harris decided to use "no increase in serum" as evidence for "*No elevation of any cytokine associated with reactogenicity*" as illustrated in the following email exchange.

From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz]
Sent: Tuesday, February 25, 2014 10:11 AM
To: 難波江 功二(nabae-koji)
Subject: RE: Doc and Video Conf

...yes, this was measured in human serum the day after vaccination – when the innate immune response and macrophages are at their busiest.

From: 難波江 功二(nabae-koji) [mailto:nabae-koji@mhlw.go.jp]
Sent: Tuesday, 25 February 2014 2:06 p.m.
To: Helen Petousis-Harris
Subject: RE: Doc and Video Conf

Great!! I understand this is in human serum. We will set the slides as I sent in my previous mail (change red color to black in page 2).
Thanks!!

1

Koji

In my opinion these emails clearly demonstrate that ***this group of WHO officials and government employees charged with the responsibility to advise the expert committee of the Japanese government on HPV vaccination safety knew before the February 26, 2014 Tokyo public hearing that one of their own experts showed scientific evidence that HPV vaccination does increase cytokines, including tumor necrosis factor (TNF), particularly at the injection site compared to other vaccines. Yet, they chose to suppress this information at the public hearing.*** Of course, this piece of scientific data which was known to all members of the group, including Dr Robert Pless, the chairperson of GACVS, is also missing from the GACVS Statement on the continued safety of HPV vaccination issued on March 12, 2014.

So why does HPV vaccination increase the level of cytokines, including TNF, at the site of injection compared to other vaccines?

The answer is: HPV vaccines contain HPV L1 gene DNA fragments, the viral DNA fragments, bound to aluminum adjuvants in the vaccines. To understand this, the members of the GACVS should keep up with the recent research and scientific publications on aluminum adjuvants. A brief summary on this subject with 22 key peer-reviewed references is presented as follows.

Use of Aluminum Adjuvant

Aluminum salts have been used as adjuvants in vaccination empirically to boost immune responses of the host to the protein antigens for many decades. However, the mechanism of the adjuvant effects of aluminum salts has only been recently investigated at the molecular level. It is now generally agreed in

the scientific community that aluminum salts used as adjuvants are toxic and always damage the cells of the host at the site of injection, causing a localized inflammation at the vaccination site. This initial cell damage by the aluminum salt is an essential and necessary step to initiate its adjuvant effects because the free host DNA molecules released from the aluminum salt-damaged host cells act as mediators to trigger augmented immune responses of the host [1, 2]. The free DNA molecules of the dying host cells, also referred to as damage-associated molecular patterns (DAMPs) [3] bind the aluminum salt adjuvant at the site of injection, and the resulting DNA/aluminum complexes are phagocytized by the antigen-presenting cells (APCs) and macrophages. It was known as early as 2003, that when bound to aluminum salts as nanoparticles, free DNA molecules undergo dramatic conformational changes and can be introduced into mammalian cells as a means of gene transfection [4]. In vaccination with aluminum adjuvants, the transfected host DNA activates the pathways that would increase their ability to interact productively with antigen-specific CD4 T cells to boost host immune responses [1, 2].

In plain language, free DNA derived from the dying host cells is needed to be carried by aluminum adjuvants into the APCs or macrophages to function as mediators for boosting immune responses in vaccination.

However, the presence of recombinant HPV L1-specific DNA fragments in the vaccine Gardasil® has disrupted this expected normal immunity response platform in vaccination. The HPV DNA molecules, being of a viral origin, are “non-self” microbial products, also referred to as pathogen-associated molecular patterns (PAMPs). The human body’s defense system can distinguish the PAMPs from the DAMPs in order to mount an appropriate immune response to either the presence of a pathogen or a tissue damage [3].

The amorphous aluminum hydroxyphosphate sulfate (AAHS) nanoparticles which are expected to bind the free host DNA at the site of vaccine injection can also bind the fragments of HPV L1 gene DNA present in the vaccine Gardasil® [5] through a ligand exchange process between the phosphate groups of the DNA molecule and the hydroxyl groups on the aluminum adjuvant surface, similar to a reaction between phospholipids and AAHS in the recombinant hepatitis B vaccine [6].

In other words, Gardasil® has been furnished with a set of ready-made instant DNA immune “mediators” already in the adjuvant, in the form of a viral DNA/aluminum chemical compound, specifically an HPV L1 gene DNA/AAHS complex. The downstream events after transfection into the human macrophages of these viral DNA fragments which are rarely found in the human genome [7] are quite different from those after the DNA of the dying host cells is introduced into the macrophages. Despite similarities between DNA molecules, mammalian cells have the remarkable ability to distinguish viral DNA from their own DNA. The human macrophages are able to recognize the HPV L1 gene DNA as a 'stranger' and a 'danger' signal, and in response produce many antiviral immune molecules, collectively referred to as type I interferons and pro-inflammatory cytokines [8-10].

Massive systemic production of these type I interferons and pro-inflammatory cytokines induces an antiviral state and protects the host, but it also can contribute to endotoxin lethality and autoimmune diseases [9]. Many of these cytokines are myocardial depressants. The two cytokines that show the greatest cardiovascular effects in animals and humans are tumor necrosis factor (TNF)-α and IL-1β [11].

Administration of recombinant TNF-α in animal models is known to cause hemodynamic changes and even death [11].

Injection of Gardasil® into animals has been shown to induce unusually early strong innate immune responses with quick releases of a variety of cytokines from the macrophages [12]. Injection of HPV DNA/AAHS complexes into the host is also known to induce a strong immune reaction and a strong CD8 T cell response [13]. Based on experiments with other viral DNA molecules, the recombinant HPV L1 gene DNA fragments transfected into human macrophages would also be recognized as "stranger" and "danger" signal, and invariably activate the macrophages to release numerous antiviral cytokines. Many of these cytokines, including TNF-α and IL-1β, are recognized myocardial depressants [14-18]. Hypotensive shock induced by TNF-α has been well documented among animals [19, 20] and humans [21, 22].

This brief review shows that there is a known molecular mechanism to explain why serious adverse reactions occur more often in people injected with HPV vaccines than with other vaccines, and why certain predisposed vaccinees may suffer a sudden unexpected death as the result of Gardasil® vaccination.

It is my opinion that Dr Pless, those whose names appeared in the emails attached to this complaint, and all who blindly dismiss the potential toxicity of the newly created HPV L1 gene DNA/AAHS compound in order to continue to promote HPV vaccinations should be held accountable for their actions. There is no excuse for intentionally ignoring the scientific evidence. There is no excuse for misleading global vaccination policy makers at the expense of public interest.

It is my contention these people have not only violated the Terms of Reference of the WHO Global Advisory Committee on Vaccine Safety (GACVS); they have violated the public trust. Immediate, independent and thorough investigations into their actions with appropriate disciplinary action is the only option available that might restore the public's confidence in worldwide health authorities.

Thank you for your attention to this matter.

Sincerely,

Sin Hang Lee, MD, F.R.C.P. (C), FCAP
Director
Milford Molecular Diagnostics Laboratory
2044 Bridgeport Avenue, Milford, CT 06460 USA
Email shlee01@snet.net

Attachments:
GACVS Terms of Reference
GACVS Statement on the continued safety of HPV vaccination on March 12, 2014
WHO GACVS emails from February 18, 2014 to February 27, 2014 in chronologic order
Original FOIA -Attachment obtained in New Zealand

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Studies and articles showing problems with vaccines

Nosocomial pertussis infection of infants: still a risk in 2009

Abstract

The Sydney West Centre for Population Health investigated a confirmed pertussis infection in a health care worker on a maternity ward and identified pertussis infection in 4 neonates cared for by this case. This report describes the public health intervention to identify and prevent further cases. Of the 4 neonates, three were laboratory-confirmed cases and one was diagnosed on clinical grounds alone. All were cared for by the infected worker during only one shift and developed symptoms six to 16 days afterwards. No other possible source of infection was identified. This investigation highlights the need to maintain awareness, particularly amongst staff working with neonates, that pertussis infection can arise despite complete vaccination. Thus it is important to investigate new coughing illnesses and exclude symptomatic staff from contact with neonates until pertussis infection is excluded or effectively treated. The burden on the health system arising from a pertussis infection in a health care worker in a high-risk setting is also described with the hospitalisation of 4 infants, and prophylactic antibiotics given to 73 new mothers, infants and health care workers. Commun Dis Intell 2010;34(4):440–443.

http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3404e.htm

This research suggests that although individuals immunized with an acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread infection to others, including young infants who are susceptible to pertussis disease.

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm376937.htm

Evolution of whooping cough bacterium could reduce vaccine effectiveness

“The bacterium that causes whooping cough, Bordetella pertussis, has changed – most likely in response to the vaccine used to prevent the disease – with a possible reduced effectiveness of the vaccine as a result, a new study shows.”

http://newsroom.unsw.edu.au/news/science/evolution-whooping-cough-bacterium-could-reduce-vaccine-effectiveness

Whooping cough beats vaccine

The strains have "swept across Australia during the epidemic period" according to Ruiting Lan, from the school of biotechnology and biomolecular sciences. More than 13,000 whooping cough cases were diagnosed in 2011 – an all-time high.

The Children's Hospital at Westmead treated 76 children for whooping cough in 2011, up from 47 the previous year. The Sydney Children's Hospital treated 34 children in 2011, up from 16 the previous year.

An acellular vaccine – introduced in Australia in 1997 after concerns about side-effects from the previous whole cell version – appeared to have promoted the spread of these variants, Dr Lan said, which overseas authorities had linked to "higher virulence on the basis of hospitalisation and case mortality data".

http://www.smh.com.au/national/health/whooping-cough-beats-vaccine-20120320-1vibp.html#ixzz2UqBYhk6H

Sharp rise in cases of new strain of whooping cough

21 March 2012

Australia's prolonged whooping cough epidemic has entered a disturbing new phase, with a study showing a new strain or genotype capable of evading the vaccine may be responsible for the sharp rise in the number of cases.

A team of Australian scientists, led by the University of New South Wales (UNSW), believe this emerging new genotype (called prn2-ptxP3) of the Bordetella pertussis bacterium may be evading the protective effects of the current acellular vaccine (ACV), and increasing the incidence of the potentially fatal respiratory illness, according to the study published in The Journal of Infectious Diseases.

"The genotype was responsible for 31 percent of cases in the 10 years before the epidemic, and that's now jumped to 84 percent – a nearly three-fold increase, indicating it has gained a selective advantage under the current vaccination regime."

http://newsroom.unsw.edu.au/news/health/sharp-rise-cases-new-strain-whooping-cough

The study, published in Emerging Infectious Disease, analysed 320 samples of Bordetella pertussis bacteria from patients with whooping cough from 2008 to 2012, with the proportion of pertactin-free bacteria jumping from 5 per cent in 2008 to 78 per cent in 2012.

Lead author Connie Lam said the "huge increase" in mutated bacteria, which has also been found in the US and France, was unexpected.

"The fact that they have arisen independently in different countries suggests it's a response to the vaccine," said Ms Lam, of the University of NSW School of Biotechnology and Biomolecular Sciences.

"It could also mean that these pertactin-free strains have gained a selective advantage over other bacteria, making it less obvious for the body to find and destroy."

http://www.smh.com.au/national/health/whooping-cough-vaccine-loses-its-effectiveness-20140414-36np3.html

Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model

http://www.ncbi.nlm.nih.gov/pubmed/?term=24277828

Waning Protection after Fifth Dose of Acellular Pertussis Vaccine in Children

http://www.nejm.org/doi/full/10.1056/NEJMoa1200850?query=featured_home&#t=articleDiscussion

Study: Whooping cough outbreak linked to vaccinated children

http://digitaljournal.com/article/323187

Why Whooping Cough Is Rising Despite a New Vaccine

http://www.webmd.com/children/vaccines/features/whooping-cough-rising-despite-new-vaccine

Acellular pertussis vaccination enhances B. parapertussis colonization

http://www.cidd.psu.edu/research/synopses/acellular-vaccine-enhancement-b.-parapertussis

Immunized People Getting Whooping Cough, Experts Spar Over New Strain

http://www.kpbs.org/news/2010/dec/14/immunized-people-getting-whooping-cough-experts-sp/

Study: Whooping cough vaccination fades in 3 years

http://news.yahoo.com/study-whooping-cough-vaccination-fades-3-years-150528753.html

The vaccine being used/promoted for pregnant women.

ADACEL® PRODUCT INFORMATION

Carcinogenicity, mutagenicity, impairment of fertility

ADACEL® has not been evaluated for carcinogenicity, mutagenicity or impairment of fertility.

Use in pregnancy (Category B2)

The effect of ADACEL® on the development of the embryo and foetus has not been assessed. Vaccination in pregnancy is not recommended unless there is a definite risk of acquiring pertussis. As the vaccine is detoxified, risk to the embryo or the foetus is highly improbable. The benefits versus the risks of administering ADACEL® in pregnancy should carefully be evaluated when there is a high probable risk of exposure to a household contact or during an outbreak in the community.

Use in lactation

The effect of administration of ADACEL® during lactation has not been assessed. As ADACEL® is detoxified, any risk to the mother or the infant is highly improbable. The benefits versus the risks of administering ADACEL® during lactation should carefully be evaluated by the health-care provider, particularly when there is a high probable risk of disease transmission through exposure to a household contact, or during an outbreak in the community. The risks of disease transmission from the infected mother to the infant who may not have been fully immunised should also be evaluated.

http://www.public.health.wa.gov.au/cproot/3580/2/adacel_PI.pdf

The aim of this study was to investigate a previously overlooked, universally introduced environmental factor, fetal and retroviral contaminants in childhood vaccines, absent prior to change points (CPs) in autistic disorder (AD) prevalence with subsequent dose-effect evidence and known pathologic mechanisms of action. Worldwide population based cohort study was used for the design of this study.

The United States, Western Australia, United Kingdom and Denmark settings were used. All live born infants who later developed autistic disorder delivered after 1 January 1970, whose redacted vaccination and autistic disorder diagnosis information is publicly available in databases maintained by the US Federal Government, Western Australia, UK, and Denmark. The live births, grouped by father's age, were from the US and Australia. The children vaccinated with MMRII, Varicella and Hepatitis A vaccines varied from 19 to 35 months of age at the time of vaccination. Autistic disorder birth year change points were identified as 1980.9, 1988.4 and 1996 for the US, 1987 for UK, 1990.4 for Western Australia, and 1987.5 for Denmark. Change points in these countries corresponded to introduction of or increased doses of human fetal cell line-manufactured vaccines, while no relationship was found between paternal age or Diagnostic and Statistical Manual (DSM) revisions and autistic disorder diagnosis. Further, linear regression revealed that Varicella and Hepatitis A immunization coverage was significantly correlated to autistic disorder cases. R software was used to calculate change points.

Autistic disorder change points years are coincident with introduction of vaccines manufactured using human fetal cell lines, containing fetal and retroviral contaminants, into childhood vaccine regimens.

This pattern was repeated in the US, UK, Western Australia and Denmark. Thus, rising autistic disorder prevalence is directly related to vaccines manufactured utilizing human fetal cells. Increased paternal age and DSM revisions were not related to rising autistic disorder prevalence.

http://www.ms.academicjournals.org/article/article1409245960_Deisher%20et%20al.pdf

Exposure to Mercury and Aluminum in Early Life: Developmental Vulnerability as a Modifying Factor in Neurologic and Immunologic Effects

http://www.mdpi.com/1660-4601/12/2/1295

Review of Vaccine Induced Immune Overload and the Resulting Epidemics of Type 1 Diabetes and Metabolic Syndrome, Emphasis on Explaining the Recent Accelerations in the Risk of Prediabetes and other Immune Mediated Diseases

http://www.omicsonline.com/open-access/vaccine-induced-immune-overload-and-the-resulting-epidemics-of-type-diabetes-and-metabolic-syndrome-1747-0862.S1-025.php?aid=24058

Recombinant hepatitis B vaccine and the risk of multiple sclerosis

http://www.neurology.org/content/63/5/838.abstract

Autoimmunity following hepatitis B vaccine as part of the spectrum of 'Autoimmune (Auto-inflammatory) Syndrome induced by Adjuvants' (ASIA): analysis of 93 cases.

http://www.ncbi.nlm.nih.gov/pubmed/22235045

'ASIA' – Autoimmune/inflammatory syndrome induced by adjuvants

http://www.sciencedirect.com/science/article/pii/S0896841110000788

Pertussis adjuvant prolongs intestinal hypersensitivity.

http://www.ncbi.nlm.nih.gov/pubmed/10436392?dopt=Abstract

Relative trends in hospitalizations and mortality among infants by the number of vaccine doses and age, based on the Vaccine Adverse Event Reporting System (VAERS), 1990–2010

http://het.sagepub.com/content/31/10/1012.full

Comparison of VAERS fetal-loss reports during three consecutive influenza seasons: was there a synergistic fetal toxicity associated with the two-vaccine 2009/2010 season?

Abstract

The aim of this study was to compare the number of inactivated-influenza vaccine-related spontaneous abortion and stillbirth (SB) reports in the Vaccine Adverse Event Reporting System (VAERS) database during three consecutive flu seasons beginning 2008/2009 and assess the relative fetal death reports associated with the two-vaccine 2009/2010 season. The VAERS database was searched for reports of fetal demise following administration of the influenza vaccine/vaccines to pregnant women. Utilization of an independent surveillance survey and VAERS, two-source capture-recapture analysis estimated the reporting completeness in the 2009/2010 flu season. Capture-recapture demonstrated that the VAERS database captured about 13.2% of the total 1321 (95% confidence interval (CI): 815-2795) estimated reports, yielding an ascertainment-corrected rate of 590 fetal-loss reports per million pregnant women vaccinated (or 1 per 1695). The unadjusted fetal-loss report rates for the three consecutive influenza seasons beginning 2008/2009 were 6.8 (95% CI: 0.1-13.1), 77.8 (95% CI: 66.3-89.4), and 12.6 (95% CI: 7.2-18.0) cases per million pregnant women vaccinated, respectively. The observed reporting bias was too low to explain the magnitude increase in fetal-demise reporting rates in the VAERS database relative to the reported annual trends. Thus, a synergistic fetal toxicity likely resulted from the administration of both the pandemic (A-H1N1) and seasonal influenza vaccines during the 2009/2010 season

http://www.ncbi.nlm.nih.gov/pubmed/23023030

"Doctors and researchers point to the worsening state of health of the child population since the 1960s, which coincided with increasingly introduced vaccinations. Allergic diseases, including asthma, autoimmune diseases, diabetes and many neurological dysfunctions – difficulty in learning, ADD (attention deficit disorder), ADHD (attention deficit hyperactivity disorder), seizures, and autism – are chronic conditions, to which attention has been brought."

http://www.greenmedinfo.com/blog/no-historical-benefit-vaccines-polish-study

“The Shanghai study, based on reported pediatric adverse drug reactions (ADRs) for 2009, found that 42 percent were caused by vaccines, with reactions ranging from mild skin rashes to deadly reactions like anaphylaxis and death. Of all the drugs causing adverse reactions among children, vaccines are the most commonly reported.

This study is particularly significant because the vast majority of reports came from physicians, pharmacists, and other health care providers. Less than three percent of the reports were from consumers.”

http://www.theepochtimes.com/n3/644090-study-vaccines-cause-children-more-adverse-reactions-than-any-other-drug/?sidebar=related-below

Mumps outbreak in a highly vaccinated school population. Evidence for large-scale vaccination failure.

Abstract

OBJECTIVES:

To describe an outbreak and to identify risk factors for mumps occurring in a highly vaccinated high school population. (Note: Highly vaccinated means a population in which more than 95% have been vaccinated.)

CONCLUSIONS:

The overall attack rate is the highest reported to date (and to our knowledge) for a population demonstrating virtually complete mumps vaccine coverage. Even verified documentation of vaccination may not be an accurate indicator of an individual's protection against mumps. Vaccination failure may play an important role in contemporary mumps outbreaks. We found no evidence to indicate that waning immunity (secondary vaccine failure) contributed significantly to this outbreak. A second dose of mumps vaccine, as recommended using measles-mumps-rubella vaccine, could potentially prevent similar outbreaks in secondary school populations in the future.

http://www.ncbi.nlm.nih.gov/pubmed/7795768

Sustained Transmission of Mumps in a Highly Vaccinated Population: Assessment of Primary Vaccine Failure and Waning Vaccine-Induced Immunity

http://jid.oxfordjournals.org/content/169/1/77.short

A prolonged mumps outbreak among highly vaccinated Aboriginal people in the Kimberley region of Western Australia

https://www.mja.com.au/journal/2009/191/7/prolonged-mumps-outbreak-among-highly-vaccinated-aboriginal-people-kimberley

Epidemiology of a Mumps Outbreak in a Highly Vaccinated Island Population and Use of a Third Dose of Measles-Mumps-Rubella Vaccine for Outbreak Control- Guam 2009-2010.

http://www.ncbi.nlm.nih.gov/pubmed/23099425

http://www.opposingviews.com/i/health/third-us-mumps-outbreak-new-jersey-patients-were-vaccinated

Mumps outbreak in Orthodox Jewish communities in the United States Update: Mumps Outbreak --- New York and New Jersey, June 2009--January 2010

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5905a1.htm

Mumps outbreak in Israel's highly vaccinated society: are two doses enough?

http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=8480501

Mumps outbreak in a highly vaccinated population

http://www.sciencedirect.com/science/article/pii/S0022347605807267

Increased female-male mortality ratio associated with inactivated polio and diphtheria-tetanus-pertussis vaccines: Observations from vaccination trials in Guinea-Bissau.

Abstract

BACKGROUND:

The 2-fold increase in female mortality after high-titer measles vaccine may have occurred because many children received diphtheria-tetanus-pertussis (DTP) vaccine or inactivated polio vaccine (IPV) after high-titer measles vaccine.

OBJECTIVE:

We examined whether DTP vaccine and IPV were associated with increased female mortality when they were the most recent vaccine administered to children who had not received measles vaccine. Setting and Design: IPV was used as a control vaccine in 4 randomized trials of early measles vaccination (MV) with enrollment at 4-6 months of age conducted in Guinea-Bissau. Many children had not received all 3 DTP vaccinations before enrollment, and therefore received DTP after IPV or MV. We examined whether DTP vaccination status at enrollment affected the female-male mortality ratio. Population: 9544 children enrolled in 4 trials. Main outcome measure: The female-male mortality ratio in different vaccine groups.

RESULTS:

Females had a higher mortality rate than males among children randomized to receive IPV (mortality rate ratio [MR] 1.52, 95% CI 1.02-2.28), but females had a similar mortality rate to males among children randomized to receive MV (MR 1.01, 0.69-1.46) and among children in the IPV group after they had received MV at 9 months of age or later (MR 0.88, 0.68-1.14). Children who had not received a third dose of DTP before enrollment (and were likely to receive DTP after MV or IPV) tended to have a higher mortality than children who had received all 3 doses of DTP (MR 1.30, 0.97-1.73). This effect was seen only among girls (MR 1.61, 1.08-2.40) and not among boys (MR 1.02, 0.67-1.54). Girls had a lower mortality when MV was the most recent vaccine received rather than DTP or IPV (MR 0.49, 0.28-0.87).

CONCLUSIONS:

Randomization to IPV was associated with higher female than male mortality. However, the increased female mortality might result from additional doses of DTP received after enrollment and before measles vaccination.

http://www.ncbi.nlm.nih.gov/pubmed/17484223

"Varicella vaccination is less effective than the natural immunity that existed in prevaccine communities. Universal varicella vaccination has not proven to be cost-effective as increased HZ (Shingles increased because of vaccine) morbidity has disproportionately offset cost savings associated with reductions in varicella disease. Universal varicella vaccination has failed to provide long-term protection from VZV disease." 2013 PMID: 20642419

http://www.ncbi.nlm.nih.gov/pubmed/22659447

Chickenpox Attributable to a Vaccine Virus Contracted From a Vaccinee With Zoster

ABSTRACT

Five months after 2 siblings were immunized with varicella vaccine, 1 developed zoster. Two weeks later the second sibling got a mild case of chicken pox. Virus isolated from the latter was found to be vaccine type. Thus, the vaccine strain was transmitted from the vaccinee with zoster to his sibling. Vaccinees who later develop zoster must be considered contagious. varicella-zoster, zoster, vaccine, transmission, rash, PstI.

http://www.ncbi.nlm.nih.gov/pubmed/10920184

Chicken Pox vaccine associated with Shingles Epidemic

New research published in the International Journal of Toxicology (IJT) by Gary S. Goldman, Ph.D., reveals high rates of shingles (herpes zoster) in Americans since the government's 1995 recommendation that all children receive chicken pox vaccine.

Goldman's research supports that shingles, which results in three times as many deaths and five times the number of hospitalizations as chicken pox, is suppressed naturally by occasional contact with chicken pox.

Dr. Goldman's findings have corroborated other independent researchers who estimate that if chickenpox were to be nearly eradicated by vaccination, the higher number of shingles cases could continue in the U.S. for up to 50 years; and that while death rates from chickenpox are already very low, any deaths prevented by vaccination will be offset by deaths from increasing shingles disease. Another recent peer-reviewed article authored by Dr. Goldman and published in Vaccine presents a cost-benefit analysis of the universal chicken pox (varicella) vaccination program. Goldman points out that during a 50-year time span, there would be an estimated additional 14.6 million (42%) shingles cases among adults aged less than 50 years, presenting society with a substantial additional medical cost burden of $4.1 billion. This translates into $80 million annually, utilizing an estimated mean healthcare provider cost of $280 per shingles case.

After a child has had varicella (chickenpox), the virus becomes dormant and can reactivate later in adulthood in a closely related disease called shingles--both caused by the same varicella-zoster virus (VZV). It has long been known that adults receive natural boosting from contact with children infected with chicken pox that helps prevent the reactivation of shingles.

Based on Dr. Goldman's earlier communications with the Centers for Disease Control and Prevention (CDC), Goldman maintains that epidemiologists from the CDC are hoping "any possible shingles epidemic associated with the chickenpox vaccine can be offset by treating adults with a 'shingles' vaccine." This intervention would substitute for the boosting adults previously received naturally, especially during seasonal outbreaks of the formerly common childhood disease.

"Using a shingles vaccine to control shingles epidemics in adults would likely fail because adult vaccination programs have rarely proved successful," said Goldman. "There appears to be no way to avoid a mass epidemic of shingles lasting as long as several generations among adults."

http://www.news-medical.net/news/2005/09/01/12896.aspx

Chickenpox Outbreak in a Highly Vaccinated School Population

http://pediatrics.aappublications.org/content/113/3/455.abstract

Diphtheria-tetanus-pertussis vaccine has negative non-specific and sex-differential effects on child survival in high-mortality countries

http://www.cviva.dk/~/media/Projekt%20sites/CVIVA/pdf/publications/Aaby_etal_2012.ashx

"Vaccine use did not affect the number of people hospitalised or working days lost but caused one case of Guillian-Barré syndrome (a major neurological condition leading to paralysis) for every one million vaccinations. Fifteen of the 36 trials were funded by vaccine companies and four had no funding declaration. Our results may be an optimistic estimate because company-sponsored influenza vaccines trials tend to produce results favorable to their products and some of the evidence comes from trials carried out in ideal viral circulation and matching conditions and because the harms evidence base is limited.."

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001269.pub4/abstract

Virus in the system

What followed has shaken public confidence in one of the world's most popular immunisation programs. In April last year, four days after baby Saba had her flu shot, Australia's Chief Medical Officer, Professor Jim Bishop, made the unprecedented decision to ban nationally all the seasonal flu vaccines for the under-5s. Fluvax, the predominant vaccine, was triggering febrile fits in one in every 100 children – 10 times the expected rate. The side-effects, in some cases, were severe, and no-one could explain what had caused them. As the mystery continues, even eminent scientists and medical specialists are now quibbling over the efficacy of flu vaccines, how they are tested and how well they are monitored. With another flu season upon us and the medical community divided, what are we, the public, to make of it all?

Eleven days before Saba received her seasonal flu shot, across the continent in Brisbane, a family was in shock. David and Nicole Epapara had vaccinated their healthy twin toddlers, two-year-old sisters Ashley and Jaime, at 3pm on April 8. At midnight, Jaime vomited in her cot, while Ashley slept peacefully. When Jaime woke the next morning, her twin lay dead. "We don't know whether it was the vaccination or some other cause," David Epapara told The Australian a few weeks later. "It just seems too much of a coincidence, that's all, for a healthy girl to pass away like that. We're so shocked, we don't know what to think."

Nor does Brisbane Coroner John Lock, who was unable to determine a cause of death after a five-month investigation. "There was no finding to causally connect the young child's death with the flu vaccination," he said. "However, I have concluded that a link between the vaccination and the death cannot be absolutely excluded."

The child's death should have set off alarm bells, but Queensland Health had initially failed to investigate the case because Ashley did not die in a hospital, and the suburban GP who inoculated her had not notified authorities of any possible link with the flu shot.

http://www.theaustralian.com.au/news/features/virus-in-the-system/story-e6frg8h6-1226063484330

http://www.dailytelegraph.com.au/news/nsw/toddler-who-was-given-an-adult-flu-shot-is-left-severely-brain-damaged-and-unable-to-walk-or-talk/story-fni0cx12-1226756398505

http://www.theaustralian.com.au/news/nation/flu-jab-meant-to-help-so-why-did-ashley-die/story-e6frg6nf-1225860820954

Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination

Summary

Premature ovarian failure in a well adolescent is a rare event. Its occurrence raises important questions about causation, which may signal other systemic concerns. This patient presented with amenorrhoea after identifying a change from her regular cycle to irregular and scant periods following vaccinations against human papillomavirus. She declined the oral contraceptives initially prescribed for amenorrhoea. The diagnostic tasks were to determine the reason for her secondary amenorrhoea and then to investigate for possible causes of the premature ovarian failure identified. Although the cause is unknown in 90% of cases, the remaining chief identifiable causes of this condition were excluded. Premature ovarian failure was then notified as a possible adverse event following this vaccination. The young woman was counselled regarding preservation of bone density, reproductive implications and relevant follow-up. This event could hold potential implications for population health and prompts further inquiry.

http://casereports.bmj.com/content/2012/bcr-2012-006879.abstract

Death after quadrivalent human papillomavirus (qHPV) vaccination: Causal or coincidental?

Abstract:

Herein reported is the case of a 15-year-old female without a relevant medical history, who developed severe headaches, speech problems, dizziness, weakness, inability to walk, depressed consciousness, confusion, amnesia and vomiting, 14 days after receiving her first qHPV vaccine injection. After the second vaccine booster, her symptoms worsened and she expired 15 days later. Autopsy revealed cerebral oedema and cerebellar herniation indicative of a focally disrupted blood-brain barrier.

There was no evidence of an active brain infection. Immunohistochemistry (IHC) examination of the brainstem, hippocampus and the cerebellum showed prominent infiltration of T-lymphocytes and macrophages in all brain areas examined. Notably, marked activation of the complement membrane attack complex (MAC) was detected in the cerebellar Purkinje cells, hippocampal neurons and portions of the brainstem. This pattern of MAC activation in the absence of an active brain infection indicates an abnormal triggering of the immune response in which the immune attack is directed towards self-tissue. Elevation of the pro-inflammatory IL-1 cytokine and intense micro- and astrogliosis were also evident in the patient's brain. Altogether these observations strongly indicate that the acute neuronal damage resulting in patient's death was due to an aberrant/excessive

autoimmune and inflammatory response triggered by the vaccinations she received. Both the timing of the onset of symptoms as well as their nature, are consistent with previous case reports where causality between vaccination and the ensuing brain damage and/or death, was either demonstrated or strongly suspected. It thus appears that in some cases vaccination may be the triggering factor of fatal autoimmune/neurological events and physicians should be aware of this association.

http://www.naturpedia.info/vaccini/cancro_utero_vaccino=morte.pdf

New Delhi, August 7

For the first time since 2010 when six tribal girls from Gujarat and Andhra Pradesh involved in the clinical trials of anti-cervical cancer HPV vaccine died, the government has admitted that 1,725 persons have lost their lives to drug trials in the last four years.

http://www.tribuneindia.com/2011/20110808/main1.htm

Gardasil in court: drug's maker sued

A MELBOURNE woman who suffered an auto-immune and neurological attack after being injected with the cervical cancer drug Gardasil is leading a class action against its manufacturer.

And another seven Victorian women who are considering joining the court case against Gardasil manufacturer Merck, say they have suffered anaphylaxis and physical breakdowns as a result of the vaccine.

One attributed her miscarriage in her local supermarket to the injections.

Naomi Snell, 28, said her life was put on hold for more than two years after she lost the ability to walk, battled crippling back and neck pain, and suffered convulsions that started soon after her first injection in July 2008.

"I never attributed it to my vaccine so I went back for my second and third dose," Ms Snell said.

"My doctors said I was a case for Dr House. They were baffled.

"They did actually diagnose me with Multiple Sclerosis, but have since retracted that and said it was just a neurological reaction to the vaccine."

It wasn't until she read an article about a Sydney neurologist uncovering Gardasil as a potential cause of MS-like symptoms in other women that she made a timeline of her deterioration from reports from her doctors and physiotherapist.

http://www.couriermail.com.au/ipad/gardasil-in-court-drugs-maker-sued/story-fn6ck51p-1226174052656

Japan Withdraws HPV Vaccine Recommendation for Girls

http://www.medscape.com/viewarticle/806645

Human papilloma virus vaccine and primary ovarian failure: another facet of the autoimmune/inflammatory syndrome induced by adjuvants.

http://www.ncbi.nlm.nih.gov/pubmed/23902317

Demyelinating diseases:

Demyelinating disease and vaccination of the human papillomavirus

http://www.ncbi.nlm.nih.gov/pubmed/21425100

CNS demyelination and quadrivalent HPV vaccination.

http://www.ncbi.nlm.nih.gov/pubmed/18805844

Demyelinating disease and polyvalent human papilloma virus vaccination.

http://jnnp.bmj.com/content/early/2010/10/08/jnnp.2010.214924.extract

ALS:

2 ALS Cases May Be Linked to Gardasil Vaccine

http://www.webmd.com/sexual-conditions/hpv-genital-warts/news/20091016/rare-disease-may-be-linked-vaccine

Report of Motor Neuron Disease After HPV Vaccine

http://www.medscape.com/viewarticle/711461

Guilain-Barré Syndrome:

Guillain-Barré syndrome after Gardasil vaccination: data from Vaccine Adverse Event Reporting System 2006-2009.

http://www.ncbi.nlm.nih.gov/pubmed/20869467

POTS and sympathetic nerve dysfunction:

Postural tachycardia syndrome following human papillomavirus vaccination

http://www.ncbi.nlm.nih.gov/pubmed/24102827

Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization with the Human Papillomavirus Vaccine

http://www.ncbi.nlm.nih.gov/pubmed/25274229

Lupus:

Human papillomavirus vaccine and systemic lupus erythematosus.

http://www.ncbi.nlm.nih.gov/pubmed/23624585

Systemic lupus erythematosus following HPV immunization or infection?

http://www.ncbi.nlm.nih.gov/pubmed/22235047

Uveitis:

Human papilloma virus vaccine associated uveitis.

Death:

Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental?

HPV vaccination is advertised as preventive for cervical cancer, but it has never been proven to prevent cancer. It has been shown to decrease the incidence of precancerous lesions in limited studies provided by the manufacturer, many of which would have resolved spontaneously or with treatment. Merck's efficacy studies show Gardasil to reduce the number of people who have early lesions related to the targeted subtypes, if they are first screened to rule out prior infection (PCR and seronegativity). Without that screening, the stats aren't so good. Efficacy drops from better than 95% to around 50% in girls and women. Also, efficacy for preventing anal lesions in men isn't great, around 75%, even with prior screening and dropping to 50% without. Penile lesions are reduced by only 20% with screening and not at all without (very small numbers). The efficacy for preventing all HPV disease without prior screening was a dismal 18% in women and 25% in men.

The Gardasil 9 prescribing information clearly states that the vaccine has “not been evaluated for the potential to cause carcinogenicity or genotoxicity”. Why might this be a concern?

The immunogenic component of the HPV vaccine is the L1 capsid protein produced by a recombinant Sacchyromyces yeast. The L1 protein is a self assembling capsid protein, producing a VLP (virion like particle), capsid without DNA, also known as a pseudovirion. This sounds well and good, but it turns out the vaccine does contain not only L1 protein, but L1 DNA. When confronted with this little whoops, the FDA didn’t even deny it: FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk. But…

Topological conformational changes of human papillomavirus (HPV) DNA bound to an insoluble aluminum salt—A study by low temperature PCR

A low temperature (LoTemp®) polymerase chain re- action (PCR), conducted at cycling temperatures not to exceed 85°C and catalyzed by a novel highly processive HiFi® DNA polymerase with proofreading function, was used to study the topological conformational changes of the human papillomavirus (HPV) L1 gene DNA fragments bound to the insoluble amorphous aluminum hydroxyphosphate sulfate (AAHS) adjuvant in the quadrivalent HPV vaccine, Gardasil®…

This melting profile of the HPV-16 L1 gene DNA was similar to that of the HPV-16 L1 gene DNA recently discovered in the postmortem blood of a young woman who suffered a sudden unexpected death 6 months after Gardasil® vaccination. The findings suggest that the topological conformational changes in the HPV L1 gene DNA residues bound to the AAHS adjuvant may be genotype-related. The special non-B-conformation may prevent the HPV-16 L1 gene DNA from being degraded in the body of the vaccine recipients after intramuscular injection.

Non-B DNA conformations, mutagenesis and disease.

Recent discoveries have revealed that simple repeating DNA sequences, which are known to adopt non-B DNA conformations (such as triplexes, cruciforms, slipped structures, left-handed Z-DNA and tetraplexes), are mutagenic. The mutagenesis is due to the non-B DNA conformation rather than to the DNA sequence per se in the orthodox right-handed Watson-Crick B-form. The human genetic consequences of these non-B structures are approximately 20 neurological diseases, approximately 50 genomic disorders (caused by gross deletions, inversions, duplications and translocations), and several psychiatric diseases involving polymorphisms in simple repeating sequences. Thus, the

convergence of biochemical, genetic and genomic studies has demonstrated a new paradigm implicating the non-B DNA conformations as the mutagenesis specificity determinants, not the sequences as such.

Simply put, Gardasil contains fragments of HPV DNA bound to an aluminum adjuvant, creating a brand new chemical compound with a conformation that is known to be mutagenic.

Dr. Sin Hang Lee found it in samples of Gardasil from all over the world. He reported at a conference in France in 2014,

I have tested 16 samples of the HPV vaccine Gardasil, each of different lot number, from 9 countries, and found that they all contained fragments of residual HPV DNA, namely viral DNA which was used to manufacture the HPV vaccine antigens by a genetic engineering technology.

Furthermore, the viral DNA fragments in a non-B conformation were firmly bound to the aluminum adjuvant in the vaccine by ligand exchange, an inadvertently created chemical compound containing viral DNA which can be transfected into the host cells, namely the human phagocytes and macrophages.

Based on established research, this viral DNA can activate the innate immune system of the macrophages to generate and release cytokines, including tumor necrosis factor in the vaccine recipients.

In certain genetically predisposed individuals, the level of tumor necrosis factor may be high enough to cause hypotension, fainting, tachycardia, unexpected sudden death and acute disseminated encephalomyelitis, namely adverse reactions which have been documented following Gardasil vaccination.

In addition, capsid protein (L1 protein) activates signal transduction. Receptors for capsid are present on most cells, including lymphoid cells. Hypothetically, the L1 protein could package the L1 DNA and gain entrance to the lymphoid cells. Once inside the cell, the L1 DNA could make an unlimited supply of L1 protein, causing disrupted immune cell behavior and abnormal proliferation.

Cellular Entry of Human Papillomavirus Type 16 Involves Activation of the Phosphatidylinositol 3-Kinase/Akt/mTOR Pathway and Inhibition of Autophagy

We recently showed that human papillomavirus (HPV) type 16 exposure activates signaling from GFRs in human keratinocytes. Thus, we predicted that the virus would induce the PI3K/mTOR pathway upon interaction with host cells. We detected activation of Akt and mTOR several minutes following exposure of human keratinocytes to HPV type 16 (HPV16) pseudovirions. Activated mTOR induced phosphorylation of the mTOR complex 1 substrates 4E-BP1 and S6K, which led to induction of the functional protein translational machinery… In summary, the HPV-host cell interaction stimulates the PI3K/Akt/mTOR pathway and inhibits autophagy, and in combination these events benefit virus infection.

In other words, could the HPV vaccine, designed to prevent cancer, actually promote it, even without infection by wild type HPV viruses?

Sudden infant death following hexavalent vaccination: a neuropathologic study.

http://www.ncbi.nlm.nih.gov/pubmed/24083600

Sudden infant death syndrome (SIDS) shortly after hexavalent vaccination: another pathology in suspected SIDS?

http://www.ncbi.nlm.nih.gov/pubmed/16231176

Aluminum vaccine adjuvants: are they safe?

http://www.ncbi.nlm.nih.gov/pubmed/21568886

Interview with PhD Immunologist, Dr Tetyana Obukhanych

http://www.vaccinationcouncil.org/2012/06/13/interview-with-phd-immunologist-dr-tetyana-obukhanych-by-catherine-frompovich/

http://www.vaccinationcouncil.org/2012/06/20/an-interview-with-research-immunologist-tetyana-obukhanych-phd-part-2/

http://www.vaccinationcouncil.org/2012/07/05/an-interview-with-research-immunologist-tetyana-obukhanych-phd-part-3-of-3-catherine-frompovich/

Herpes zoster after varicella-zoster vaccination

Abstract

A five-year-old girl, vaccinated against varicella-zoster virus (VZV) presented with clinical symptoms of herpes zoster in the 6th cervical dermatome. A VZV direct immune-fluorescence assay was negative three times but additional genotypical analysis showed a VZV strain genotype 2 (Oka vaccine strain). Therefore the diagnosis of a breakthrough varicella disease with the vaccine strain was established. An immunodeficiency was ruled out and the patient responded well to the initiated therapy. This case demonstrates that a negative VZV direct immunofluorescence assay does not exclude an infection with the vaccine strain.

http://www.ncbi.nlm.nih.gov/pubmed/23358727

"The review showed that reliable evidence on influenza vaccines is thin but there is evidence of widespread manipulation of conclusions and spurious notoriety of the studies. The content and conclusions of this review should be interpreted in the light of this finding."

"It was surprising to find only one study of inactivated vaccine in children under two years, given current recommendations to vaccinate healthy children from six months of age in the USA, Canada, parts of Europe and Australia. If immunisation in children is to be recommended as a public health policy, large-scale studies assessing important outcomes, and directly comparing vaccine types are urgently required. The degree of scrutiny needed to identify all global cases of potential harms is beyond the resources of this review."

"The review authors found that in children aged from two years, nasal spray vaccines made from weakened influenza viruses were better at preventing illness caused by the influenza virus than injected vaccines made from the killed virus. Neither type was particularly good at preventing 'flu-like illness' caused by other types of viruses. In children under the age of two, the efficacy of inactivated vaccine was similar to placebo. It was not possible to analyse the safety of vaccines from the studies due to the lack of standardisation in the information given, but very little information was found on the safety of inactivated vaccines, the most commonly used vaccine in young children."

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004879.pub4/abstract;jsessionid=ECC69035877BDE2A22362F742DCA056C.d04t04

Flu Vaccines in elderly

"The available evidence is of poor quality and provides no guidance regarding the safety, efficacy or effectiveness of influenza vaccines for people aged 65 years or older. To resolve the uncertainty, an adequately powered publicly-funded randomised, placebo-controlled trial run over several seasons should be undertaken."

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004876.pub3/abstract

2010 Swine flu vaccine debacle

Peter Collignon, professor of microbiology at the Australian National University and director of infectious diseases at Canberra Hospital, believes last year's flu vaccine might have caused more harm than good in ¬otherwise healthy children. Awarded a Member of the Order of Australia last year for his work in clinical microbiology, infectious diseases and infection control, he has been taken aback by the controversy his comments created within the medical community. Citing data from NSW Health, he has found that the risk of a healthy child or teenager dying from swine flu in 2009, before a vaccine was available, was less than one in two million for those without underlying health problems such as asthma or heart disease.

"To stop two or three children going to intensive care we had to immunise 600,000 people," he says. "We need to be very careful before we recommend universal vaccination against influenza every year until we have better data. Otherwise we're talking about faith-based medicine, instead of evidence-based medicine."

"The 2009 version of Fluvax was not tested in children, Greenberg explains, because "it is not routine to do clinical trials in children, it's not required". (Australian health authorities do not require clinical trials of the seasonal flu vaccine on the grounds that four decades of use have not revealed any safety issues, and it would slow down production. But clinical trials for children are required in Europe.) Yet a scientific paper published in October 2009 reveals that a previous version of the vaccine, which did not include the swine flu strain, had been linked to the hospitalisation of two of the 298 children tested in a clinical trial in Melbourne and Perth four years earlier. Its co-authors were Professor Terry Nolan – the Federal Government's chief adviser on vaccines – and Dr Peter Richmond, a fellow adviser who headed vaccine trials at the hospital where Saba was treated. Neither would be interviewed, but CSL's Greenberg insists the results were not a "red flag" for severe side-effects."

"Collignon has also upset the nation's top medico by suggesting that regular flu shots for healthy people could weaken their natural immunity against any new wildfire influenza. but Collignon's view has a foothold within the scientific community. Research from Canada and Hong Kong indicates that people who received a seasonal flu vaccine in 2008 had double the risk of contracting swine flu when the pandemic struck a year later."

"Epidemiologist John Mathews, from the School of Population Health at the University of Melbourne and a former senior adviser to the federal Health Department, agrees that natural infection with the flu grants broader immunity than vaccination. "Seasonal vaccines do not boost the broadly reactive protection that can be induced by infection with live virus. We need more research to better understand the interactions between the immunity induced by natural infection with seasonal virus, and that induced by vaccination."

http://www.abc.net.au/news/2011-03-04/vaccines-may-have-increased-swine-flu-risk/1967508

Neuromuscular disorders associated with Hepatitis B vaccination.

http://www.ncbi.nlm.nih.gov/pubmed/20207367

Multiple sclerosis and hepatitis B vaccination: could minute contamination of the vaccine by partial hepatitis B virus polymerase play a role through molecular mimicry?

http://www.ncbi.nlm.nih.gov/pubmed/15908138

Multiple sclerosis and hepatitis B vaccination: adding the credibility of molecular biology to an unusual level of clinical and epidemiological evidence.

http://www.ncbi.nlm.nih.gov/pubmed/16176857

Acquired autoimmunity after viral vaccination is caused by molecular mimicry and antigen complimentarity in the presence of an immunologic adjuvant and specific HLA patterns.

http://www.ncbi.nlm.nih.gov/pubmed/17630224

Autoimmune hazards of hepatitis B vaccine.

http://www.ncbi.nlm.nih.gov/pubmed/15722255

Multiple sclerosis after hepatitis B vaccination in a 16-year-old patient

http://www.cmj.org/periodical/PaperList.asp?id=LW8451

Recombinant hepatitis B vaccine and the risk of multiple sclerosis

A prospective study

http://www.neurology.org/content/63/5/838.abstract

Acellular pertussis vaccination enhances B. parapertussis colonization

An acellular whooping cough vaccine actually enhances the colonization of Bordetella parapertussis in mice; pointing towards a rise in B. parapertussis incidence resulting from acellular vaccination, which may have contributed to the observed increase in whooping cough over the last decade.

http://www.cidd.psu.edu/research/synopses/acellular-vaccine-enhancement-b.-parapertussis

Invasive pneumococcal disease caused by nonvaccine serotypes among alaska native children with high levels of 7-valent pneumococcal conjugate vaccine coverage.

RESULTS:

In the first 3 years after introduction of routine vaccination with heptavalent pneumococcal conjugate vaccine, overall invasive pneumococcal disease decreased 67% in Alaska Native children younger than 2 years (from 403.2 per 100,000 in 1995-2000 to 134.3 per 100,000 per year in 2001-2003, P<.001). However, between 2001-2003 and 2004-2006, there was an 82% increase in invasive disease in Alaska Native children younger than 2 years to 244.6/100,000 (P = .02). Since 2004, the invasive pneumococcal disease rate caused by nonvaccine serotypes has increased 140% compared with the prevaccine period (from 95.1 per 100,000 in 1995-2000 to 228.6 in 2004-2006, P = .001). D

Alaska Native children are experiencing replacement invasive pneumococcal disease with serotypes not covered by heptavalent pneumococcal conjugate vaccine. The demonstration of replacement invasive pneumococcal disease emphasizes the importance of ongoing surveillance and development of expanded valency vaccines.

http://www.ncbi.nlm.nih.gov/pubmed/17456820

Invasive Haemophilus influenzae disease in Utah children: an 11-year population-based study in the era of conjugate vaccine.

RESULTS:

“We identified 91 cases of invasive H. influenzae disease in children. Children aged <5 years accounted for 78 cases (86%). H. influenzae serotype a (Hia) was the most common serotype (22 cases), representing 28% of all cases of invasive disease among children aged <5 years. The majority (15 cases [93%]) of Hib disease cases occurred among children aged <5 years and accounted for 18% of all cases of H. influenzae invasive disease in this age group. The mean incidence of Hia disease increased from 0.8 cases per 100,000 child-years in 1998 to 2.6 cases per 100,000 child-years in 2008. The incidence of Hib disease among children aged <5 years remained steady at 0.5 cases per 100,000 child-years. Bacteremia accounted for 61% of all cases of invasive disease. One-half (13 of 26) of cases of H. influenzae meningitis were due to Hia.”

http://www.ncbi.nlm.nih.gov/pubmed/20178414

Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and autoimmunity.

Abstract

We have examined the neurotoxicity of aluminum in humans and animals under various conditions, following different routes of administration, and provide an overview of the various associated disease states. The literature demonstrates clearly negative impacts of aluminum on the nervous

system across the age span. In adults, aluminum exposure can lead to apparently age-related neurological deficits resembling Alzheimer's and has been linked to this disease and to the Guamanian variant, ALS-PDC. Similar outcomes have been found in animal models. In addition, injection of aluminum adjuvants in an attempt to model Gulf War syndrome and associated neurological deficits leads to an ALS phenotype in young male mice. In young children, a highly significant correlation exists between the number of pediatric aluminum-adjuvanted vaccines administered and the rate of autism spectrum disorders. Many of the features of aluminum-induced neurotoxicity may arise, in part, from autoimmune reactions, as part of the ASIA syndrome.

http://www.ncbi.nlm.nih.gov/pubmed/23609067

http://www.collective-evolution.com/2013/09/12/22-medical-studies-that-show-vaccines-can-cause-autism/

What is regressive autism and why does it occur? Is it the consequence of multi-systemic dysfunction affecting the elimination of heavy metals and the ability to regulate neural temperature?

Abstract

"There is a compelling argument that the occurrence of regressive autism is attributable to genetic and chromosomal abnormalities, arising from the overuse of vaccines, which subsequently affects the stability and function of the autonomic nervous system and physiological systems. That sense perception is linked to the autonomic nervous system and the function of the physiological systems enables us to examine the significance of autistic symptoms from a systemic perspective. Failure of the excretory system influences elimination of heavy metals and facilitates their accumulation and subsequent manifestation as neurotoxins: the long-term consequences of which would lead to neurodegeneration, cognitive and developmental problems. It may also influence regulation of neural hyperthermia. This article explores the issues and concludes that sensory dysfunction and systemic failure, manifested as autism, is the inevitable consequence arising from subtle DNA alteration and consequently from the overuse of vaccines. Abnormal measles-mumps-rubella antibodies and CNS autoimmunity in children with autism."

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3364648/

Abnormal measles-mumps-rubella antibodies and CNS autoimmunity in children with autism.

Singh VK1, Lin SX, Newell E, Nelson C.

Abstract

Autoimmunity to the central nervous system (CNS), especially to myelin basic protein (MBP), may play a causal role in autism, a neurodevelopmental disorder. Because many autistic children harbor

elevated levels of measles antibodies, we conducted a serological study of measles-mumps-rubella (MMR) and MBP autoantibodies. Using serum samples of 125 autistic children and 92 control children, antibodies were assayed by ELISA or immunoblotting methods. ELISA analysis showed a significant increase in the level of MMR antibodies in autistic children. Immunoblotting analysis revealed the presence of an unusual MMR antibody in 75 of 125 (60%) autistic sera but not in control sera. This antibody specifically detected a protein of 73-75 kD of MMR. This protein band, as analyzed with monoclonal antibodies, was immunopositive for measles hemagglutinin (HA) protein but not for measles nucleoprotein and rubella or mumps viral proteins. Thus the MMR antibody in autistic sera detected measles HA protein, which is unique to the measles subunit of the vaccine. Furthermore, over 90% of MMR antibody-positive autistic sera were also positive for MBP autoantibodies, suggesting a strong association between MMR and CNS autoimmunity in autism. Stemming from this evidence, we suggest that an inappropriate antibody response to MMR, specifically the measles component thereof, might be related to pathogenesis of autism.

http://www.ncbi.nlm.nih.gov/pubmed/12145534

Theoretical aspects of autism: Causes—A review

http://www.ncbi.nlm.nih.gov/pubmed/21299355

https://www.facebook.com/notes/ginger-taylor/81-research-papers-showing-that-vaccines-can-cause-autism/10151550806568920

Developmental Regression and Mitochondrial Dysfunction in a Child With Autism

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2536523/

Mitochondrial Disease in Autism Spectrum Disorder Patients: A Cohort Analysis

http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0003815

HEPATITIS B VACCINATION OF MALE NEONATES AND AUTISM DIAGNOSIS, NHIS 1997–2002

http://www.tandfonline.com/doi/pdf/10.1080/15287394.2010.519317

Do aluminum vaccine adjuvants contribute to the rising prevalence of autism?

http://www.sciencedirect.com/science/article/pii/S0162013411002212

Empirical Data Confirm Autism Symptoms Related to Aluminum and Acetaminophen Exposure

http://www.mdpi.com/1099-4300/14/11/2227

Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats.

http://www.ncbi.nlm.nih.gov/pubmed/21549155

Autism Epidemic, Is Foreign DNA in MMR II Vaccine Responsible? CBCD Suggests CDC Study Microcompetition Theory

http://www.prweb.com/releases/2012/4/prweb9359508.htm

Sorting out the spinning of autism: heavy metals and the question of incidence

http://www.ane.pl/pdf/7021.pdf

A possible central mechanism in autism spectrum disorders, part 1.

http://www.ncbi.nlm.nih.gov/pubmed/19043938

Hypothesis: Conjugate vaccines may predispose children to autism spectrum disorders

http://www.ncbi.nlm.nih.gov/pubmed/21993250

Phenotypic expression of autoimmune autistic disorder (AAD): A major subset of autism

RESULTS: Autoimmunity was demonstrated by the presence of brain autoantibodies, abnormal viral serology, brain and viral antibodies in CSF, a positive correlation between brain autoantibodies and viral serology, elevated levels of proinflammatory cytokines and acute-phase reactants, and a positive response to immunotherapy. Many autistic children harbored brain myelin basic protein autoantibodies and elevated levels of antibodies to measles virus and measles-mumps-rubella (MMR) vaccine. Measles might be etiologically linked to autism because measles and MMR antibodies (a viral marker) correlated positively to brain autoantibodies (an autoimmune marker)—salient features that characterize autoimmune pathology in autism. Autistic children also showed elevated levels of acute-phase reactants—a marker of systemic inflammation.

CONCLUSION: The scientific evidence is quite credible for our autoimmune hypothesis, leading to the identification of autoimmune autistic disorder (AAD) as a major subset of autism. AAD can be identified by immune tests to determine immune problems before administering immunotherapy. The author has advanced a speculative neuroautoimmune (NAI) model for autism, in which virus-

induced autoimmunity is a key player. The latter should be targeted by immunotherapy to help children with autism.

http://www.jfponline.com/Pages.asp?AID=7937

"Acquired autoimmunity syndromes occur after viral vaccinations. Molecular mimicry is involved in these phenomena as is the necessity for the presence of two chemically complimentary antigens and an immunologic adjuvant. The HLA pattern of the host is also an important factor. The example used to explain these phenomena is demyelinating disease that follows hepatitis B vaccination. The somatic antigen of the hepatitis B virus in the vaccine has chemical complimentarity with the Epstein-Barr virus antigen in the vaccine recipient. The Epstein-Barr virus shows molecular mimicry with human myelin. The immunologic adjuvant is either present in the vaccine or muramyl peptides in the individual who is vaccinated. Why more than one type of autoimmune disease occurs is explained by the fact that specific autoimmune T-cells have been shown to develop clones that attack multiple human tissues."

http://www.ncbi.nlm.nih.gov/pubmed/17630224

Infection, vaccines and other environmental triggers of autoimmunity.

Abstract

The etiology of autoimmune diseases is still not clear but genetic, immunological, hormonal and environmental factors are considered to be important triggers. Most often autoimmunity is not followed by clinical symptoms unless an additional event such as an environmental factor favors an overt expression. Many environmental factors are known to affect the immune system and may play a role as triggers of the autoimmune mosaic. Infections: bacterial, viral and parasitic infections are known to induce and exacerbate autoimmune diseases, mainly by the mechanism of molecular mimicry. This was studied for some syndromes as for the association between SLE and EBV infection, pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection and more. ***Vaccines, in several reports were found to be temporally followed by a new onset of autoimmune diseases. The same mechanisms that act in infectious invasion of the host, apply equally to the host response to vaccination. It has been accepted for diphtheria and tetanus toxoid, polio and measles vaccines and GBS. Also this theory has been accepted for MMR vaccination and development of autoimmune thrombocytopenia, MS has been associated with HBV vaccination.*** Occupational and other chemical exposures are considered as triggers for autoimmunity. A debate still exists about the role of silicone implants in induction of scleroderma like disease. Not only foreign chemicals and agents have been associated with induction of autoimmunity, but also an intrinsic hormonal exposure, such as estrogens. This might explain the sexual dimorphism in autoimmunity. Better understanding of these environmental risk factors will likely lead to explanation of the mechanisms of onset and progression of autoimmune diseases and may lead to effective preventive involvement in specific high-risk groups. So by diagnosing a new patient with autoimmune disease a wide anamnesis work should be done.

http://www.ncbi.nlm.nih.gov/pubmed/16126512

"Although there is no information regarding the duration of acceptable observation period, 1–3 months may not be long enough for the purpose, considering that it takes 2–6 months for adjuvant oils to induce lupus autoantibodies in mice [8,9,34] and that the oil-induced granulomatous inflammation can last for years."

"An important factor to consider in vaccine-induced autoimmunity is the fact that vaccines contain a microbial component (or other type of antigens) and adjuvant [75]. Differentiating adverse reactions caused by these two factors is often difficult, or it can even be a result of the combination of both. Nevertheless, the microbial components are generally considered responsible for adverse reactions and minimum attention has been paid to the potential effects of the adjuvant component. Molecular mimicry of a microbial antigen in a vaccine and a host tissue self-antigen is often considered important [61]. Immune complexes also may be formed following vaccination [61,76], deposit in vascular endothelium and induce vasculitis. Induction of cytokines or shifting cytokine balance may also play an important role."

http://www.ncbi.nlm.nih.gov/pubmed/15194169

"Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM (insulin depedent diabetes)."

http://www.ncbi.nlm.nih.gov/pubmed/12911277

Investigating Viruses in Cells Used to Make Vaccines; and Evaluating the Potential Threat Posed by Transmission of Viruses to Humans

'Xenotropic murine leukemia virus-related virus (XMRV) is a recently discovered human retrovirus that has been found in both chronic fatigue syndrome & prostate cancer patients. There is a potential safety concern regarding XMRV in cell substrates used in vaccines...'

http://www.fda.gov/biologicsbloodvaccines/scienceresearch/biologicsresearchareas/ucm127327.htm

"Although persons often use vaccination and immunization interchangeably in reference to active immunization (VACCINES), the terms are not synonomous because the administration of an immunobiologic cannot be automatically equated with the development of adequate immunity."

http://www.cdc.gov/mmwr/PDF/rr/rr4301.pdf

"Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7 to 28 days after vaccination."

http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf

"Vaccine-type rotavirus was detected in all 50 antigen-positive specimens and 8 of 8 antigen-negative specimens. Nine (75%) of 12 EIA-positive and 1 EIA-negative samples tested culture-positive for vaccine-type rotavirus. Fecal shedding of rotavirus vaccine virus after the first dose of RV5 occurred over a wide range of post-vaccination days not previously studied."

http://www.ncbi.nlm.nih.gov/pubmed/21477676

"Repeated immunization with antigen causes systemic autoimmunity in mice otherwise not prone to spontaneous autoimmune diseases. Overstimulation of CD4+ T cells led to the development of autoantibody-inducing CD4+ T (aiCD4+ T) cell which had undergone T cell receptor (TCR) revision and was capable of inducing autoantibodies." "Systemic autoimmunity appears to be the inevitable consequence of over-stimulating the host's immune 'system' by repeated immunization with antigen, to the levels that surpass system's self-organized criticality."

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2795160/

http://pediatrics.aappublications.org/content/106/2/e28.full

"Although persons often use vaccination and immunization interchangeably in reference to active immunization (VACCINES), the terms are not synonomous because the administration of an immunobiologic CANNOT be automatically equated with the development of adequate immunity."

http://www.cdc.gov/mmwr/PDF/rr/rr4301.pdf

"Vaccination against 2 avian viruses, the Marek disease virus, and the infectious bursal disease virus, were associated with the emergence of more virulent strains (33). An important role of host immunity in selecting for virulence is also suggested by the co-evolution of the myxomatosis virus and rabbits (34). Furthermore, immune pressure was shown to select for more virulent Plasmodium chabaudi parasites in mice (35). Based on mathematical modeling, vaccines designed to reduce pathogen growth rate and/or toxicity may result in the evolution of pathogens with higher levels of virulence (36)."

http://wwwnc.cdc.gov/eid/article/15/8/08-1511_article.htm

"Hib immunization contributed to an increased risk for H. influenzae type a meningitis through selection of circulating H. influenzae type a clones." " the incidence for H. influenzae type a meningitis increased 8-fold"

http://jid.oxfordjournals.org/content/187/1/109.full.pdf+html

"Together, our data suggest that the high level of vaccine failure in Nicaraguan is probably not due to antigenic drift of commonly circulating virus strains nor the emergence of new antigenetically distinct virus strains. Furthermore, our data suggest that the widespread use of the RotaTeq vaccine has led to the introduction of vaccine genes into circulating human RotaViruses" Infect Genet Evol. 2012 Aug;12

http://www.ncbi.nlm.nih.gov/pubmed/22487061

Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM (insulin dependent diabetes)."

http://www.ncbi.nlm.nih.gov/pubmed/12911277

“Successful induction of antiphospholipid syndrome (APS) in two different non-autoimmune prone mouse strains, BALB/c and C57BL/6, was achieved by tetanus toxoid (TTd) hyperimmunization using different adjuvants (glycerol or aluminum hydroxide), and different adjuvant pretreatments (glycerol or Complete Freund's Adjuvant (CFA)). APS had different manifestations of reproductive pathology in BALB/c and C57BL/6 mice: fetal resorption (as a consequence of extreme T-cell activation obtained in the course of pretreatment), and lowering of fecundity (as a consequence of polyclonal B-cell stimu/lation), respectively. In BALB/c mice fetal resorption coincided with glycerol and CFA pretreatments, while in C57BL/6 mice lowering of fecundity was most obvious in CFA-A pretreated mice immunized with TTd in aluminum hydroxide. Both molecular mimicry and polyclonal B-cell activation occur in APS induction, with molecular mimicry effects being dominant in BALB/c mice, and polyclonal cell activation being dominant in C57BL/6 mice. Confirmation of molecular mimicry effects, which in the condition of T-cell stimulation generated fetal resorptions in the BALB/c strain, was achieved by passive infusion of monoclonal antibody (MoAb) T-26 specific for TTd and anti-β(2)-glycoprotein I obtained after TTd hyperimunization. High polyclonal B-cell activation in C57BL/6 mice prevented fetal resorption but induced fecundity lowering, as was the case in passive administration of MoAb T-26 in this mouse strain. Passive infusion of anti-idiotypic MoAb Y7 into C57BL/6 mice induced fetal resorptions and confirmed the above suggestion on the protective role of polyclonal B-cell stimulation in fetal resorptions.”

http://www.ncbi.nlm.nih.gov/pubmed/22235053

“Experimental evidence also shows that simultaneous administration of as little as two to three immune adjuvants can overcome genetic resistance to autoimmunity. In some developed countries,

by the time children are 4 to 6 years old, they will have received a total of 126 antigenic compounds along with high amounts of aluminum (Al) adjuvants through routine vaccinations. According to the US Food and Drug Administration, safety assessments for vaccines have often not included appropriate toxicity studies because vaccines have not been viewed as inherently toxic. Taken together, these observations raise plausible concerns about the overall safety of current childhood vaccination programs." Lupus (2012) 21, 223–230

http://www.ncbi.nlm.nih.gov/pubmed/22235057

"We initiated and funded a collaborative study with Tuomilehto on the effect of the Haemophilus influenzae type b vaccine on type 1 diabetes and found that the data support a causal relation (paper submitted for publication). Furthermore, the potential risk of the vaccine exceeds the potential benefit. We compared a group that received four doses of the vaccine, a group that received one dose, and a group that was not vaccinated. The cumulative incidence of diabetes per 100000 in the three groups receiving four, one, and no doses of the vaccine was 261, 237, and 207 at age 7 and 398, 376, and 340 at age 10 respectively."

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1116914/

Vaccine induced allergies

http://www.smartvax.com/index.php?option=com_content&view=article&id=73:vaccine-induced-allergies

"These findings are consistent with the hypothesis that immunization with the recombinant hepatitis B vaccine is associated with an increased risk of MS, and challenge the idea that the relation between hepatitis B vaccination and risk of MS is well understood."

http://www.neurology.org/content/63/5/838.abstract

"Hepatitis B vaccination does not "generally" increase the risk of CNS inflammatory demyelination in childhood. However, the Engerix B vaccine appears to increase this risk, particularly for confirmed multiple sclerosis, in the longer term."

http://www.ncbi.nlm.nih.gov/pubmed/18843097

"Hepatitis B vaccine might be followed by various rheumatic conditions and might trigger the onset of underlying inflammatory or autoimmune rheumatic diseases."

http://www.ncbi.nlm.nih.gov/pubmed/10534549

Environmental Health Perspectives, July 2006.

Samuel R. Goth, Ruth A. Chu Jeffrey P. Gregg

This study demonstrates that very low-levels of Thimerosal can contribute to immune system disregulation.

Excerpt: "Our findings that DCs primarily express the RyR1 channel complex and that this complex is uncoupled by very low levels of THI with dysregulated IL-6 secretion raise intriguing questions about a molecular basis for immune dyregulation and the possible role of the RyR1 complex in genetic susceptibility of the immune system to mercury."

Abstract

Dendritic cells (DCs), a rare cell type widely distributed in the soma, are potent antigen presenting cells that initiate primary immune responses. DCs rely on intracellular redox state and calcium (Ca2+) signals for proper development and function, but the relationship between these two signaling systems is unclear. Thimerosal (THI) is a mercurial used to preserve vaccines, consumer products, and experimentally to induce Ca2+ release from microsomal stores. We tested ATP-mediated Ca2+ responses of DCs transiently exposed to nanomolar THI. Transcriptional and immunocytochemical analyses show murine myeloid immature and mature DC (IDCs, MDCs) express inositol 1, 4, 5-trisphosphate and ryanodine receptor (IP3R, RyR) Ca2+ channels, known targets of THI. IDCs express the RyR1 isoform in a punctate distribution that is densest near plasma membranes and within dendritic processes whereas IP3Rs are more generally distributed. RyR1 positively and negatively regulates purinergic signaling since ryanodine (Ry) blockade (1) recruited 80 percent more ATP responders, (2) shortened ATP-mediated Ca2+ transients >2-fold, (3) and produced a delayed and persistent rise (≥2-fold) in baseline Ca2+. THI (100nM, 5min) recruited more ATP responders, shortened the ATP-mediated Ca2+ transient (≥1.4-fold) and produced a delayed rise (≥3-fold) in the Ca2+ baseline, mimicking Ry. THI and Ry, in combination, produced additive effects leading to uncoupling of IP3R and RyR1 signals. THI altered ATP-mediated IL-6 secretion, initially enhancing the rate of but suppressing overall cytokine secretion in DCs. DCs are exquisitely sensitive to THI, with one mechanism involving the uncoupling of positive and negative regulation of Ca2+signals contributed by RyR1.

Exp Toxicol Pathol. 2009 Mar;61(2):133-6. Epub 2008 Sep 3.

Branch DR, Departments of Medicine and Laboratory Medicine and Pathobiology, University of Toronto, Ontario, Canada.

Abstract

A recent report shows a correlation of the historical use of thimerosal in therapeutic immunizations with the subsequent development of autism; however, this association remains controversial. Autism occurs approximately four times more frequently in males compared to females; thus, studies of thimerosal toxicity should take into consideration gender-selective effects. The present study was originally undertaken to determine the maximum tolerated dose (MTD) of thimersosal in male and female CD1 mice. However, during the limited MTD studies, it became apparent that thimerosal has a differential MTD that depends on whether the mouse is male or female. At doses of 38.4-76.8mg/kg using 10% DMSO as diluent, seven of seven male mice compared to zero of seven female mice tested succumbed to thimerosal. Although the thimerosal levels used were very high, as we were originally only trying to determine MTD, it was completely unexpected to observe a difference of the MTD between male and female mice. Thus, our studies, although not directly addressing the controversy surrounding thimerosal and autism, and still preliminary due to small numbers of mice examined, provide, nevertheless, the first report of gender-selective toxicity of thimerosal and indicate that any future studies of thimerosal toxicity should take into consideration gender-specific differences.

International evidence against MMR

Dr Arthur Krigsman, a gastroenterologist from New York, revealed that he had evaluated 43 autistic children after a colleague observed a large proportion of autistic patients suffering from chronic, unexplained gut symptoms.

These children had developed normally for 12-18 months, with a vocabulary of some 15-25 words. They made normal eye contact; they were playful and interactive and not overly irritable.

At some point they had suffered a precipitous or gradual decline in all their developmental markers, and 90 per cent were suffering from the same bowel disease as identified at the Royal Free.

Dr Karoly Horvath at the University of Maryland in the U.S. investigated 36 autistic children and concluded that 'unrecognised gastrointestinal disorders' might be contributing to their behavioural problems.

And the day after Wakefield departed the Royal Free, Dr Timothy Buie, a paediatric gastroenterologist at Harvard, announced that he had found similar bowel disease in 16 out of 89 autistic children.

Wakefield's group had speculated that the route from bowel disease to brain disorder might be through toxins leaking through the gut. But now a flurry of researchers started to indicate another route, a possible connection between measles virus and auto-immunity.

Their evidence suggested that the measles virus in MMR could leave a child so weakened that the body effectively turns on itself, mistaking friendly cells for enemies and attacking them by producing too many antibodies.

Back in 1989, some Russian researchers had found high levels of measles antibodies in patients with auto-immune disorders. Others suggested a connection between autoimmunity problems and autism.

Potentially the most significant work was by Dr Vijendra Singh at the University of Utah. He found not only measles vaccine virus antibodies in autistic children, but brain antibodies, too.

In other words, MMR was causing the immune system of these children to attack their brains, a phenomenon that was not occurring in normal children.

Singh accepted that his work still needed to be reproduced by other scientists (the litmus test in medical research) but he did not pull his punches about the implications.

If no attention were paid to this danger, he warned, an 'epidemic of autism' was a real possibility.

Certainly, with so many tantalising but disparate fragments of research accumulating, Singh's theory - if true - might provide a crucial missing piece of the jigsaw. But is it true?

Several doctors have voiced deep scepticism. Sir Peter Lachmann, an eminent immunologist and president of the Academy of Medical Sciences, told me: 'Singh's work in these papers is not particularly reproducible or good.

'There are many diseases which show raised antibodies to measles, for example chronic active hepatitis or multiple sclerosis, yet there is nothing to associate these with MMR. There is no persuasive evidence that autism is caused by autoimmunity.'

But others disagree. At New Jersey medical school, paediatric immunologist Professor James Oleske has also found raised levels of measles antibodies in a preliminary study of autistic children. He is now following this up with a further study which he hopes will provide more definitive results.

Oleske has reservations about Singh's data but supports his line of reasoning, saying: 'I do think there's some link between patients with autism and the immune system which we do not yet understand.'

Andrew Wakefield agrees. He does not claim to have the answers, but he has now examined hundreds of children from around the world and says he keeps hearing the same story from parents.

No one has ever claimed that MMR is the sole cause of autism, or that it affects all children in the same way. The vast majority of children who are vaccinated with MMR have no adverse effects at all.

What Wakefield is saying is that there may be a small sub-set of children who are particularly vulnerable to MMR, for a number of possible reasons.

He has noted certain factors that frequently crop up: a current or recent infection, being on antibiotics at the time of the vaccination, a history of allergies, a strong family history of autoimmune disease or a maternal history of MMR or rubella vaccination just before pregnancy.

His critics accuse him of constantly moving the goalposts by drawing in these other factors. He replies that the research is constantly evolving.

Certainly, the association between autistic symptoms and bowel disease, which was scorned when he first raised it, is now much more commonly accepted among gastroenterologists.

And theories about how MMR might trigger this association are developing all the time. Progress is slowly being made in unravelling the mystery.

Above all, Wakefield stresses, it is vital to listen to the patients - or in this case, the parents. 'You go with the story the parents give you,' he says.

'Ultimately you've got to decide what kind of doctor you want. Do you want one who, when you describe your symptoms, says it's all in the mind; or gives you two minutes and a prescription to get rid of you; or one who is prepared to listen?'

A London GP, Dr Richard Halvorsen, agrees. 'I was simply staggered when I read the research and I became convinced there was something in this.

'There were simply so many parents all saying this had happened to their children.

'Of course there's such a thing as coincidence; but we were taught as doctors, if parents tell you something about their children, you assume they are right rather than wrong. Parents know their children better than anyone else.'

http://www.dailymail.co.uk/health/article-171540/International-evidence-MMR.html

Febrile seizures following measles and varicella vaccines in young children in Australia.

http://www.ncbi.nlm.nih.gov/pubmed/25444797

Nonfebrile Seizures after Mumps, Measles, Rubella, and Varicella-Zoster Virus Combination Vaccination with Detection of Measles Virus RNA in Serum, Throat, and Urine

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3697452/

PCV1, PCV2 DNA detected in RotaTeq

May 10, 2010

Evidence of contamination with porcine circovirus type 1 and type 2 has been found in RotaTeq, Merck’s pentavalent rotavirus vaccine, according to an FDA official who spoke during a hearing on rotavirus vaccines.

After discovering “very low levels” of porcine circovirus type 1 and type 2 (PCV1 and PCV2) DNA in RotaTeq, Merck researchers revealed their findings to the FDA. Officials said, however, these results do not indicate an immediate health threat.

“There is no evidence at this time that DNA from PCV causes any disease in humans,” Merck said on its website. “We remain confident in the safety profile and quality of RotaTeq.”

The FDA suspended use of the monovalent rotavirus vaccine Rotarix from GlaxoSmithKline in March after detecting PCV1, although officials said the virus did not appear to be harmful to humans. Despite the evidence of similar contamination in RotaTeq, however, the FDA has not recommended against using the vaccine.

http://www.healio.com/pediatrics/vaccine-preventable-diseases/news/online/%7B6c07783b-adee-4066-a4d1-0cdbe54cce61%7D/pcv1-pcv2-dna-detected-in-rotateq

Statement on Rotavirus vaccines

18 May 2010

“Two oral rotavirus vaccines, Rotarix (sponsored by GlaxoSmithKline) and RotaTeq (sponsored by Merck) are currently approved for use in Australia and are included in the National Immunisation Program (NIP) for babies aged 2 to 6 months. These are used to prevent rotavirus infection in babies and young children. Rotavirus is a virus that may cause a form of gastroenteritis of particular concern as it can be severe or even fatal.”

“On 5 May 2010 Merck notified the TGA and other regulatory agencies that it had identified fragments of DNA from PCV1 and a related virus, PCV2, in its bulk rotavirus vaccine RotaTeq.

PCV1 and PCV2 are viruses that can infect pigs. There is no evidence that either PCV1 or PCV2 cause any illness in humans.”

http://www.tga.gov.au/safety/alerts-medicine-rotavirus-100324.htm

Evaluation of the human host range of bovine and porcine viruses that may contaminate bovine serum and porcine trypsin used in the manufacture of biological products.

http://www.ncbi.nlm.nih.gov/pubmed/22000165

Porcine Circovirus (Associated) Disease (PCVD)

Porcine Circovirus (Associated) Disease (PCVD) causes wasting and mortality in piglets from 6 weeks of age onwards. Clinical disease was first described in Western Canada in 1991. The syndrome is becoming of considerable concern in modern pig production especially in Canada, the US and Europe.

http://www.respig.com/diseases/porcine-circovirus-2.asp

Rotavirus vaccines: viral shedding and risk of transmission.

Abstract

Rotavirus causes gastroenteritis in almost all children by 5 years of age. Immunity to rotavirus is incomplete, with potential for recurrent infections occurring throughout life. Live rotavirus vaccines have been developed for the protection of children from severe wildtype rotavirus infections. Transmission of vaccine virus strains from vaccinated children to unvaccinated contacts harbours the potential for herd immunity, but also the risk of vaccine-derived disease in immunocompromised contacts. A review of rotavirus vaccine prelicensure studies shows that viral shedding and transmission were higher with the old tetravalent rhesus rotavirus vaccine than with the current human attenuated monovalent rotavirus vaccine and the pentavalent bovine-human reassortant vaccine. Immunocompromised contacts should be advised to avoid contact with stool from the immunised child if possible, particularly after the first vaccine dose for at least 14 days.

http://www.ncbi.nlm.nih.gov/pubmed/18922486

http://www.examiner.com/article/whistleblowing-virologists-sue-merck-for-alleged-falsification-of-mumps-data

Polio outbreak sparked by vaccine, experts say

Since 2005, 69 children paralyzed by virus derived from the oral medicine

A recent polio outbreak in Nigeria revealed another potential problem: the vaccine commonly used against it. Last week, the World Health Organization and the U.S. Centers for Disease Control reported that since 2005, 69 Nigerian children have been paralyzed by a polio virus derived from the oral vaccine. Two other cases made it to Niger.

http://www.nbcnews.com/id/21149823/#.UagxL9LI2Pw

Paralysis cases soar after oral polio vaccine introduced

A new report by two Delhi pediatricians suggests that the sharp rise in childhood paralysis in India is due to the increased usage of the oral polio vaccine, a drug that was banned in the U.S. over a decade ago.

"In 2011, there were an extra 47500 new cases of NPAFP [in India]. Clinically indistinguishable from polio paralysis but twice as deadly, the incidence of NPAFP was directly proportional to doses of oral polio received."

http://digitaljournal.com/article/323371#ixzz211olXr1w

http://www.integrativepediatricsonline.com/blog/2014/12/16/giving-the-tdap-during-pregnancy-associated-with-increased-chorioamnionitis-infection/

Varicella Shedding Detected Up to Month After Zoster Vaccination

NEW ORLEANS – Varicella zoster virus DNA was detected in subjects' saliva for a month after immunization with the Zostavax herpes zoster vaccine in a prospective study.

Genotypic analysis demonstrated that the varicella zoster virus that was present in saliva was indeed the Zostavax live attenuated vaccine virus, Dr. Catherine M. DiGiorgio said at the annual meeting of the American Academy of Dermatology.

http://www.internalmedicinenews.com/news/infectious-diseases/single-article/varicella-shedding-detected-up-to-month-after-zoster-vaccination/8f6b51d39f.html

Outbreak of Measles Among Persons With Prior Evidence of Immunity, New York City, 2011

"Conclusions. This is the first report of measles transmission from a twice-vaccinated individual with documented secondary vaccine failure. The clinical presentation and laboratory data of the index patient were typical of measles in a naive individual. Secondary patients had robust anamnestic antibody responses. No tertiary cases occurred despite numerous contacts. This outbreak underscores the need for thorough epidemiologic and laboratory investigation of suspected cases of measles regardless of vaccination status."

http://cid.oxfordjournals.org/content/58/9/1205

Measles Outbreak among Vaccinated High School Students -- Illinois

Editorial Note: This outbreak demonstrates that transmission of measles can occur within a school population with a documented immunization level of 100%. This level was validated during the outbreak investigation. Previous investigations of measles outbreaks among highly immunized populations have revealed risk factors such as improper storage or handling of vaccine, vaccine administered to children under 1 year of age, use of globulin with vaccine, and use of killed virus vaccine (1-5). However, these risk factors did not adequately explain the occurrence of this outbreak.

http://www.cdc.gov/mmwr/preview/mmwrhtml/00000359.htm

AN EXPLOSIVE POINT-SOURCE MEASLES OUTBREAK IN A HIGHLY VACCINATED POPULATION
MODES OF TRANSMISSION AND RISK FACTORS FOR DISEASE

“In 1985, 69 secondary cases, all in one generation, occurred in an Illinois high school after exposure to a vigorously coughing Index case. The school's 1,873 students had a pre-outbreak vaccination level of 99.7% by school records.”

http://aje.oxfordjournals.org/content/129/1/173.short

Children of mothers vaccinated against measles and, possibly, rubella have lower concentrations of maternal antibodies and lose protection by maternal antibodies at an earlier age than children of mothers in communities that oppose vaccination. This increases the risk of disease transmission in highly vaccinated populations.

http://jid.oxfordjournals.org/content/early/2013/04/29/infdis.jit143.long

“CDC figures show how this has changed the face of measles. In 1976, just 3% of all cases occurred in children under age 1. Typically their mothers were born in the 1950s, well before the measles vaccine became routinely available a decade later.

In the 1980s, as teen-agers who were vaccinated as children began to have babies, those numbers started to change. In 1985, almost 8% of measles cases were in infants younger than 1. By 1991, it had climbed to 19%. And so far this year, 28% of all measles cases have occurred in babies under a year old.”

“Dr. Mark Papania and others looked at families where infants were exposed to people with measles. They found that the babies of mothers born after 1968, when vaccination became common, were 3 1/2 times more likely to get measles than were infants of older mothers.”

http://articles.latimes.com/1992-12-27/news/mn-5079_1_measles-vaccine/2

http://news.sciencemag.org/health/2014/04/measles-outbreak-traced-fully-vaccinated-patient-first-time

Detection of measles vaccine in the throat of a vaccinated child.

Abstract

Measles vaccine is widely used, most often in association with mumps and rubella vaccines. We report here the case of a child presenting with fever 8 days after vaccination with a measles-mumps-rubella vaccine. Measles virus was isolated in a throat swab taken 4 days after fever onset. This virus was then further genetically characterised as a vaccine-type virus. Fever occurring subsequent to measles vaccination is related to the replication of the live attenuated vaccine virus. In the case presented here, the vaccine virus was isolated in the throat, showing that subcutaneous injection of an attenuated measles strain can result in respiratory excretion of this virus.

http://www.ncbi.nlm.nih.gov/pubmed/11858860?dopt=AbstractPlus

Detection of measles virus RNA in urine specimens from vaccine recipients.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC228449/

Vaccines for measles, mumps and rubella in children.

The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate. The evidence of adverse events following immunisation with the MMR vaccine cannot be separated from its role in preventing the target diseases.

http://www.ncbi.nlm.nih.gov/pubmed/22336803

According to two whistle blowing former Merck virologists who filed a 2010 Federal False Claims Act complaint two years ago in 2010 when the Act first passed, as of June 28, 2012, the scientist's complaint at last has been unsealed. The complaint reports that the corporate pharmaceutical vaccine manufacturer, Merck allegedly "knowingly falsified its mumps vaccine test data, spiked blood samples with animal antibodies, and sold a vaccine that actually promoted mumps and measles outbreaks."

http://www.huffingtonpost.ca/lawrence-solomon/merck-whistleblowers_b_5881914.html

“While an estimated 350 children could be saved from Hib disease on immunising 25 million babies in India, 3,125 children will die due to AEFI,” Dr Puliyel writes, questioning the rationale behind introducing the vaccine when the incidence of the disease in India is so low.

http://www.newindianexpress.com/cities/bangalore/Medical-experts-divided-over-use-of-pentavalent-vaccine-on-Children/2013/07/29/article1707186.ece

http://www.virology.ws/2010/03/29/deep-sequencing-reveals-viral-vaccine-contaminants/

Viral Nucleic Acids in Live-Attenuated Vaccines: Detection of Minority Variants and an Adventitious Virus

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2876658/

Bacteriophages and Endotoxin in Licensed Live-Virus Vaccines

http://jid.oxfordjournals.org/content/131/5/588.short

Foreign DNA Fragments Cause Most Major Diseases

http://www.cbcd.net/index.php

Computational Detection of Homologous Recombination Hotspots in X-Chromosome Autism-Associated Genes

http://www.cogforlife.org/SCPIIMFARHR.pdf

In the now developed countries, mortality due to tuberculosis, measles, whooping cough, typhoid fever, diarrhoeal diseases and many other infections began to fall long before the responsible microbial agents had been identified and before specific measures of control or treatment were known.

This decline – much greater than anything achieved since through the use of vaccination and antimicrobial drugs – paralleled the improvement in general living conditions. Microbes and the diseases caused by them prosper, therefore, only in environmental conditions favourable to them.

Behar, M. A deadly combination; World Health Feb-Mar, 1974

http://www.homeopathyoz.org/downloads/Vaccine%20Ingredients.pdf

http://vactruth.com/2013/11/13/dangerous-vaccine-contamination/

Unfortunately, the MDG28 monitoring process relies heavily on predicted statistics. The same applies to monitoring progress in major disease interventions.

For example, the assessment of a recent change in measles mortality from vaccination is mostly based on statistics predicted from a set of covariates such as the number of live births, vaccine coverage, vaccine effectiveness and case-fatality ratios. It is understandable that estimating causes of death over time is a difficult task. However, that is no reason for us to avoid measuring it when we can also measure the quantity of interest directly; otherwise the global health community would continue to monitor progress on a spreadsheet with limited empirical basis. This is simply not acceptable.

This mismatch was created partly by the demand for more timely statistics (i.e. on an annual basis) from their users and partly by a lack of data and effective measurement strategies among statistics producers. Users must be realistic, as annual data on representative cause-specific mortality are difficult to obtain without complete civil registration or sample registration systems.

If such data are needed, the global health community must seek indicators that are valid, reliable and comparable, and must invest in data collection (e.g. adjusting facility-based data by using other representative data sources).

Regardless of new disease-specific initiatives or the broader WHO Strategic Objectives, the key is to focus on a small set of relevant indicators for which well-defined strategies for monitoring progress are available.

Only by doing so will the global health community be able to show what works and what fails.

http://www.who.int/bulletin/volumes/85/6/07-042887/en/index.html

“The committee chose cautious and scientific language for our conclusions, because, especially with rare events, it is not possible to prove a negative (i.e., the vaccine did not and cannot cause the event). The committee cannot say that in a certain person at a certain time, some event cannot happen; there is much about biology that is not known.”

http://books.nap.edu/openbook.php?record_id=13164&page=633

"In 1995 the proportion of fully vaccinated children based on the 1994 vaccination schedule was around one-third of children aged 0 to six years. However, the timing of changes in the NHMRC's recommended schedule, particularly the introduction of the Hib vaccine in 1993, was a major factor contributing to this result. When measured against the previous (1991) vaccination schedule, the proportion of children reported as fully vaccinated in 1995 was 53% of children."

http://www.abs.gov.au/ausstats/abs@.nsf/mf/4813.0.55.001

Infant mortality rates in Australia from 1912-2012

http://www.abs.gov.au/AUSSTATS/abs@.nsf/2f762f95845417aeca25706c00834efa/d37892d01d1832c3ca2570ec000ace6e!OpenDocument

Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity?

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3170075/

"Dr. Wilma Wooten said the current vaccine used in the United States is only 80 percent effective. She believes the vaccine itself is more to blame than the perception that fewer people are getting vaccinated."

"The Pertussis outbreak has no relationship to personal belief exemption," she said. "This really is about the effectiveness of the vaccine itself."

http://www.nbcsandiego.com/news/local/Del-Mar-Mom-Frustrated-Family-Got-Whooping-Cough-After-Vaccinating-288340101.html#ixzz3PG2jSml9

Neurologic adverse events following vaccination

http://www.rescuepost.com/files/prog-health-sci-2012-vol-2-no1-neurologic-adverse-events-vaccination.pdf

No Antibodies Required For Immunity Against Some Viruses

http://www.medicalnewstoday.com/releases/242403.php

Vaccination and Allergic Disease: A Birth Cohort Study

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448377/

Vaccination and autoimmunity-'vaccinosis': a dangerous liaison?

Kenyan Bishops not Satisfied with Government Response to Vaccine Controversy.

The concern that the neonatal tetanus vaccines in Kenya sponsored by the World Health Organization are laced with sterilizing agents first arose months ago, and the uncertainty continues as the newest round of testing produced another inconclusive standoff between the Catholic Health Commission of Kenya and the Ministry of Health.

http://pop.org/content/kenyan-bishops-not-satisfied-government-response-vaccine-controversy

http://www.ncbi.nlm.nih.gov/pubmed/10648110

Dose of measles virus destroys woman's incurable cancer

http://www.medicalnewstoday.com/articles/276966.php

http://www.vaccinationcouncil.org/2013/01/18/the-ineffectiveness-of-measles-vaccines-and-other-unintended-consequences-by-dr-viera-scheibner-phd/

http://www.vaccinationcouncil.org/2013/01/29/measles-vaccines-part-ii-benefits-of-contracting-measles-by-dr-viera-scheibner-phd/

Controversial vaccine studies: Why is Bill & Melinda Gates Foundation under fire from critics in India?

http://articles.economictimes.indiatimes.com/2014-08-31/news/53413161_1_hpv-vaccine-cervarix-human-papilloma-virus

"Vaccines, vaccines, wonderful business," Chris Viehbacher, the Canadian-born CEO of Sanofi-Aventis, told investment analysts on a conference call a few months ago."

http://www.theglobeandmail.com/life/health-and-fitness/health/conditions/how-vaccines-became-big-business/article572731/?page=all

http://www.forbes.com/2005/08/19/merck-vioxx-graham_cx_mh_0819graham.html

http://www.drugwatch.com/avandia/lawsuit.php

Vaccines Market worth $57.8 Billion by 2019

http://www.sys-con.com/node/3285724

FOR IMMEDIATE RELEASE-AUGUST 27,2014

STATEMENT OF WILLIAM W. THOMPSON, Ph.D., REGARDING THE 2004 ARTICLE EXAMINING THE POSSIBILITY OF A RELATIONSHIP BETWEEN MMR VACCINE AND AUTISM

My name is William Thompson. I am a Senior Scientist with the Centers for Disease Control and Prevention, where I have worked since 1998.

I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal *Pediatrics.* The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed.

I want to be absolutely clear that I believe vaccines have saved and continue to save countless lives. I would never suggest that any parent avoid vaccinating children of any race. Vaccines prevent serious diseases, and the risks associated with their administration are vastly outweighed by their individual and societal benefits.

My concern has been the decision to omit relevant findings in a particular study for a particular sub group for a particular vaccine. There have always been recognized risks for vaccination and I believe it is the responsibility of the CDC to properly convey the risks associated with receipt of those vaccines.

I have had many discussions with Dr. Brian Hooker over the last 10 months regarding studies the CDC has carried out regarding vaccines and neurodevelopmental outcomes including autism spectrum disorders. I share his belief that CDC decision-making and analyses should be transparent. I was not, however, aware that he was recording any of our conversations, nor was I given any choice regarding whether my name would be made public or my voice would be put on the Internet.

I am grateful for the many supportive e-mails that I have received over the last several days.

I will not be answering further questions at this time. I am providing information to Congressman William Posey, and of course will continue to cooperate with Congress. I have also offered to assist with reanalysis of the study data or development of further studies. For the time being, however, I am focused on my job and my family.

Reasonable scientists can and do differ in their interpretation of information. I will do everything I can to assist any unbiased and objective scientists inside or outside the CDC to analyze data collected by the CDC or other public organizations for the purpose of understanding whether vaccines are associated with an increased risk of autism. There are still more questions than answers, and I appreciate that so many families are looking for answers from the scientific community.

My colleagues and supervisors at the CDC have been entirely professional since this matter became public. In fact, I received a performance-based award after this story came out. I have experienced no pressure or retaliation and certainly was not escorted from the building, as some have stated.

Dr. Thompson is *represented by Frederick M. Morgan,Jr., Morgan Verkamp, LLC, Cincinnati, Ohio, www.morganverkamp.com.*

http://www.morganverkamp.com/august-27-2014-press-release-statement-of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/

Results

A male overrepresentation was observed regarding the total number of reports. The most frequently reported group of drugs were vaccines (42.15%). Skin rash and fever were the commonest symptoms reported in the total pediatric dataset. The proportion of children that suffered from a serious ADR was 2.16% and that for drug related deaths was 0.34%. And we found that the multiple drug exposure experienced a high proportion of serious ADRs compared with the single drug use ($\chi 2 = 15.99$, $P<0.0001$). Sixty-five percent of ADRs were for children less than 6 years of age. And more than half of reports were from doctors.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3933652/
Why Is China Having Measles Outbreaks When 99% Are Vaccinated?

http://www.globalresearch.ca/why-is-china-having-measles-outbreaks-when-99-are-vaccinated/5404067

Merck Has Some Explaining To Do Over Its MMR Vaccine Claims

Merck, the pharmaceutical giant, is facing a slew of controversies over its Measles-Mumps-Rubella (MMR) vaccine following numerous allegations of wrongdoing from different parties in the medical field, including two former Merck scientists-turned-whistleblowers. A third whistleblower, this one a scientist at the Centers for Disease Control, also promises to bring Merck grief following his confession of misconduct involving the same MMR vaccine.

The controversies will find Merck defending itself and its vaccine in at least two federal court cases after a U.S. District judge earlier this month threw out Merck's attempts at dismissal. Merck now faces federal charges of fraud from the whistleblowers, a vaccine competitor and doctors in New Jersey and New York. Merck could also need to defend itself in Congress: The staff of representative Bill Posey (R-Fla) -- a longstanding critic of the CDC interested in an alleged link between vaccines and autism -- is now reviewing some 1,000 documents that the CDC whistleblower turned over to them.
http://www.huffingtonpost.ca/lawrence-solomon/merck-whistleblowers_b_5881914.html

http://www.fiercevaccines.com/story/lawsuits-claiming-merck-lied-about-mumps-vaccine-efficacy-headed-trial/2014-09-09

http://www.reuters.com/article/2009/12/21/us-merck-gerberding-idUSTRE5BK2K520091221

http://www.jsonline.com/watchdog/watchdogreports/fda-reporting-system-comes-up-short-on-new-diabetes-drugs-potential-dangers-b99402916z1-286529331.html

http://www.rtl.org/prolife_issues/LifeNotes/VaccinesAbortion_FetalTissue.html

Expression of privilege in vaccine refusal

http://www.sciencedaily.com/releases/2014/08/140827141702.htm

http://www.livescience.com/43577-why-rich-educated-parents-avoid-vaccinations.html

Neoliberal mothering and vaccine refusal: Imagined gated communities and the privilege of choice.

http://gas.sagepub.com/content/early/2014/05/09/0891243214532711.full.pdf+html?ijkey=fUokCLKdAFzI2&keytype=ref&siteid=spgas

http://www.news.com.au/lifestyle/health/einstein-parents-say-no-to-kids-vaccination/story-fneuzlbd-1226617741216

http://blogs.discovermagazine.com/intersection/2009/05/08/who-doesnt-vaccinate/#.VQzkY-EwAaA

Pertussis notifications from 1991-2013 NNDSS

http://www9.health.gov.au/cda/source/rpt_2.cfm?RequestTimeout=500

Pertussis vaccination rates for 2011

http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3704-pdf-cnt.htm/$FILE/cdi3704a.pdf

Pertussis Vaccination rates in 1990-2001

http://www.abs.gov.au/ausstats/abs@.nsf/mf/4813.0.55.001#4.%20RESULTS%20-%20VACCINATION%20COVERAGE

http://www.propublica.org/article/how-many-die-from-medical-mistakes-in-us-hospitals

“But one would think Los Alamos would be different. It’s a town founded on science, and the scientific evidence is overwhelming that vaccines don’t cause autism or other developmental disabilities. Many people in Los Alamos don’t just have college degrees – they’re scientists, with lots of degrees. Los Alamos National Laboratory in fact has done some heavy research on infectious disease and development of an HIV vaccine.
“That’s a curiosity to me, as well,” said Los Alamos schools superintendent Gene Schmidt of his district’s relatively high rate of vaccination exemptions among what he called “a pretty scientific and literate community.”

“It does seem more educated people have a variety of opinions,” Schmidt said, although he said he hasn’t personally encountered any anti-vaxer sentiment.
So what’s the deal with higher education levels correlating with vaccine exemptions, which New Mexico allows for medical reasons certified by a physician or for religious beliefs?

“It’s basically people who feel they do know more and question authority more,” said Amy Pisani, executive director of the Washington, D.C.-based Every Child By Two immunization advocacy group.”

http://www.abqjournal.com/557820/news/los-alamos-top-in-nm-for-vaccine-exemptions.html

"Q. In recent years, many parents have blamed vaccines for causing autism. That theory has been discredited by recent research. What do you think?

There's one study that still hasn't been done. There's a type of autism where the child gets language... can say a few words... and then loses it. There's a regression at about 18 months or 2 years. That subgroup needs to be studied separately. Until that study is done, the book is not closed.

Q. So you think it's possible vaccines could play a role?

I'm leaving that open. That study has to be done. I've brought that up with some of the top experts and they get very silent. That's all I'm going to say about it."

http://www.ageofautism.com/2010/10/temple-grandins-logical-mind-on-early-intervention-vaccines-and-more.html

Dr Tomljenovic on vaccine adjuvants and overstimulation of immune response

http://articles.mercola.com/sites/articles/archive/2015/03/29/vaccine-adjuvants-brain-effects.aspx

Mercury in Vaccines from the Australian Childhood Immunization Program Schedule

http://www.tandfonline.com/doi/abs/10.1080/15287391003613994#.VSIh45PMikY

Severe tetanus in immunized patients with high anti-tetanus titers

http://www.neurology.org/content/42/4/761

Generalized Tetanus Despite Prior Vaccination and a Protective Level of Anti-Tetanus Antibodies

http://dspace.biblioteca-innsz.org/bitstream/handle/123456789/6418/1705B.pdf?sequence=1

Severe tetanus in immunized patients with high anti-tetanus titers.

Crone NE, Reder AT.

Source

Department of Neurology, University of Chicago, IL 60637.

Abstract

Severe (grade III) tetanus occurred in three immunized patients who had high serum levels of anti-tetanus antibody. The disease was fatal in one patient. One patient had been hyperimmunized to produce commercial tetanus immune globulin. Two patients had received immunizations 1 year before presentation. Anti-tetanus antibody titers on admission were 25 IU/ml to 0.15 IU/ml by hemagglutination and ELISA assays; greater than 0.01 IU/ml is considered protective. Even though one patient had seemingly adequate anti-tetanus titers by in vitro measurement (0.20 IU), in vivo mouse protection bioassays showed a titer less than 0.01 IU/ml, implying that there may have been a hole in her immune repertoire to tetanus neurotoxin but not to toxoid. This is the first report of grade III tetanus with protective levels of antibody in the United States. The diagnosis of tetanus, nevertheless, should not be discarded solely on the basis of seemingly protective anti-tetanus titers.

http://www.ncbi.nlm.nih.gov/pubmed/1565228

Elevated antitoxin titers in a man with generalized tetanus.

Pryor T, Onarecker C, Coniglione T.

Source

St Anthony Hospital Family Practice Residency, Oklahoma City, OK 73102, USA.

Abstract

Vaccination programs have significantly reduced the incidence of tetanus in the United States. The disease develops almost exclusively in those who have been inadequately immunized. This report describes severe, generalized tetanus in a 29-year-old man who had received a primary series as a child and two booster injections. Serum obtained before administration of tetanus immune globulin showed antibody titers to tetanus greater than 100 times the level considered protective. Aggressive supportive care can usually prevent serious consequences. Since most physicians have never seen a case of tetanus, however, the diagnosis can be difficult. Many disorders that exhibit signs and symptoms similar to tetanus must be carefully considered during the evaluation of these patients. Tetanus is a preventable disease. Prevention, however, requires both appropriate immunizations and prompt wound care. While controversy exists regarding the most effective policy to adequately immunize all individuals, this case shows that vaccination alone does not preclude the possibility of tetanus.

http://www.ncbi.nlm.nih.gov/pubmed/9071251

Neonatal tetanus despite protective serum antitoxin concentration.

Maselle SY, Matre R, Mbise R, Hofstad T.

Source

Department of Microbiology and Immunology, Muhimbili Medical Centre, Tanzania.

Abstract

Using the ELISA technique to estimate serum antibodies against tetanus toxin, seven neonates with clinical tetanus were found to have antibody levels 4-13 times higher than the presumed minimum protective level of 0.01 IU/ml. All but one of their mothers had been vaccinated with tetanus toxoid in pregnancy. In two other neonates, whose mothers had received multiple booster doses of toxoid during pregnancy, the anti-toxin concentrations were 100- and 400-times the presumed protective level. Therefore the toxin dose may overwhelm the pre-existing anti-toxin level and produce disease. Furthermore, multiple booster injections of tetanus toxoid may not only enhance serum anti-toxin titres, but could also lead to an ineffective immune response.

http://www.ncbi.nlm.nih.gov/pubmed/1878260

Immunisation does not rule out tetanus

David R Vinson, staff physician

Author information ► Copyright and License information ►

Editor—Shimoni et al illustrate a needed caution to clinicians: do not exclude a diagnosis of tetanus in a patient who has been fully immunised.[1] Their report adds to the list of rare cases of tetanus that have occurred despite complete immunisation. Although the authors state that all reported cases of tetanus in the United States have occurred in people who have not been immunised, this is not altogether true. A catalogue of the 740 tetanus cases reported by the Centers for Disease Control since 1982 discloses that of the minority whose immunisation status was known, 53 cases had completed a primary series, 22 had received their latest booster between five and nine years before, and two had received a booster within five years (table).

In light of their patient's adequate immunisation record, Shimoni et al presume that he should have mounted a protective titre of neutralising antibody. With this I agree. But against what, in particular, does this titre confer protection—clinical infection or fatal infection? The understanding of “protection” was derived from animal studies that correlated serum concentrations of tetanus antibody with symptoms of tetanus.[2] The threshold of 0.01 IU/ml was established because guinea pigs with titres above this level were protected from fatal tetanus, not from clinical tetanus; six of 45 animals with protective levels developed non-fatal tetanus.[3] Similarly, in humans, non-fatal tetanus has been described in 10 out of 64 consecutive patients with antitetanus titres greater than 0.01 IU/ml.[4] More recent cases have borne this out.[5]

A number of rare and exceptional cases of tetanus occur despite adequate immunisation and protective levels of neutralising antibodies. Since tetanus is likely to be fatal if not recognised and treated properly, the caveat from Shimoni et al[1] merits repeating: doctors should entertain the diagnosis of tetanus in the proper clinical setting, regardless of the patient's immunisation record.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1127160/

Tetanus of immunized children.

Luisto M, Iivanainen M.

Source

Department of Neurology, Käpylä Rehabilitation Centre, Helsinki, Finland.

Abstract

Five children aged five to 15 years contracted tetanus in Finland between 1969 and 1985, together with 101 adults. Four of the five had been adequately immunized against tetanus. The clinical picture of tetanus was mild or moderate, and none of the children needed respirator treatment. Epilepsy, meningitis and psychogenic symptoms were considered in the differential diagnosis. The course of tetanus in immunized patients is atypical and often benign, but the diagnosis is problematic--in contrast to affected children in developing

countries, whose populations are not adequately immunized and where neonatal tetanus is common and often fatal.

http://www.ncbi.nlm.nih.gov/pubmed/8335151

Case report of tetanus in an immunized, healthy adult and no point of entry.

Hahn BJ, Erogul M, Sinert R.

Source

Department of Emergency Medicine, State University of New York-Downstate Medical Center, Brooklyn, New York 11203, USA.

Abstract

We report the case of a 58-year-old man born in the United States with a history of complete childhood immunizations who presented to the Emergency Department with trismus. Past medical history was significant only for Elephantiasis. After an exhaustive workup the patient was found to have Tetanus, with no identifiable portal of entry. The patient was successfully treated for Tetanus with complete recovery. Tetanus is caused by the organism Clostridium Tetani, which usually requires an open lesion to cause infection. Our patient was unique in that he was previously immunized with no obvious lesion. Tetanus should be suspected and treated empirically in any patient presenting with typical signs and symptoms even without an apparent entry site.

http://www.ncbi.nlm.nih.gov/pubmed/15388212

A case of clinical tetanus in a patient with protective antitetanus antibody level.

http://www.ncbi.nlm.nih.gov/pubmed/17269536

Tetanus in an immunized, healthy adult.

http://www.ncbi.nlm.nih.gov/pubmed/16982368

Apnea after immunization of preterm infants.

http://www.ncbi.nlm.nih.gov/pubmed/9152284

Apnea and its possible relationship to immunization in ex-premature infants

http://www.sciencedirect.com/science/article/pii/S0264410X0800491X

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including MENHIBRIX, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination. (5.3)

http://us.gsk.com/products/assets/us_menhibrix.pdf

Same warning for the Pentacel vaccine as well

https://www.vaccineshoppe.com/image.cfm?doc_id=11169&image_type=product_pdf

Apnea after immunization of preterm infants.

http://www.ncbi.nlm.nih.gov/pubmed/9152284

Apnea and its possible relationship to immunization in ex-premature infants

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http://us.gsk.com/products/assets/us_menhibrix.pdf

Acute Disseminated Encephalomyelitis (ADEM)

Clinical features — Clinical features of the postvaccination and parainfectious syndromes are similar, with the exception that the postrabies vaccination complications frequently involve the peripheral nervous system as well as the CNS. Many patients with postrabies immunization illness have only mild clinical features of fever, headache, or myalgia without CSF pleocytosis.

The hallmark clinical feature of the disorder is the development of a focal or multifocal neurologic disorder following exposure to virus or receipt of vaccine. In some, but not all cases, a prodromal phase of several days of fever, malaise, and myalgias occurs. The onset of the CNS disorder is usually rapid (abrupt or up to several hours), reaching peak dysfunction within several days. Initial features include encephalopathy ranging from lethargy to coma, seizures, and focal and multifocal signs reflecting cerebral (hemiparesis), brain stem (cranial nerve palsies), and spinal cord (paraparesis) involvement. Other reported findings include movement disorders and ataxia. Each of these findings may occur as isolated features or in various combinations.

http://www.adem.org/

Food Labeling Chaos

The case for reform

CENTER FOR Science IN THE Public Interest

Food Labeling Chaos

Food Labeling Chaos

The case for reform

Bruce Silverglade
Ilene Ringel Heller

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This report was written by Bruce Silverglade, Director of Legal Affairs, and Ilene Ringel Heller, Senior Staff Attorney, at the Center for Science in the Public Interest. The authors would especially like to thank Dr. Michael Jacobson for his counsel and thoughtful review; Bonnie Liebman and David Schardt for their input; Professor Marsha Cohen, University of California Hastings College of Law for her review and comments; Hayley Reynolds for her excellent research assistance, writing and analysis; and Debra Brink for design and formatting.

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The Center for Science in the Public Interest (CSPI), founded in 1971, is a non-profit health-advocacy organization. CSPI conducts innovative research and advocacy programs in the areas of nutrition, food safety, and alcoholic beverages and provides consumers with current information about their own health and well-being. CSPI is supported by more than 850,000 subscribers in the United States and Canada to its *Nutrition Action Healthletter* and by foundation grants.

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Contents

List of Abbreviations

AARP	Formerly American Association of Retired Persons
AHA	American Heart Association
ANPR	Advance Notice of Proposed Rulemaking
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
CSPI	Center for Science in the Public Interest
DV	Daily Value
EU	European Union
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FSA	Food Standards Agency (United Kingdom)
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
GAO	Government Accountability Office (originally General Accounting Office)
GDA	Guideline Daily Amounts
GRAS	Generally Recognized as Safe
HHS	US Department of Health and Human Services
IFIC	International Food Information Council
IOM	National Academy of Sciences Institute of Medicine
NFP	Nutrition Facts Panel
QHC	Qualified Health Claim
QUID	Quantitative Ingredient Declarations
RACC	Reference Amount Customarily Consumed
US	United States
USDA	United States Department of Agriculture
UK	United Kingdom
WHO	World Health Organization

Update

April 2010

Since the publication of this report, the Food and Drug Administration (FDA) has taken major enforcement actions demanding that food companies change the labeling of about two dozen products that violate FDA regulations. Four of those products are mentioned in this report, including Nestlé Juicy Juice Brain Development Fruit Juice Beverage (Part VI-7), Diamond of California Shelled Walnuts (Part VII-5), Edy's Dibs Bite Sized Frozen [Ice Cream] Snacks (Part VIII-2), and Gorton's Crispy Fish Fillets (Part VIII-3).

While the FDA's enforcement actions represent much welcomed progress toward cracking down on misleading food labeling, the agency must solidify its approach by issuing industry-wide regulations, tackling additional problems not covered by its enforcement actions, and establishing new regulatory policies as discussed in this report.

For example, the FDA should establish a new regulatory framework for stopping misleading structure/function claims on conventional foods, such as "Strengthens your immune system." The agency should also issue regulations requiring that label claims like "Made with whole wheat" be accompanied by a statement disclosing what percentage of total grains in the product are whole. Presently, many products making such claims are made primarily from ordinary wheat flour. The FDA further needs to simplify the format of ingredient lists, require that caffeine content be disclosed, and issue rules defining the term "Natural."

To ensure that the FDA takes further action, Congress should exert oversight, provide the agency with adequate resources, and determine if legislation is needed to mandate FDA action within a specified time frame.

Part viii

Food Labeling Chaos

Executive Summary

Accurate, easy-to-read, and scientifically valid nutrition and health information on food labels is an essential component of a comprehensive public health strategy to help consumers improve their diets and reduce their risk of diet-related diseases.

However, as Food and Drug Administration (FDA) Commissioner Dr. Margaret Hamburg recognized in a 2009 speech to the National Food Policy Conference, "[T]he public health importance of food labeling as an essential means for informing consumers about proper nutrition . . . has not been substantially addressed since the FDA implemented the Nutrition Labeling and Education Act, more than 16 years ago."

> "[W]e've seen the emergence of claims that may not provide the full picture of their products' true nutritional value."
>
> *— FDA Commissioner Margaret Hamburg*

Hamburg also noted, "[W]e've seen the emergence of claims that may not provide the full picture of their products' true nutritional value. It will be important to reestablish a science-based approach to protect the public. . . . " Indeed, misleading claims, ranging from promises that a food can "strengthen" your immune system to misleading pictures on the fronts of food labels that misrepresent the type and quantity of fruits and vegetables in a processed food, are out of control and interfere with the consumer's ability to make healthy food choices.

Problems with food labels can be broken down into three basic categories:

- The Nutrition Facts Panel needs to be improved;
- Ingredient labels need to be modernized; and
- Health-related claims need more stringent regulation.

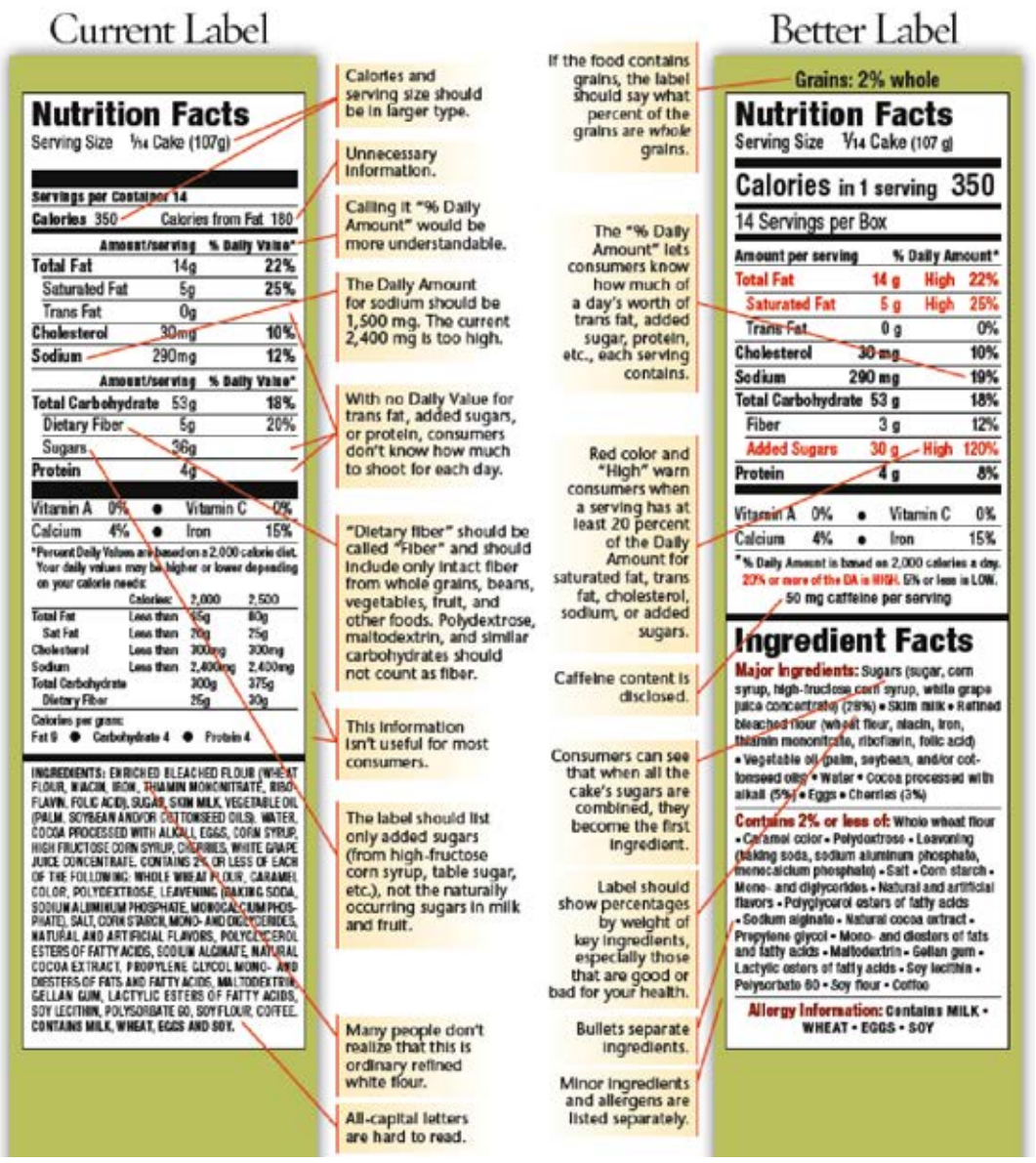
The FDA and the United States Department of Agriculture (USDA) have recently begun addressing some of those challenges. The FDA has announced it will test consumer reactions to simplified nutrition labels that could be used on the fronts of packages, pressured General Mills to drop exaggerated health claims for Cheerios cereal and stopped the use of industry's Smart Choices program. The USDA has re-proposed rules requiring nutrition labeling on fresh meat and poultry and published an Advance Notice of Proposed Rulemaking in an effort to stop misleading "All Natural" claims on meat and poultry labels. But much more work needs to be done.

Summary of Recommendations

1. Front-of-Package Nutrition Labeling: Key nutrition information should be summarized, using easy-to-comprehend symbols, on the fronts of food packages.

2. Improving the Nutrition Facts Panel: The existing nutrition label needs to be simplified by:

- Deleting extraneous information;
- Providing clearer, more accurate information on calorie, sugars, and fiber content;
- Changing disclosures for "Amount Per Serving," and "Serving Size" to statements like "Amount Per ½ Cup Serving";
- Prohibiting deceptive nutrition disclosures for large single-serving packages;
- Making nutrition labeling mandatory for single-ingredient meat and poultry products.



The mock-up on the right shows changes that are needed.

3. Ingredient Labels: The format of ingredient labels should be modernized by:

- Redesigning the ingredient list so that ingredient information is presented in a format similar to that used for nutrition information;
- Requiring that sources of added sugars be grouped together to give a better indication of total sugar content;
- Requiring that the amounts of key ingredients be disclosed as percentages of the total weight of the product; and
- Mandating that caffeine content be disclosed in a conspicuous location on the information panel.

The side-by-side comparison on the previous page illustrates some of the changes that need to be made to the Nutrition Facts Panel and the ingredient list.

While the FDA and the USDA have started making greater efforts to reduce the prevalence of misleading health-related claims, the agencies are merely scraping the tip of the iceberg. This mock-up of a food label illustrates some of the misleading claims that need to be addressed.

This illustration shows many of the misleading claims that should be stopped by the FDA.

These problems can be resolved by taking the following steps:

4. Health-Related Claims: The FDA and the USDA should issue regulations prohibiting misleading health-related claims on packages:
    - The agencies should establish a comprehensive regulatory framework for prohibiting misleading claims that a substance in a food can affect the structure or function of a bodily system (i.e., structure/function claims).
    - The FDA should cease the practice of exercising its enforcement discretion to permit "qualified health claims" for conventionial foods that, by definition, are based on weak scientific evidence.
    - Both agencies should prohibit "0 g trans fat" claims on foods that are not also low in saturated fat and cholesterol.
    - Both agencies should issue regulations controlling misleading "natural" claims.
    - Both agencies should promulgate new rules to stop companies from claiming that a food is made with whole wheat or other whole grains unless the percentage of grains that are whole is prominently disclosed.

Each of these recommendations is more comprehensively discussed at the end of each Part of this report and at greater length in Part XI.

The Need for Rulemaking

The FDA and the USDA should develop regulations instead of relying only on case-by-case enforcement actions. While the latter approach may signal to the food industry that the agencies are serious about enforcing the law, binding regulations are much more likely to ensure that companies do not break the law in the first place.

A Role for Congress

Many of the actions recommended in this report can and should be taken by the FDA and the USDA under existing legal authority. However, the broad scope and nature of the problem and competing agency priorities demand that Congress exert close oversight, ensure that each agency has sufficient resources and allocates them efficiently, and provide the FDA and the USDA with specific statutory mandates in areas where agency jurisdiction is unclear or motivation is lacking.

The time is ripe for comprehensive, coordinated action. Health experts, consumers, and even some food companies agree that food labeling reform will help consumers improve their diets, reduce the costs of diet-related disease, and provide companies that produce more healthful foods with a level competitive playing field.

Part I: Introduction

Expert Consensus on Food Labeling, Diet, and Health

Accurate, easy-to-read, and scientifically valid nutrition and health information on food labels is an essential component of a comprehensive public health strategy to help consumers improve their diets and reduce their risk of diet-related diseases. Improved food labeling could provide consumers with easy-to-read nutrition and ingredient information that they can use to reduce their risk of the leading causes of death in the United States today, including heart attack, stroke, certain forms of cancer, and diabetes.

Congress recognized the importance of nutrition and health information on food labels when it passed the Nutrition Labeling and Education Act of 1990 (NLEA). The House report accompanying the bill stated:

> The Surgeon General has advised Americans that diets low in fats, low in salt and high in fiber can reduce the risk of chronic diseases such as cancer and heart disease. . . . [S]tatements regarding the level of these nutrients in foods will assist Americans in following the Surgeon General's guidelines.[1]

This statement is supported by numerous public health authorities ranging from the National Academy of Sciences Institute of Medicine (IOM)[2] to the World Health Organization (WHO).[3]

Nutrition and health information could also play a key role in combating the current obesity epidemic that is plaguing both adults and children. About two-thirds of American adults are overweight and obese and 18% of American adolescents age 12-19 are overweight.[4] Obesity increases the risk of diet-related disease, and according to the Centers for Disease Control and Prevention (CDC), cost approximately $147 billion dollars last year in health care costs alone.[5] The First Lady of the United States has stated that she intends to help her children learn to read food labels in

1 H.R. Rep. No. 101-538, at 9-10 (1990).

2 *See* National Academy of Sciences Institute of Medicine (IOM), *Nutrition Labeling: Issues and Directions for the 1990s* (1990); IOM, *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* 1-2 (2003), *available at* http://books.nap.edu/openbook.php?record_id=10872&page=1.

3 World Health Organization, *Global Strategy on Diet, Physical Activity, and Health* (2004).

4 Centers for Disease Control and Prevention (CDC), Fast Stats Home Page, Obesity and Overweight, *available at* http://www.cdc.gov/nchs/fastats/overwt.htm (last visited Dec. 11, 2009).

5 Press Release, CDC, Study Estimates Medical Cost of Obesity May Be As High as $147 Billion Annually. *New Community Recommendations Show Ways to Reduce Burden* (July 27, 2009), *available at* http://www.cdc.gov/media/pressrel/2009/r090727.htm.

order to help them maintain healthy weight levels and develop healthy eating patterns that will serve them well into adulthood.[6]

Requirements for Nutrition Facts Labels and Ingredient Lists are Out of Date

As Food and Drug Administration (FDA) Commissioner Dr. Margaret Hamburg recognized recently in a speech to the National Food Policy Conference, "[T]he public health importance of food labeling as an essential means for informing consumers about proper nutrition . . . has not been substantially addressed since the FDA implemented the Nutrition Labeling and Education Act, more than 16 years ago."[7] Indeed, consumer research demonstrates that the majority of Americans do not understand the "% DV fat" disclosure required on Nutrition Facts labels, which is supposed to indicate whether a food is high or low in fat.[8] The current Nutrition Facts label fails to provide any "Daily Value" at all for trans fats[9] and added sugars, two nutrients that play a major role in diet-related disease.

Some improvements to the Nutrition Facts Panel (NFP) are relatively straightforward —calories should be listed more prominently, and nutrient content should be disclosed for realistic serving sizes.[10] For example, products such as Healthy Choice Minestrone Soup—sold in cups intended both for heating the product in the microwave and for use as a soup bowl—should not be permitted to state that the product contains "about 2 servings." It is highly unlikely that the soup will be consumed by more than one person. The "per serving" information provided on the front of the package should relate to the entire contents of the container. Other improvements may require greater changes regarding how nutrition information is disclosed.[11]

Some countries, such as the United Kingdom (UK), have developed alternatives to traditional nutrition labeling as required in the United States. The key features of these alternatives are to 1) place a modicum of nutrition information on the fronts

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6 Darlene Superville, *Trainer Spills Secrets of Michelle Obama's Arms*, Associated Press, Sept. 7, 2009, *available at* http://today.msnbc.com.

7 Margaret Hamburg, M.D., Comm'r of Food and Drugs, Keynote Address at the National Food Policy Conference, Washington, D.C. (Sept. 8, 2009), *available at* www.fda.gov/NewsEvents/Speeches.

8 L. Levy *et. al., How well do consumers understand percentage daily values on food labels?* Am. J. Health Promotion 14:157-60. (2000). "Only 29 percent correctly selected the definition of % Daily Value for fat (%DV), as 'percent of the maximum daily recommended amount of fat.'" *Id.*

9 Providing a DV for trans fat is only an interim solution. Artificial trans fat should be banned by the FDA.

10 The FDA's Obesity Working Group recommended that FDA solicit comments on how to give more prominence to calories on the food label and asked FDA to reexamine its serving size regulations. FDA, *Calories Count: Report of the Working Group on Obesity* 26-28 (Mar. 12, 2004).

11 A USDA study on consumer use of nutrition labels concluded that "consumers may benefit from a change in the format of nutrition information on labels, particularly one that brings the format more in line with specified USDA dietary guidelines." Jessica E. Todd *et. al.*, USDA 20 (Aug. 2008).

of packages, and 2) use symbols (such as a keyhole icon on more-healthful foods or red, yellow and green dots on all foods) to indicate a food's overall healthfulness. The European Union (EU) has proposed a regulation requiring the amounts of six key nutrients to be disclosed on the fronts of all food packages.[12] In contrast, the FDA has only held a public meeting on the issue and commissioned some consumer research. Congress has appropriated $500,000 for a study by the IOM on the issue[13] and the FDA and Congress may contribute additional funds. The failure to take stronger steps in the United States reduces the full potential of the role that food labeling could play in reducing diet-related disease.

In addition to the Nutrition Facts label not being updated for more than one and one-half decades, requirements for ingredient listings on processed foods have not been comprehensively updated since 1938. Ingredients are still allowed to be listed in tiny print, percentages of key ingredients are not generally required to be disclosed (as they are in more than 25 other countries around the world), and allergen information, while subject to new statutory requirements that took effect in 2006, is according to one recent study,[14] still difficult to utilize by the more than 12 million Americans who suffer from food allergies.[15] Statements such as "may contain [name of allergen]" can be overly broad and fail to provide allergy sufferers with useful information. In addition, the quantity of caffeine is not required to be disclosed on foods, including energy drinks that often make health-related claims.

FDA Policies Lead to Marketplace Chaos

Additional problems are caused by inadequate regulation of misleading claims on food labels.

As FDA Commissioner Hamburg has noted, "[W]e've seen the emergence of claims that may not provide the full picture of their products' true nutritional value. It will be

12 These include energy (calories), fat, saturated fat, carbohydrates with specific reference to sugars and salt content. *Commission Proposal for a Regulation of the European Parliament and of the Council on the Provision of Food Information to Consumers,* at 8, COM (2008) 40 final (Jan. 30, 2008).

13 Within the total provided for Nutrition, Physical Activity, and Obesity, the bill includes $500,000 for a study by the Institute of Medicine (IOM) that will examine and provide recommendations regarding front-of-package nutrition symbols. These should include, but not be limited to, a review of systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad and the overall merits of front-label nutrition icons, the advantages and disadvantages of various approaches, and the potential benefits of a single, standardized front-label food guidance system regulated by the Food and Drug Administration. Based upon its work, the IOM should recommend one or several of the systems, along with means of maximizing the use and effectiveness of front-label symbols, that it has identified as best at promoting consumers' health.

Omnibus Appropriations Act 2009, Pub L. No. 111-8, Div. F (2009).

14 *Allergy study faults labels as ambiguous*, Food Chem. News, Aug. 31, 2009, at 17.

15 The Food Allergy and Anaphylaxis Network (2009), http://foodallergy.org/page/facts-and-stats (last visited Dec. 15, 2009). Food allergy affects up to 6-8% of children four years old or younger and close to 4% of adults. U.S. Dep't of Health and Human Services (HHS), National Institute of Allergy and Infectious Disease 1 (2007), *available at* http://www3.niaid.nih.gov/topics/foodAllergy/understanding/quickFacts.htm.

important to reestablish a science-based approach to protect the public. . . . "[16]

The 1990 NLEA set up a pre-market approval requirement for health claims (claims that a nutrient in a food can help reduce the risk of a specific disease or health-related condition when consumed from generally healthful foods that form the basis of an overall healthful diet). During the Bush Administration, the agency essentially adopted a policy of non-enforcement.[17]

Further, the NLEA left major categories of other types of health-related claims unregulated, such as those that claim that a nutrient in a food can positively affect the structure or function of the body[18] (e.g. that the antioxidants and nutrients in Kellogg's Cocoa Krispies "now helps support your child's immunity" or that the omega-3 in Diamond chopped walnuts can help maintain a healthy heart). Such claims for foods are viewed by the typical consumer as health claims,[19] but are completely unregulated by the FDA. The agency issued a weak enforcement policy for structure/function claims on dietary supplements (which are subject to a different, weaker statutory scheme), but never established rules for structure/function claims for foods. Such standards should indicate which claims are permissible and set forth requirements for the type of evidence a company needs to substantiate the label claim. In the absence of effective regulation, structure/function claims have become one of the most deceptive forms of claims on food labels today.

The NLEA also set up a pre-market approval requirement for nutrient content claims (e.g. claims that a food is "low" in fat or "high" in fiber) and required the FDA to define certain commonly used terms at the time such as "lite" and "healthy." The regulations implemented by the FDA have not kept up with the new scientific developments and marketing trends in the food industry. For example, the FDA prohibits claims that a food is "saturated fat free" if a serving contains more than 0.5 g of trans fat, but the agency has failed to prohibit "0 g Trans Fat" claims for foods that are high in saturated fat.

Further, the NLEA ignored an increasingly common category of claims emphasizing the presence of healthful ingredients, such as whole grains, fruits, and vegetables. The amounts of such ingredients are not disclosed on either the Nutrition Facts Panel or the ingredient list. Many companies, such as S. B. Thomas, manufacturer of Thomas'

16 Margaret Hamburg, M.D., Comm'r FDA, Keynote Address at the National Food Policy Conference, Washington, D.C. (Sept. 8, 2009) (*available at* www.fda.gov/NewsEvents/Speeches).

17 Food Labeling: Health Claims; Dietary Guidance; Advance Notice of Proposed Rule Making (ANPR), 68 Fed. Reg. 66040-41 (Nov. 25, 2003). FDA noted that the July 11, 2003 *Guidance for Industry and FDA: Interim Procedures for Health Claims in the Labeling of Human Food and Human Dietary Supplements* has been implemented on an interim basis. That Guidance permits use of qualified health claims as an exercise of FDA's enforcement discretion. FDA has issued many letters permitting claims based on evidence that does not meet the significant scientific agreement standard.

18 When the NLEA was passed, structure/function claims were rarely made for foods. But when the Dietary Supplement Health and Education Act of 1994 permitted dietary supplements to carry such claims, structure/function claims proliferated on supplements and, eventually, on conventional food products.

19 International Food Information Council (IFIC), *Qualified Health Claims Consumer Research Project Executive Summary* 8 (Mar. 2005).

Hearty Grains English Muffins, imply that their products contain significant quantities of those ingredients by claiming that a product is "made with whole grains." Others, like Gerber, plaster the front of a package of chewy fruit-flavored "Juice Treats" with pictures of real fruits, when only juice from some of the pictured fruits is actually in the product. This problem can be remedied by requiring on the front of the package or in the ingredient list the percentage by weight of the highlighted ingredient.

The FDA has also largely not regulated other claims, such as "natural," that some consumers may interpret as indicating a more nutritious or wholesome food product than is actually the case. Thus, while not an explicit health or nutrient content claim, claims such as "natural" are worthy of the agency's attention as part of a comprehensive program to improve food labeling and help consumers reduce their risk of diet-related disease.

"By 2005, Congress was so concerned that it asked the FDA to report on the types of food labeling violations (other than those relating to safety) that the agency had uncovered and the actions taken to address them.... The FDA's answer to Congress was largely non-responsive. . . ."

Enforcement Declines at the FDA

In general, since 2001, there has been a significant decline in labeling enforcement by the FDA.[20] By 2005, Congress was so concerned that it asked the FDA to report on the types of food labeling violations (other than those relating to safety) that the agency had uncovered and the actions taken to address them. The Senate Appropriations Committee wanted to ensure that "[F]ood labels can be easily understood and reflect information that is factual" and not misleading.[21] The House of Representatives was concerned that consumers would lose confidence in the trustworthiness of the food label because of inaccuracies in the amount of nutrients declared in the Nutrition Facts Panel, the misuse of terms such as "low calorie" and "healthy," misleading heart health claims, and the use of product names that violate standards of identity.[22]

The FDA's answer to Congress[23] was largely nonresponsive to the Committees' requests. The answer did, however, reveal a lack of commitment on the part of the agency.[24]

In October 2008, the congressional watchdog agency, the Government Accountability Office (GAO), gave the FDA failing grades for preventing false and misleading labeling.

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20 CSPI, *Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health-Related Claims on Food Labels* (July 18, 2006), *available at* http://cspinet.org/new/pdf/fn5rep.pdf.

21 S. Rep. No. 109-92, at 153 (2005).

22 H.R. Rep. No. 109-102, at 83 (2005).

23 FDA, *Report to Congress on Compliance with Food Label Regulations under the Food and Drug Administration's Purview Senate Report 109-92* (2005); FDA, *Report to Congress on Compliance with Food Label Regulations under the Food and Drug Administration's Purview House Report 109-102* (2005), *available at http://cspinet.org/new/pdf/sen_and_hou_rpt_109-92_food_label_reg.pdf.*

24 CSPI, *Rebuttal to FDA Report to Congress, supra* note 20.

GAO found that while the number of food firms and products has increased dramatically, the FDA's oversight and enforcement actions "have not kept pace." As a result, the "FDA has little assurance that companies comply with food labeling laws and regulations. . ."[25]

But if the FDA had the will, it could convince companies to obey the law. For example, the Center for Science in the Public Interest (CSPI) stopped numerous misleading labeling claims by leading national food companies. CSPI, working under state consumer protection laws, has secured agreements improving food labeling, marketing, or product formulation with Frito-Lay, Kellogg, KFC, Kraft, Sara Lee, and other companies. The FDA, an agency with approximately 1,000 employees assigned to ensuring that foods are safe and properly labeled, could certainly achieve as many successes as a relatively small nonprofit organization like CSPI.

USDA Policies – Comparisons and Contrasts

The United States Department of Agriculture (USDA) generally follows the same rules for Nutrition Facts labeling and health and nutrient content claims as the FDA.[26] The USDA, however, follows a system of prior label approval—labels of processed foods containing any significant amounts of meat and poultry (such as beef stew or sausage pizza) are approved by USDA officials prior to marketing. The USDA has issued a series of policy memoranda summarizing many of its decisions to approve or disapprove a particular label. This practice has generally resulted in fewer misleading claims on USDA regulated products.

But, there are ways in which the USDA labeling rules are weaker than the FDA's:

- The USDA does not require the amount of trans fatty acids per serving to be listed on Nutrition Facts Panels;
- The USDA does not require Nutrition Facts labeling on packages of single ingredient raw meat and poultry (a rule was proposed, but never finalized);[27]
- The USDA allows % lean claims on ground beef, which imply that the product is lower in fat than comparable non-meat foods;
- The USDA allows poultry to be labeled "all natural" even when it has been injected with salty broth.

Consumers do not expect a pepperoni pizza label to be regulated by the government any differently from a cheese pizza label. The USDA and the FDA should harmonize

25 GAO, Food Labeling: *FDA Needs to Better Leverage Resources, Improve Oversight and Effectively Use Available Data to Help Consumers Select Healthy Foods*, Highlights of GAO-08-597 (Sept. 2008), *available at http://www.gao.gov/new.items/d08597.pdf.*

26 *See* James T. O'Reilly, *Food and Drug Administration*, ch.24:5 n. 9. (Thomson West 2007).

27 Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products; 66 Fed. Reg. 4969 (proposed Jan. 18, 2001).

their regulations and enforcement policies to the greatest extent possible, following a system of "best practices" that draws upon the strength of each agency's approach to a specific labeling issue.

Economic Impact of Past Labeling Reforms

The economic impact of food labeling reforms has been extensively studied. The FDA's major economic impact analysis of its regulations implementing the 1990 NLEA concluded that "[E]stimates of the number of discounted life years gained nationwide for the first 20 years after implementation of the act range from a high of nearly 1.2 million to a low of 40,000." According to this study, the value of life years saved by mandatory nutrition labeling ranged from more than $106 billion to $3.6 billion over the same 20-year period based on 1988 dollars. Thus, the FDA concluded that "[R]elatively small changes in nutrient intakes may generate substantial public health benefits."[28]

"The FDA concluded that '[R]elatively small changes in nutrient intakes may generate substantial public health benefits.'"

A later estimate of a modification to the Nutrition Facts Panel in 2006, which required manufacturers to disclose the number of grams of trans fatty acids per serving, found that in three years, this single change alone would prevent from 600 to 1,200 cases of coronary heart disease and prevent from 240 to 480 deaths annually. It would also result in total benefits ranging from $4.1 billion to $8.3 billion per year.[29] Those were likely gross underestimates, because the FDA assumed that only a small fraction of trans fat would be eliminated; in fact, probably more than half of trans fat has been eliminated.

Although the protocols for these two economic impact analyses were different, they both concluded that changes that provide consumers with certain better and more easily understood nutrition information on food labels would be cost-beneficial. Consumer research has shown that many consumers use the Nutrition Facts Panel and that, while cause-and-effect relationships are difficult to establish, the use of nutrition labeling is associated with healthier diets.[30]

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28 Gary A. Zarkin, PhD, *et. al, Potential Health Benefits of Nutrition Label Changes,* 83 Am. J. of Pub. Health 717-724 (May 1993).

29 Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41434, 41488, 41,467 (July 11, 2003).

30 *See* Sung-Yong Kim, *et. al., The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis*, 25 Journal of Agricultural and Resource Economics 215 (July 2000) (finding that nutrition label users consume fewer calories from fat, less cholesterol and sodium, and more fiber, than non-label users); Alan R. Kristal *et al. Predictors of self-initiated, healthful dietary change,*101 *J Am Diet Assoc.* 762-765 (2000) (finding that the use of food labels is strongly associated with fat reduction); Alan D. Mathios, *The Impact of Mandatory Disclosure Laws of Product Choices: An Analysis of the Salad Dressing Market.* Alan D. Mathios, *J. Law & Econ.*651-677 (2000) (finding that the addition of the NFP to food packages reduced the sale of high fat foods); The American Dietetic Association. *Nutrition Trends Survey 1997* (Sept. 1997) (finding that approximately two-thirds of those reading the NFP reported that they stopped or started buying a food product because of something they read on the label, and 56% of consumers said the information on the nutrition label had caused them to switch brands). Some of those studies found associations between reading labels and healthier diets, but could not establish cause and effect.

A Challenge for the Administration and Congress

Many of the actions recommended in this report can and should be taken by the FDA and the USDA under existing legal authority. However, the broad scope and nature of the problem and competing agency priorities demand that Congress exert close oversight, ensure that each agency has sufficient resources and allocates them efficiently, and provide the FDA and the USDA with specific statutory mandates in areas where agency jurisdiction is unclear or motivation is lacking.

The time is ripe for comprehensive, coordinated action. The public health community, consumers, and even some segments of the food industry agree that food labeling reform will help consumers improve their diets, reduce the costs of diet-related disease, and provide companies who want to produce more healthful foods with a level competitive playing field.

This report suggests how legislators and regulators can confront these challenges by addressing three basic questions:

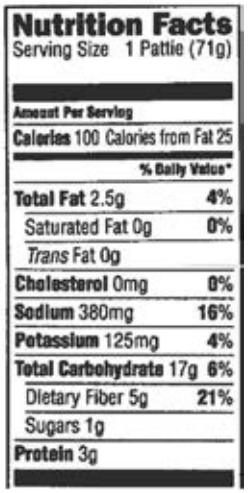
- How should nutrition information on food labels be improved?
- How should ingredient information be clarified?
- What should be done to prevent misleading health-related claims on food labels?

To answer each of these questions, this report summarizes major health-related issues involving specific food labeling controversies, examines current laws, regulations, and enforcement policies, and outlines recommendations for reform.

Part II: Improving the Nutrition Facts Panel

The Problem

Nutrition information on food labels can play an important role in the battle against obesity and diet-related disease, which are responsible for hundreds of thousands of premature deaths in the United States each year.[1] Almost all foods are required to contain a Nutrition Facts Panel that discloses nutrition information for key ingredients. One glaring omission is meat and poultry, which are not currently required to be labeled. That matter is currently being addressed by the USDA.[2]



To reach its full potential, however, the content and format of the Nutrition Facts Panel needs to be modernized. Twenty years ago, Congress drafted The Nutrition Labeling and Education Act of 1990, which established the requirement for an NFP. Now, two thirds of all adults are overweight or obese[3] and, 18% of children age 12-19 are overweight.[4] The current Nutrition Facts label was not specifically designed to help prevent obesity and needs to be revised to help reverse this alarming trend. Information on calories needs to be improved, superfluous information needs to be deleted, serving sizes need to be rationalized, and a Daily Value (DV) for added sugar needs to be established.[5] The FDA and the USDA should take the following measures.

A. Calories per serving should be disclosed more prominently on the Nutrition Facts Panel

The most important declaration on the Nutrition Facts Panel when it comes to obesity prevention is the disclosure of calorie content. Yet, this information is presented in the same size type as other listings on the nutrition label. "Calories" should be

1 A 2005 CDC study estimated that approximately 112,000 deaths are associated with obesity each year in the United States, making obesity the second leading contributor to premature death. *See* Flegal KM, et al. "Excess Deaths Associated with Underweight, Overweight, and Obesity." *JAMA* 2005, vol. 293, pp. 1861-1867.

2 See note 40 *infra* and accompanying text.

3 Trust for America's Health, *F as in Fat 2009* http://healthy Americans/reports/obesity2009 (last visited Dec. 24, 2009).

4 CDC, Fast Stats Home Page, Overweight Prevalence, *available at* http://www.cdc.gov/nchs/fastats/overwt.htm (accessed Dec. 10, 2009.) Statistics are from 2005-2006. In that period, 15% of children age 6-11 were overweight and 11% of children age 2-5 were overweight. *Id.*

5 Although the accuracy of the Nutrition Facts Panel is another important issue, it is beyond the scope of this report. The FDA has not conducted a systematic examination of food labels to test for accuracy since 1996. *Analysis of 300 Foods with Nutrition Labeling and Education Act (NLEA) Label Requirements,* FDA Contract Number: 2233-91-2185. Some market observers speculate that one out of every four labels is inaccurate. Inaccuracies may include sugar in sugar-free products and fat and sodium content exceeding labeled claims. Mitch Lipka, *Use food labels to know what you're eating? There's a 1 in 4 chance they're wrong,* http://www.walletpop.com/blog/2009/09/22/use-food-labels-to-inow-what-youre-eating (Sept. 22, 2009). CSPI has urged the FDA to periodically conduct systematic tests of the accuracy of the Nutrition Facts Panel. CSPI, *Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health-Related Claims on Food Labels* (July 18, 2006).

listed in larger type and highlighted with a contrasting background.

In addition, the label should integrate the calorie disclosure line with the serving size line. For example, a 12 fl. oz. can of Coke currently states:

- Serving size 1 can
- Amount per serving
- Calories 140

The revised NFP that CSPI recommends would state "140 calories per 1 can serving" all on one or two lines. That disclosure would be simpler for consumers to read and understand.

B. Extraneous information should be eliminated

1. The "calories from fat" line of the NFP should be eliminated

Currently, the FDA's nutrition labeling regulations require that "calories from fat" be listed along side or directly below "calories."[6] (This currently required disclosure should not be confused with "% of calories from fat" which has never been required to be listed on the NFP.)

Current label

Nutrition Facts

Serving Size 1 Pattie (71g)

Amount Per Serving
Calories 100 Calories from Fat 25

	% Daily Value
Total Fat 2.5g	**4%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 380mg	**16%**
Potassium 125 mg	**4%**
Total Carbohydrate 17g	**6%**
Dietary Fiber 5g	**21%**
Sugars 1g	
Protein 3g	

Proposed revision

Nutrition Facts

Serving Size 1 Pattie (71g)

100 Calories per 1 Pattie Serving (71g)

Amount per serving:

	% Daily Value
Total Fat 2.5g	**4%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 380mg	**16%**
Potassium 125 mg	**4%**
Total Carbohydrate 17g	**6%**
Dietary Fiber 5g	**21%**
Sugars 1g	
Protein 3g	

Enlarging the required font size for calories will heighten consumer awareness of its importance.

Deleting "calories from fat" would make more room on the label for a larger disclosure of "calories" per serving. The FDA's own Working Group on Obesity recommended that the FDA publish an Advance Notice of Proposed Rulemaking (ANPR) requesting comments on how best to give prominence to calories that would include eliminating "calories from fat." The Working Group stated that the "calories from fat" listing "takes the emphasis away from 'total calories.'"[7]

2. The footnote on the Nutrition Facts Panel should be eliminated

Another portion of the NFP that could be deleted to simplify the label is a footnote that includes a table of percent DVs for the macro-nutrients in the product based on both a 2,000 and 2,500 calorie diet.[8]

6 21. C.F.R. § 101.9(c)(1)(ii).

7 FDA, *Calories Count: Report of the Working Group on Obesity* 20 (2004).

8 21 C.F.R. § 101.9(d).

The footnote reflects a 1993 political compromise between the FDA and the USDA. The FDA wanted the %DV to be based on a 2,000 calorie diet, but the USDA wanted %DVs to be based on 2,500 calories. The higher calorie level would make the %DVs for the fat content of meat products appear lower, thereby improving a meat product's apparent nutrient profile.[9] When the two agencies could not agree, the issue ultimately ended up on the desk of President George H. W. Bush. The FDA ultimately prevailed, but the footnote was created as a consolation prize for the USDA—consumers were given the option to use the information in the footnote for a 2,500 calorie per day diet favored by the USDA.

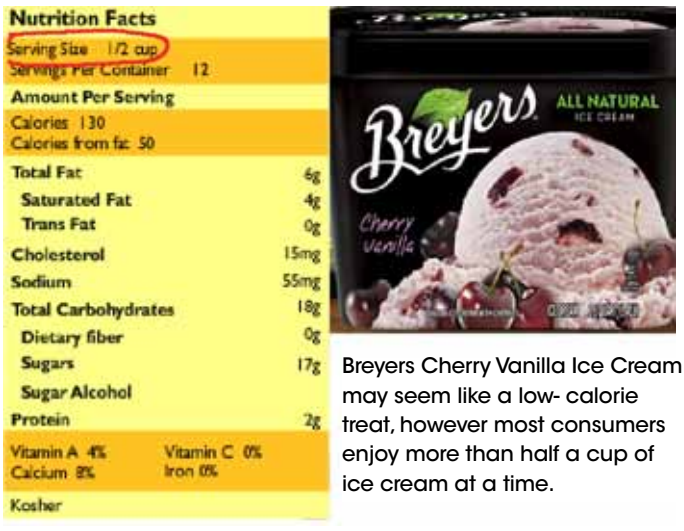
But it is doubtful that many consumers use the footnote in this manner. According to results of focus groups conducted by the FDA, the footnote may be little used.[10] The footnote should, therefore, be removed, because it is unnecessary and doing so would make room for more important information.

Few consumers use the information contained in the NFP "footnote" according to focus group studies conducted by the FDA.

C. Serving size regulations should be updated

One of the most important changes to the NFP is to rationalize the serving sizes on which all nutrient disclosures and DVs are based. The law requires that the calorie content of a food be disclosed on a per serving basis, which the statute defines as an amount "customarily consumed."[11] The FDA issued regulations setting out serving sizes for 140 food categories in 1993.[12] These serving sizes are referred to as the "Reference Amount Customarily Consumed (RACC)."[13]

Many of those regulations have become outdated; they were based on the 1977-78 and 1987-88 Nationwide Food Consumption Surveys developed by the USDA. Those surveys are now more than 20 years out of date.[14] Newer food consumption data show that consumers are eating larger portion sizes than they did in the 1970s and 1980s. Some consumers typically eat more than the amount the FDA specified in 1993 as a customary serving. For example, the RACC for ice cream is ½ cup. Many consumers eat considerably more than that amount and may not realize that they need to recalculate the calorie information based on the number of servings they actually consume.



Breyers Cherry Vanilla Ice Cream may seem like a low- calorie treat, however most consumers enjoy more than half a cup of ice cream at a time.

9 Of course, doing this also lowers the apparent vitamin and mineral content of meat and poultry products.

10 FDA, *Calories Count: Report of the Working Group on Obesity* 18 (2004).

11 Federal Food, Drug and Cosmetic Act (FDCA) § 403(q)(1)(A)(i), 21 U.S.C. § 343(q)(1)(A)(i).

12 58 Fed. Reg. 2229 (Jan. 6, 1993).

13 21 C.F.R. § 101.9(b)(2).

14 70 Fed. Reg. 17,010, 17,011 (Apr. 4. 2005).

Food Labeling Chaos

According to the label, this soup has "about 2 servings." But half of consumers surveyed consumed the contents of the entire 18.8 oz. can.

Similarly, although soup has a reference amount of about one cup, many consumers eat at least double that amount during a single meal. A January 2010 survey conducted for CSPI by Opinion Research Corporation indicated that 50% of survey participants consumed an entire 18.8 oz. can of Campbell's Chunky Soup which is labeled as containing "about 2 servings."

Deciding whether to update RACCs raises complicated policy issues. If RACC amounts are updated to reflect current consumption, the FDA is afraid that consumers will construe the RACC amount as the amount recommended for consumption.[15] In any event, the FDA should arrive at a solution that is consistent with the NLEA mandate that nutrient content information be based on amounts customarily consumed. Congress's rationale for this requirement was that manufacturers should be required to disclose the amounts of calories, fat, sodium and other nutrients that are *actually* consumed, rather than what consumers should be consuming based on public health recommendations. It was expected that reasonably health-conscious consumers would reduce their consumption of food items that provided high DVs for saturated fat, sodium, cholesterol, and other undesirable nutrients, if that information was presented clearly and concisely.

The label of this 18.5 oz. bottle of Fuze Orange Mango Vitalize states 100 calories per serving but is labeled as containing about 2 servings.

D. Regulations should be issued requiring that nutrition information be provided for large single servings

Consumers may be misled when they look at the nutrition information for a product that they assume to be a single serving and do not realize that the nutrition information is based on only a fraction of the product. For example, consumers may buy an individually packaged blueberry muffin that is labeled as containing 200 calories. But that disclosure may be based on the number of calories in only half the muffin. The actual calorie content of the muffins as packaged could be 400 calories. Some consumers may not have purchased the product, or eaten only half, if the calorie content of the product were accurately stated on the label.

Under existing law, only products that are under 200% of the RACC are

15 *Id.* at 17,012.

required to be labeled as single servings. Otherwise, manufacturers have the discretion to choose how many servings to declare.[16] For example, because a soft drink has a RACC of 8 oz., manufacturers of 20 oz. beverages can legally claim the container has 2.5 servings[17] and disclose calorie, sugar, and other nutrition information for only 8 oz. Similarly, certain brands of frozen pizzas, baked goods, snacks and other products are labeled as multi-serving products, despite the fact that they are really packaged to be consumed by a single person on one occasion. Many manufacturers prefer listing nutrition information on a RACC basis as opposed to a per package basis (even though consumers are likely to eat the entire package), apparently because doing so makes the calorie content of the product look more modest.

One could reasonably assume that the small packages typically sold in convenience stores, vending machines and snack shops indicate that the nutrition information applies to the entire package. But nutrition information for many such products is based on the misleading premise that each package contains multiple servings.

Similarly, labels for Healthy Choice Minestrone soup sold in a microwaveable bowl claim to contain about 2 servings, and disclose sodium and other information on the Nutrition Facts Panel for only half of what is clearly a single-serving container. We note that the label does contain a banner stating "This entire package contains 210 calories," but sodium information is presented for only one-half of the container. If the manufacturer provided sodium and other nutrition information for the entire package, the product could no longer be labeled as "healthy" because

Given the small package size, consumers are likely to assume that each of these products contains just one serving. But each supposedly contains about 2.5 servings.

This product is "Healthy" based on FDA official serving sizes, but has too much sodium to qualify for a healthy claim if the entire 14 oz microwave container is consumed.

16 21 C.F.R. § 101.9(b)(6). The FDA's rules for serving size are, in the agency's own words, "very technical." The regulations start from the premise that all products under 200% of the RACC are a single serving unless the terms of an exception are met. Manufacturers of products that have 200% or more of the RACC have discretion to label a product as a single serving "if the entire contents of the package can reasonably be consumed at a single eating occasion." *Id. FDA, Letter to Food Manufacturers about Accurate Serving Size Declaration on Food Products*, 2 (Mar. 12, 2004) *available at* http://www.cfsanfda.gov/~dms/fl-ltr4.html.

17 Coca-Cola, Pepsi, and other beverages list nutrition information for both the RACC and the entire (often a single-serving) bottle.

The "vitaminwater" label uses a confusing dual column format to disclose nutrition information by both the RACC and the entire (single serving) container for healthy nutrients that it wishes to highlight.

the sodium content would be about 800 mg, instead of 400 mg as declared on the label. FDA regulations require that a food cannot be labeled as "healthy" unless it contains no more than 480 mg of sodium per RACC or per labeled serving.[18]

Some manufacturers have attempted to address the single serving issue by providing nutrition information in two columns—one for the RACC and one for the entire container. An example is Coca-Cola's "Vitaminwater," which is sold in a 20-oz. bottle. The NFP states that it contains 50 calories per serving and has 2.5 servings. Adding dual columns makes the label even more confusing. The bottle is certainly likely to be consumed by one person at a single eating occasion who will take in 125 calories.

Makers of large single-serving packages should not be allowed to pretend that those packages really contain multiple servings. A more straight forward way to communicate nutrition information would be to simply disclose the nutrient content for the entire container when it is likely to be consumed by one individual at a single eating occasion. The dual-column format is misleading and should be barred.[19]

E. A Daily Value should be established for added sugars, the DV and the amount of added sugars per serving should be disclosed on the NFP, and the term "low sugar" should be defined

In 1999, CSPI and dozens of leading health experts and organizations petitioned the FDA to require that food labels declare how much added sugar is used in soft drinks, ice cream, and other foods, and adopt a Daily Value of 10 teaspoons, about 40 g for added sugar. That amounts to 160 calories or 8% of total calories. Numerous health authorities have urged consumers to limit added sugars to 6% to 10% of calories.[20]

Reducing the consumption of added sugars is an essential public health measure. Diets high in added sugars, from such foods as soft drinks, fruit drinks, candy, cakes, and cookies, squeeze healthier foods out of the diet. In some people, diets high in

18 21 C.F.R. § 101.65(d)(2)(ii)(healthy requirements); FDA, *Food Labeling Guide*, App. B X-4. (Apr. 2008).

19 FDA regulations permit dual-column labeling only for two or more forms of the same food, e.g., "as purchased," "as prepared," or for two or more groups for which RDIs are established, such as infants and children less than 4 years. 21 C.F.R. § 101.9 (e). That section provides that if dual labeling is used, *all* nutrient information must be provided on a per serving and a per container basis, something that the "vitaminwater" label fails to do. *Id.*

20 In 2003, the World Health Organization (WHO) recommended a limit of less than 10% of energy in the form of "free" sugars (or "extrinsic" sugars, which includes the sugars in fruit juice) WHO-FAO, *Diet, nutrition and the prevention of chronic diseases,* 56 TRS 916 (2003) *available at http://www.who.int/dietphysicalactivity/publications/trs916/summary/en/index.html* (last visited Dec. 24, 2009). The HHS, USDA 2005 *Dietary Guidelines for Americans* recommended a limit of 6.4% of calories or 32 grams for a 2,000 calorie diet. Dietary Guidelines for Americans, *available at* http://www.health.gov/Dietaryguidelines/dga2005/document/html/AppendixA.htm (last visited Dec. 24, 2009) Appendix A-3.

added sugars contribute to obesity. Obesity, in turn, increases the risk of diabetes, heart disease, high blood pressure and other health problems. In addition, frequent consumption of foods rich in added sugars promotes tooth decay.

In "The Food Guide Pyramid," the USDA advises consumers to try to limit themselves to about 10 teaspoons of added sugars per day (40 g)[21] based on a 2,000 calorie per day diet. Most recently, the American Heart Association (AHA) set an upper limit for added sugar intake that is no more than 100 calories per day for most American women and no more than 150 calories for men.[22] To put this in perspective, just one 12 oz. can of Coca-Cola contains 140 calories and has about 10 teaspoons of added sugars.

Further, the U.S. Dietary Guidelines, the Institute of Medicine, and other health authorities have urged consumers to restrict their intake of sweetened beverages and foods.[23] The American Academy of Pediatrics, the World Health Organization, and other authorities specifically recommend limiting the consumption of added sugars from diluted fruit juices.[24] The failure to disclose added sugars on the Nutrition Facts Panel is a glaring omission. Using current labels, it is difficult or impossible for consumers to determine how much sugar has been added to a

Kellogg misrepresents an IOM study on the label of Smart Start Strawberry Oat Bites Cereal.

21 USDA, Pamphlet, *The Food Guide Pyramid Home and Garden Bulletin No, 252.* (Aug. 1992)(rev'd Oct. 1996 at 17.)

22 Am. Heart Asso'n, *Dietary Sugars Intake and Cardiovascular Health. A Scientific Statement from the Am. Heart Asso'n,* Circulation (Aug. 24, 2009).

23 *Dietary Guidelines, supra* note 20, at 37-38.

24 Comm. on Nutrition. "The Use and Misuse of Fruit Juice in Pediatrics." Pediatrics. 2001 May;107(5): 1210-1213;. Popkin BM, et al. "A new proposed guidance system for beverage consumption in the United States;"Am J Clin Nutr. 2006 Mar;83(3):529-42. Erratum in: Am J Clin Nutr. 2007 Aug; 86(2):525; WHO. "Diet, Nutrition and the Prevention of Chronic Diseases." WHO Technical Report Series No.916. Geneva 2003 http://libdoc.who.int/trs/WHO_TRS_916.pdf.

food such as yogurt, canned fruit, applesauce, or diluted juice drinks.

At least one major food company has intentionally exploited the vacuum caused by the FDA's failure to establish a DV for added sugar. Kellogg, on the label of its Smart Start cereal (shown on the previous page), cites an IOM report as the basis for telling consumers that they should aim to limit their consumption of added sugars to 25% of calories "to help minimize the consumption of foods with empty calories." Kellogg advises consumers that they can have up to 125 g of added sugar per day.

But, as the president of the IOM has clarified, the report "is not meant to convey a desirable or even acceptable standard intake…. Interpretations suggesting that a sugar intake of 25% of total calories is endorsed by the Institute's report are incorrect."[25] Nonetheless, Kellogg continues to use its discredited interpretation of the IOM report.

Kellogg's Frosted Mini Wheats claim to be "lightly sweetened," but contain 12 grams of sugar per serving or about 20% sugar by weight.

Moreover, although the FDA has issued a regulation governing the use of "sugar free," "reduced" and "no added sugars," it has not issued a regulation governing "low sugar."[26] As a result, companies are permitted to say "Fat Free" or "Low Fat" on the labels of highly sugared foods, without saying "See nutrition information [on back panel] for sugar content." This gap in FDA's regulatory framework has given some consumers the impression that they can consume large portions of fat free or low fat foods without gaining weight, resulting in what has become known as the "Snackwell Syndrome."[27]

Companies have come up with their own terms such as "lightly sweetened," which appears on numerous brands of breakfast cereals and other products. The use of the term "lightly sweetened" may convey the impression that the product is low in sugar. Whether Kellogg's Frosted Mini-Wheats

25 Letter from Harvey V. Fineberg, M.D., Ph.D., President IOM to Hon. Tommy Thompson, Secretary of HHS (April 15, 2003).

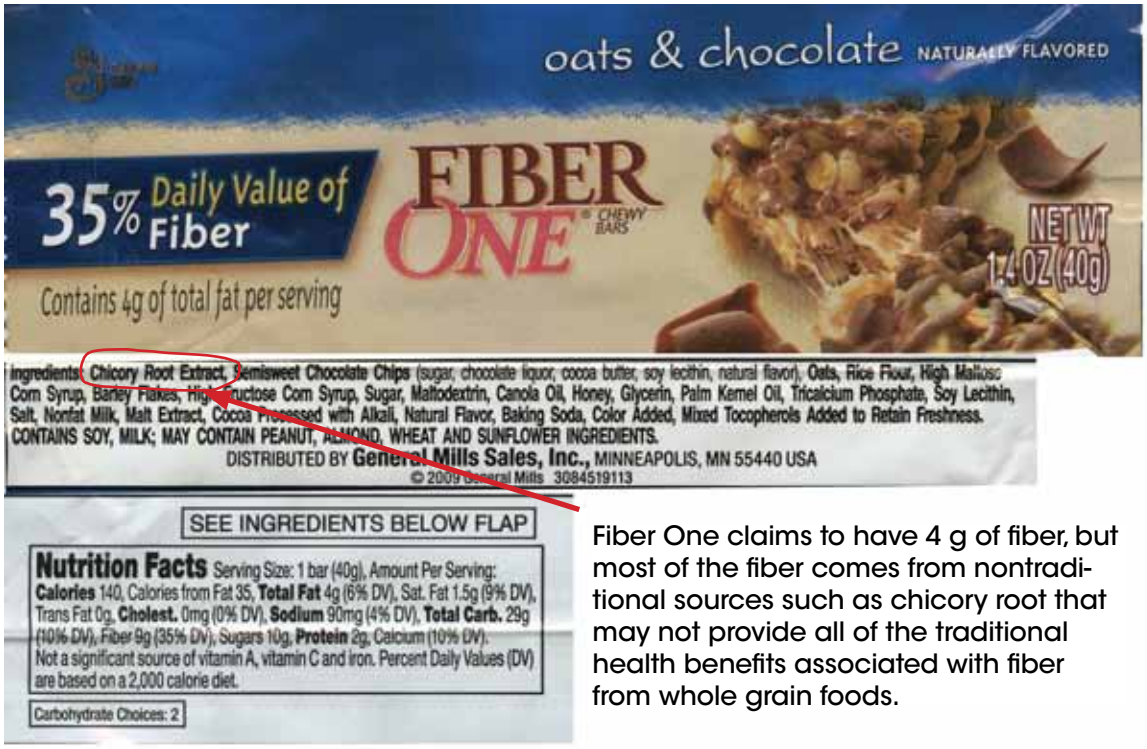
26 21 C.F.R. § 101.60(c).

27 Delroy Alexander et. al., *For Every Fad, Another Cookie* Chi. Trib., Aug. 23, 2005, *available at* http://www.chicagotribune.com/news/watchdog/chi-oreo-3,0,7414698.story.

Bite Size is "lightly sweetened" should be determined by federal rules, not the marketing executives of a manufacturer.

F. Fiber content disclosures should be modified

The FDA should also clarify that the definition of fiber only includes intact fibers from whole grains, beans, vegetables, fruit and other foods. In addition, the term "dietary fiber" on the Nutrition Facts Panel should be changed to "fiber." Currently, fiber is being added to foods such as ice creams, yogurts, juices and drinks so that manufacturers can brag about their fiber content. But these products do not contain the traditional sources of fiber associated with a variety of health benefits. Instead,



Fiber One claims to have 4 g of fiber, but most of the fiber comes from nontraditional sources such as chicory root that may not provide all of the traditional health benefits associated with fiber from whole grain foods.

they are adding what is known as "isolated fibers," that are mostly purified powders called inulin, polydextrose and maltodextrin. It is unlikely that inulin, polydextrose and maltodextrin lower blood cholesterol or blood sugar. Polydextrose may help with regularity, but inulin and maltodextrim do not. The FDA published an Advance Notice of Proposed Rulemaking addressing this issue and other matters related to the nutrients and DVs listed on the Nutrition Facts panel in November 2007.[28]

28 72 Fed. Reg. 62149, 62166 (Nov. 2, 2007).

Regulatory and Legislative Status

A. Increasing prominence of calories and deleting extraneous information from the NFP

The FDA issued an ANPR on April 4, 2005, seeking comment on whether its labeling regulations should give more prominence to calories.[29] The issue has received little attention since the comment period ended. The FDA has still not even issued a proposed rule. Thus, valuable space on the food label is still occupied by "calories from fat" and a confusing footnote. The space currently utilized for these requirements could be used much more effectively to increase the font size of the calorie declaration. The FDA should make it a priority to review the comments on the ANPR and develop a proposed rule.

B. Eliminating deceptive single-size servings and providing nutrition information for large single serving containers

In August 2003, the FDA created the Obesity Working Group to develop an action plan to help address the nation's obesity problem, and the group issued a report in 2004.[30] In response to its recommendations, the FDA issued an ANPR on April 4, 2005, seeking suggestions on ways in which it could make serving size information on the Nutrition Facts Panel easier for consumers to use when deciding which foods and how much of these foods they should eat.[31]

Before that ANPR was issued, the FDA issued a Letter to Food Manufacturers in 2004 attempting to address the problem of supersized, single-serving products being marketed as multi-serving products. The FDA encouraged them to:

> provide the most accurate and useful nutrition information to consumers by taking advantage of the flexibility in current regulations . . . and label food packages as containing a single-serving if the entire contents of the package can reasonably be consumed at a single-eating occasion.[32]

Makers of large single-serving packages should not be allowed to pretend that those packages really contain multiple servings. The FDA's Letter to Manufacturers does not sanction that practice, but the agency's request for voluntary action by the industry has been ineffective at stopping deceptive labeling of single serving containers. The FDA should propose a mandatory regulation requiring that nutrition information

29 70 Fed. Reg. 7,008 (Apr. 4, 2005).

30 FDA, *Calories Count: Report of the Working Group on Obesity* (Feb. 2004).

31 70 Fed. Reg. at 17,010.

32 FDA, *Letter to Food Manufacturers about Accurate Serving Size Declaration on Food Products*, 2 (Mar. 12, 2004) *available at* http://www.cfsan.fda.gov/~dms/fl-ltr4.html.

be disclosed for the entire container if it is likely to be consumed by one person on a single eating occasion. The regulation should also propose prohibiting the use of dual columns on foods packaged in containers likely to be consumed as a single serving.

C. Establishing a DV for added sugars; requiring the disclosure of added sugar content; and defining the term "low sugar"

As discussed above, in 1999, CSPI and dozens of leading health experts and organizations petitioned the FDA to require that food labels declare how much refined sugars are added to soft drinks, ice cream, and other foods and adopt a DV of 10 teaspoons, about 40 g.[33]

"The 2005 Dietary Guidelines for Americans notes that someone eating a healthy 2,000 calorie diet (with 29% of calories from fat) has room for only 8 teaspoons of added sugar per day. [A 12-oz. can of Coke contains about 10 teaspoons of sugar.]"

In 2000, the FDA invited public comment on whether "added sugars" should be included on the food label,[34] but the issue has languished, in part, because of the FDA's unwillingness to press this matter. On August 28, 2008, CSPI sent the FDA updated information on research conducted and expert opinions expressed since its petition was filed. In this update, CSPI stated that:

- The 2005 Dietary Guidelines for Americans notes that someone eating a healthy 2,000 calorie diet (with 29% of calories from fat) has room for only 8 teaspoons of added sugar per day.
- Some food industry officials have mischaracterized the IOM report as concluding that any level of added sugars under 25% of calories is healthful.
- An IOM report on school snacks noted that labeling added sugar on packages would help schools identify foods with less added sugar.
- The CDC advised consumers to limit sugar-sweetened beverages.[35]

The FDA's lack of interest in adopting a DV for added sugars was evident at a recent public meeting of international officials. The FDA told attendees that the United States objects to such labeling because the difficulty in distinguishing between added and naturally occurring sugars for labeling purposes would "present significant enforcement challenges."[36] We do not believe that the FDA's rationale is a sufficient reason to avoid providing consumers with important information. For many foods and beverages (such as soft drinks) that contain only added sugars, the analytical

33 CSPI, *Petition to the FDA to Require Better Sugar Labeling on Foods* (Aug. 3, 1999).

34 65 Fed. Reg. 39,414 (June 26, 2000).

35 CDC, *Rethink Your Drink* (undated; ca. 2006).

36 Stephen Clapp, *Codex Labeling Panel to Focus on Anti-Obesity Strategy,* Food Chem. News, Apr. 13, 2009, at 10-11 (quoting US Delegate Barbara Schneeman, who heads FDA's office of Nutrition, Labeling and Dietary Supplements.

difficulty is irrelevant. For other foods, the FDA could challenge companies that it believes have inaccurate labels to provide information substantiating the labels' accuracy.[37] In any case, the measurement problem could be solved very simply if Congress gave the FDA new authority to inspect company records. Legislation expanding the FDA's authority is pending in the Congress.[38]

D. Revising reference values and mandatory nutrients

On November 2, 2007, FDA published an ANPR to revise the Daily Values and list of mandatory nutrients on the Nutrition Facts Panel. The agency stated that since 1990, new nutrition data and information has emerged including the IOM's series of reports, published from 1997 to 2004, on the Dietary Reference Intakes for vitamins and other micronutrients, minerals, dietary antioxidants and related compounds, and energy and macronutrients. In addition, the IOM released a 2003 report, *Guiding Principles for Nutrition Labeling and Fortification,* on recommended use of its Daily Reference Intakes in nutrition labeling.

In its ANPR, the FDA requested input as to which nutrients should be listed on Nutrition Facts labels, what new reference values should be used to determine percent Daily Values and which factors should be considered in calculating DVs,[39] as well as several specific issues regarding calories, fats, cholesterol, carbohydrate, protein, dietary fibers, sugar alcohols, sodium, chloride, vitamins and minerals.

The FDA stated that its action was only an ANPR and that the rulemaking process can be expected to require three years or longer.

E. Requiring nutrition labeling of meat and poultry

On January 18, 2001, the USDA published a proposed rule in the *Federal Register* entitled, "Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products."[40] The rule would have extended nutrition labeling requirements to meat and poultry. The Department then let the proposed rule languish for eight years during the Bush Administration.

37 In a few cases, the problem might also be addressed by assessing the amount of added sugars by subtracting the naturally occurring sugar known to be in the ingredients used in a product from the total amount of sugar in the product. Thus, where the level of naturally occurring sugar is known, comparison with the level of sugar in the final product would give some, albeit not the exact, indication of the level of any added sugar. For example, in apple sauce or jam, the level of sugars in the indigenous fruit could be compared with that in the final product.

38 H.R. 2749 § 106 (a). An inspector can "have access to and copy all records relating to. . . whether the food is adulterated or misbranded, or otherwise in violation of this Act . . ." *Id.* The bill has passed the House. Legislation is still pending in the Senate.

39 The FDA stated that "The IOM report recommended using a population-weighted method of calculating the percent DV, rather than the current population-coverage method. If FDA were to adopt this recommendation, the percent DVs for most nutrients would probably decrease." 72 Fed. Reg. 62149 (Nov. 2, 2007), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/07-5440.pdf.

40 66 Fed. Reg. 4969 (Jan. 18, 2001).

On December 18, 2009, the proposed rule was given a new life when the USDA announced that it will solicit further public comments. The Department explained that because of the length of time since the publication of the original proposed rule, the USDA is providing the public a new opportunity to comment welcoming comments on relevant issues for which there is new evidence since the proposed rule was originally issued in 2001.

Recommendations

- The declaration of calories per serving should appear in a larger font on a contrasting background on the Nutrition Facts Panel. Instead of saying "Amount Per Serving," labels should state "Amount Per ½ Cup Serving."
- Little-used information, such as calories from fat and the NFP footnote allowing consumers to convert DVs based on a 2,000-calorie a day diet to a 2,500-calorie a day diet, should be eliminated to simplify the label and create additional space for more important information.
- Products that may reasonably be consumed by one person at a single eating occasion should be considered a single serving and their labels should disclose nutrition information for the entire package. Dual columns that also show nutrition information for the RACC should be prohibited.
- The FDA and the USDA should update certain RACCs in light of current consumption data.
- A Daily Value should be established for added sugars, and the %DV and added sugar content per serving (in terms of teaspoons and grams) should be required on the Nutrition Facts Panel.
- The FDA should also clarify that the definition of fiber only includes intact fibers from whole grains, beans, vegetables, fruit, and other foods.
- The FDA should define "low sugar" and prohibit health claims for products that are not low in sugar, prohibit the use of the term "healthy" on such products, and restrict "fat free" and "low fat" claims on products that are not low in sugar.
- The USDA should adopt the same requirements for foods under its jurisdiction, including the listing of trans fat content on the Nutrition Facts Panel, and finalize its proposed rule requiring nutrition labeling on single-ingredient meat and poultry products.

Food Labeling Chaos

Part III: Standardizing Front-of-Pack Nutrition Labeling

The Problem

The FDA, consumer groups, and the food industry have all recognized that simply addressing deficiencies in the Nutrition Facts Panel does not go far enough in providing consumers with easy-to-use nutrition information. There is a widespread belief that, in addition to improving the NFP, a front-of-pack labeling system using universal symbols should be instituted to further guide consumers, especially those who are less educated, more rushed, or less interested in nutrition, to make healthier choices when shopping for packaged foods.

Some countries, such as the United Kingdom, have developed alternatives to traditional nutrition labeling as required in the US. While 80% of the food products in the UK bear a modicum of nutrition information on the back label,[1] the UK Food Standards Agency (FSA), after extensive consumer research, has developed and urged the use of a front-of-pack nutrition labeling system using red, amber, and green dots (a "traffic light" or "signposting" symbol) that permits consumers to tell at a glance whether the amounts of total fat, saturated fat, salt, and sugars are within healthful limits. (A calorie statement is printed adjacent to the "traffic light"). Since its introduction in 2006, the system has been voluntary and limited to particular categories of foods. Several companies, particularly retailers like Sainsbury and Asda supermarkets (owned by Walmart), have widely adopted the system for their store-brand items. Sainsbury, one of the largest UK retailers, reported that use of the scheme has significantly influenced sales patterns in a positive manner.[2]

Example of UK "Traffic Light" nutrition labeling system for fronts of food packages

1 Conversation with Claire Boville, Head of Promotions, Nutrition, Labelling & Dietetic Foods Branch, UK Food Standards Agency, in Washington, D.C. (Dec. 16, 2009).

2 British Retail Consortium, *British Retailing: A Commitment to Health* 23 (June 2009), *available at* http://www.brc.org.uk/policycontent04.asp?iCat=46&iSubCat=610&sPolicy=Food&sSubPolicy=British+Retailing%3A+A+Commitment+to+Health.

Other countries have taken different courses of action. For instance, Sweden has developed "healthy food" criteria for a variety of food categories. Foods that meet those criteria are permitted to use a keyhole-shaped symbol. Finland has set sodium limits for various categories of foods and requires companies to state "high in sodium" on products containing levels that exceed the specified limit.

The European Union has proposed a regulation requiring that the amounts of six key nutrients be disclosed on the fronts of all food packages. The European Commission and Parliament are currently debating whether such information should be accompanied by the "Guideline Daily Amount" (GDA) (similar to a Daily Value) for each nutrient or a universal set of symbols as used in the UK.[3]

In the US, manufacturers such as PepsiCo and Kraft developed company systems such as "Smart Spot" or "Sensible Solutions" in an effort to identify "better for you" foods on the front of the package. Eventually, these and other leading food companies recognized that the proliferation of different symbols, each based on different nutrition criteria, was leading only to marketplace confusion.

In the summer of 2009, large food manufacturers joined together to introduce a "Smart Choices Program" that used a standard check-mark symbol based on uniform nutrition criteria.[4] The logo purportedly identified "more nutritious choices within specific product categories," and products also displayed calorie information on the front of the package. The program was dropped because of severe criticism.

To qualify for the front label symbol, products had to meet the following guidelines:

- Total fat: less than or equal to 35% of calories from fat (for some foods less than 3 g of fat per serving)
- Saturated fat: less than or equal to 10% of calories from saturated fat (for some foods less than 1 g per serving)
- Trans fat: less than or equal to 0.5 g per serving ("0" g as labeled)
- Cholesterol: less than or equal to 60 mg per serving (meat and poultry have higher limits)
- Added sugars: less than or equal to 25% of total calories (except for breakfast cereals, which can be less than or equal to 12 g)

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3 These include energy (calories), fat, saturated fat, carbohydrates with specific reference to sugars and salt content. *Comm. Proposal for a Regulation of the European Parliament and of the Council on the Provision of Food Information to Consumers* at 8, COM (2008) 40 final (Jan. 30, 2008).

4 CSPI initially participated in a consensus conference run by the industry and operated by the Keystone Center. The purpose was to develop a uniform symbol and a uniform set of criteria on which to permit its use. CSPI, however, dropped out of the effort because of certain flaws in the criteria and because CSPI's top priority was to advocate an Institute of Medicine study, involving consumer and other research, to identify the system that most effectively helped consumers choose the healthiest foods. *See*, Letter from Michael F. Jacobson, Exec. Dir., CSPI to Brad Sperber, The Keystone Center (Oct. 2, 2008).

- Sodium: less than or equal to 480 mg (or other amount, depending on product type and serving size) per serving.[5]

However, the Smart Choices program used certain weak criteria that are inconsistent with the Dietary Guidelines for Americans. For example, Froot Loops and Cocoa Puffs bore the Smart Choices label, implying that they were healthy foods. Such labeling is inconsistent with the advice in the US Dietary Guidelines to "choose and prepare foods and beverages with little added sugars or caloric sweeteners. . . ."[6] As Congresswoman Rosa DeLauro stated in a letter to FDA Commissioner Hamburg, "If Froot Loops and other highly sugary cereals can be considered 'Smart Choices' for children's nutrition, then it is clear the designation is not particularly useful for American families . . . ."[7]

Further, the Smart Choices program criteria did not require that approved cereals and other grain products contain any whole grains. The promotion of cereals and other grain products lacking whole grains is inconsistent with the US Dietary Guidelines, which emphasizes the importance of consuming whole grains and recommends that at least 50% of grains in the diet should be whole.[8] Furthermore, Smart Choices' nutrient criteria could be met through fortification, thereby allowing companies to get the label icon onto non-nutritious products simply by adding inexpensive nutrients. "A basic premise of the *Dietary Guidelines* is that nutrient needs should be met primarily through consuming foods."[9] To use an extreme example, a snack made of vitamin-fortified sawdust could meet the Smart Choices' criteria.

One of the problems with having numerous rating systems in the marketplace is that they may be inconsistent. The American Heart Association licenses its "heart-check" symbol for use on products meeting certain nutrition criteria.[10] For a standard certification, the AHA does not consider levels of added sugars or the presence of whole grains – key factors in preventing heart disease and obesity – because it follows 1990-era FDA rules that do not consider the amounts of added sugars or whole grains in

5 http://www.smartchoicesprogram.com/nutrition.html.

6 HHS, USDA, *Dietary Guidelines for Americans 2005* at 36. The *Guidelines* indicate that healthy diets have room for little added sugar, suggesting, for example, that diets of 1,200 to 1,600 calories, appropriate for many young children, should contain no more than 16 to 20 g of added sugars per serving. *Id.* at 55. The *Guidelines* also note that "In some cases, small amounts of sugars added to nutrient dense foods, such as breakfast cereals and reduced-fat milk products, may increase a person's intake of such foods by enhancing the palatability of these products, thus improving nutrient intake without contributing excessive calories." *Id.* at 37.

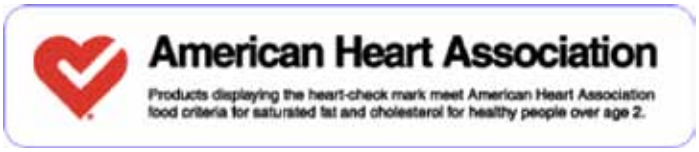
7 Letter from Rep. Rosa DeLauro to Margaret Hamburg, MD, Comm. FDA (Sept. 21, 2009), *available at* http://www.house.gov/delauro/.

8 *Dietary Guidelines, supra* note 6 at 24-25.

9 *Id.* at 3. "Foods contain not only the vitamins and minerals that are often found in supplements, but also hundreds of naturally occurring substances, including carotenoids, flavonoids and isoflavones, and protease inhibitors that may protect against chronic health conditions." *Id.* at 6. The *Guidelines* note that supplementation may be appropriate, for example, where certain nutrients may only be present in low amounts in some food or where fortification addresses a documented public health need. *Id.*

10 http://www.heart.org/presenter.jhtml?identifier=4973.

determining whether a product can make a claim that the product may help prevent the risk of heart disease.[11] However, the AHA has recently announced that it will no longer permit the use of its logo on desserts. In addition, the Association also offers a separate whole grain certification program for products with 51% or more whole grains and 3 g of fiber. Nonetheless, products such as Quaker Instant Oatmeal Cinnamon & Spice qualify for the AHA standard certification seal, despite the fact that the product contains 15 g of sugar per 46 g serving. That amount of sugar would not even have met the Smart Choices criteria which had notoriously weak sugar limits. Similarly, the AHA symbol appears on Uncle Ben's Instant Rice, a refined grain that would also not have met the Smart Choices criteria.



Foods can earn the AHA heart check symbol despite being high in sugar.

In the last few years, some supermarkets have also developed their own shelf-marking systems for relatively healthful foods. Hannaford Brothers, for example, has established a "Guiding Stars" system for foods in which some products receive zero, one, two, or three stars on a shelf marker next to the item price. Product ratings are calculated based on nutrients per 100 calories.[12] One star indicates a good choice, two stars indicate a better choice, and three stars indicate the healthiest choice. Three-quarters of the products sold receive no stars because they are not especially healthful, as explained in a point-of-sale brochure.[13] But Guiding Stars, the AHA's Heart Check, and other brand-specific programs use inconsistent criteria, resulting in different ratings for the same products.[14]

Meanwhile, a totally different system, NuVal, calculates nutrition ratings between 1 and 100 for all foods. Participating supermarkets put those NuVal ratings on shelf markers. That system may be more or less effective than other systems. Comparative tests have never been conducted.

Kellogg prints nutritional content and Guideline Daily Amounts (similar to Daily Values) in green colored boxes on the front label of Frosted Flakes and other cereals to indicate levels of calories, total fat, sodium, total sugars, and up to two of the following

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11 58 Fed. Reg. 2478 (Jan. 6, 1993). Any third party endorsement or reference that meets the definition of a health claim or nutrient content claim must be consistent with the FDA's regulations. *Id.* at 2485. The FDA's list of disqualifying nutrient levels for health claims does not include added sugars or *trans* fat. 21 C.F.R. § 101.14(a)(4). Moreover, the American Heart Association's Heart-Check program has allowed its logo to be used on such foods as Uncle Ben's Instant Rice and Kraft Macaroni and Cheese Baked Cheese Crackers (Parmesan). All are "highly processed" foods or "refined grains." FDA's letter to the sponsors of the Smart Choices program expressed concerns about the use of the Smart Check symbol on such products, *infra* note 24 and accompanying text.

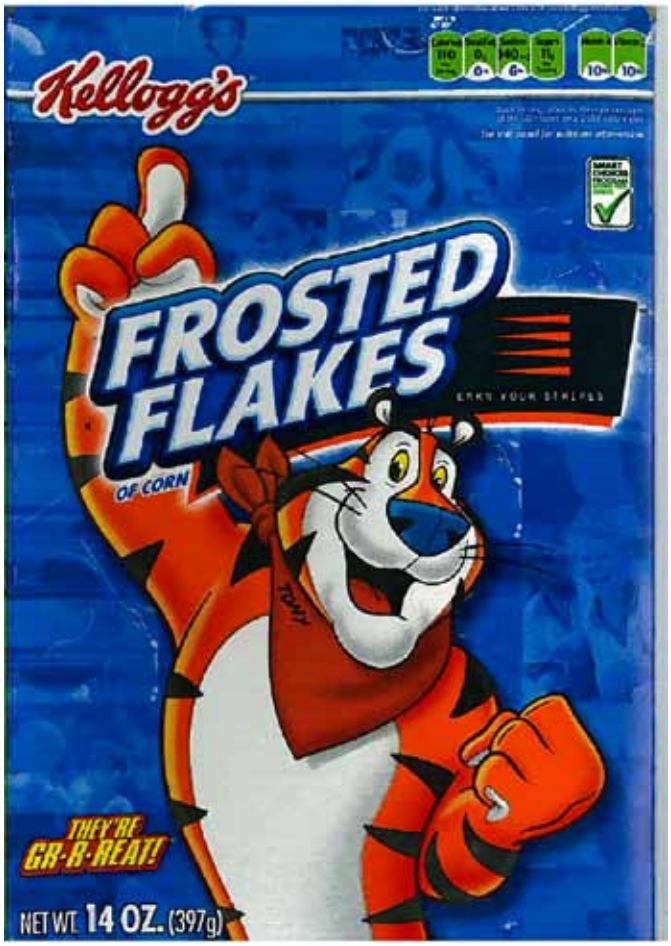
12 Hannaford Guiding stars – Frequently Asked Questions at 5, *available at* http://www.hannaford.com/Contents/Healthy_Living/Guiding_Stars/faqs.shtml.

13 Meeting between Lisa Sullivan *et. al.*, Hannaford Foods and CSPI in Washington, DC (Aug. 18, 2006).

14 *Hannaford, Q & A, supra,* note 12, at 4.

nutrients: fiber, calcium, potassium, magnesium and vitamins A, C and E.[15]

But Kellogg's front label symbols may be misleading. They all appear in green (a color that people associate with "go"). It is possible that the use of a green symbol for sugar content, even if that number is high, could imply good nutrition to some American consumers especially in the absence of a Daily Value for added sugars. For example, the green boxes on the front of Frosted Flakes cereal disclose that a serving size contains 11 g of sugar. The placement of this information in a green box suggests that this product contains a healthful level of sugar when, in fact, it is approximately 37% sugar by weight.



Kellogg's Frosted Flakes illustrates the misleading use of a green-colored Guideline Daily Amount (similar to a Daily Value) box for sugars that implies that a product is healthful.

Regulatory and Legislative Status

The legislative history of the NLEA indicates that Congress gave the FDA the option to use "universal symbols to indicate desirable or undesirable levels of particular nutrients."[16] But, the FDA did not formally consider that option until it received a petition from CSPI in November 2006.[17] In 2007, the agency held a public meeting on front-label symbols, and the following year the Government Accountability Office urged the FDA to collaborate "with other federal agencies and stakeholders experienced in nutrition and health issues, to evaluate labeling approaches and options for developing a simplified, empirically valid system that conveys overall nutritional quality to mitigate labels that are misleading to consumers."[18]

In December, 2008, the FDA issued Guidance for Industry on Front-of-Package Symbols, cautioning that some symbols could constitute "nutrient content claims" that characterize the level of a particular nutrient in a food.[19] Nutrient content claims may

15 http://investor.kelloggs.com/releasedetail.cfm?ReleaseID=264476.

16 H.R. Rep. 101-538 at 18 (June 13, 1990).

17 CSPI, Petition for ANPR on the Use of Symbols on the Principal Display Panel to Communicate the Healthfulness of Foods (Nov. 30, 2006).

18 GAO, *Food Labeling, FDA Needs to Better Leverage Resources, Improve Oversight and Effectively Use Available Data to Help Consumers Select Healthy Foods*, 44-45 GAO-08-597 (Sept. 2008).

19 FDA, *Guidance for Industry, Dear Manufacturer Letter Regarding Front-of-Package Symbols* (Dec. 2008), *available at* http://www.cfsan.fda.gov/~dms.flsymgui.html.

only be made if the FDA has issued regulations defining their use, and the claims are made in accordance with those definitions.[20] In addition, products that exceed disqualifying levels for certain nutrients require the use of disclosure statements, alerting consumers that one or more nutrients in the food may increase the risk of a disease or health-related condition that is diet related.[21]

In response to GAO's report on the FDA's management of food-labeling issues, Congress has funded an Institute of Medicine study that will examine and provide recommendations to the FDA regarding front-of-label nutrition symbols used by manufacturers, supermarkets, health organizations, and governments in the US and abroad.[22] The study began in January 2010.[23] A related research project by the FDA appears to be on a faster track, *infra* note 28 and accompanying text.

The Smart Choices program was quickly identified as a potential problem area by the FDA[24] and has been criticized by leading members of Congress.[25] It also drew fire from state attorneys general. On October 20, 2009, the FDA and the USDA announced that they were attacking the issue by:

- Taking enforcement actions against products with front-of-pack symbols that are false or misleading or violate current requirements for claims characterizing the level of a nutrient.
- Proposing a regulation that would specify nutrient levels that a serving of a product must contain in order to indicate on the package in any format that it is a better-for-you, or healthier, choice than other foods;
- Undertaking its own consumer research program and working with the IOM to determine how consumers use front-of-pack nutrition symbols

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20 FDCA § 403(r)(2)(a)(i), 21 U.S.C. § 343(r)(2)(a)(i).

21 FDCA § 403(r)(2)(B), 21 U.S.C. § 343(r)(2)(B), 21 C.F.R. § 101.13(h). The label is only required to state "See nutrition information for [fat, sodium, etc.] content." 21 C.F.R. § 101.13(h).

22 House Appropriations Committee Print, Omnibus Appropriations Act, 2009 (H.R. 1105); Public Law 1121-8, Division F – Department of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2009 at 1398. The FY '10 appropriations bill contains another $500,000 for the IOM study, but at this time, has not passed the full Congress.

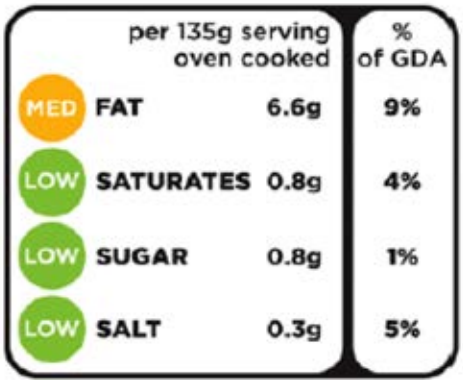
23 In Apr. 2009, the FDA issued a memorandum summarizing the comments received during the public meeting and indicated areas where there are still information gaps. Memorandum from Vincent De Jesus, Office of Nutrition, Labeling and Dietary Supplements, FDA to Division of Dockets Management, Apr. 21, 2009.

24 FDA Response to Representative DeLauro (Oct. 19, 2009), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm187369.htm.; FDA, *Guidance for Industry: Letter Regarding Point of Purchase Food Labeling, available at* htttp://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabeling-Nutrition/ucm187208.htm; Letter from Michael R. Taylor, Senior Advisor to the Comm. FDA, and Jerold R. Mande, Deputy Under Secretary for Food Safety, USDA, to Sarah Krol, General Manager Smart Choices Program (Aug. 19, 2009).

25 Press Release, Rep. Rosa DeLauro, *Representative DeLauro Calls for FDA Investigation into "Smart Choices" Labeling* (Sept. 21, 2009), *available at* http://www.house.goc/delauro/.

and which type of symbols communicate nutrition information most effectively;

- Working with manufacturers and retailers to voluntarily adopt the front-of-pack nutrition symbol(s) created by the FDA (regardless, companies would have to follow the FDA nutrition criteria if they chose to use their own symbols);
- Retaining the authority to issue mandatory regulations requiring manufacturers and retailers to use government-mandated front-of-pack nutrition symbols.[26]



This front-of-pack nutrition label scored the highest in consumer comprehension in an extensive study conducted by the UK Food Standards Agency.

In May 2009, the FSA in the UK completed its most comprehensive study comparing consumer reactions to, and comprehension of, several front-of-pack nutrition labeling schemes, including one utilizing only nutrient-content disclosure and Guideline Daily Amounts (GDAs) and one utilizing that Agency's color-coded traffic light nutrition labeling system. The study found that a combination of approaches worked the best, i.e., color-coded traffic lights for key nutrients accompanied by both the words "high," "medium," or "low" and the percent of the GDA per serving.[27] Of course, the formats studied did not include approaches similar to NuVal, the Swedish keyhole, or Guiding Stars. Moreover, we recognize that for various reasons British consumers might react differently to particular formats than consumers in the United States. Appropriate consumer research in the United States is vitally important.

On January 19, 2010, the FDA obtained approval from the Office of Management and Budget for two experimental studies addressing consumer understanding and use of a variety of front-of-package labeling schemes so that the FDA can determine which approach is most effective in communicating nutrition information to consumers. The first study will address five labeling approaches: (1) the Smart Choices scheme, (2) Guideline Daily Amounts; (3) a scheme similar to the Multiple Traffic Light approach used in the United Kingdom; (4) a control using only the Nutrition Facts label; and (5) a control showing no front-of-pack information. The second study will test various "Nutrition Tips" schemes showing per serving amounts of calories, total fat, saturated fat, sugar and sodium; interpretative words relating to the Daily Value (i.e., high, low, etc.) and color coding of the amounts of those nutrients.[28]

The label formats being tested by the FDA appear on the following page.

26 *FDA Guidance 2009*, *supra* note 24, at 3.

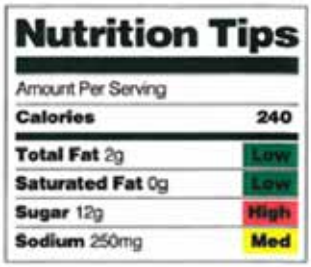
27 UK Food Standards Agency, *Comprehension and use of UK nutrition signpost labelling schemes* (May 2009).

28 OIRA Conclusion, OMB Control No. 0910-0655 (Jan. 19, 2010), available at http://www.reginfo.gov/public; 74 Fed. Reg. 62,786 (Dec. 1, 2009)

Food Labeling Chaos

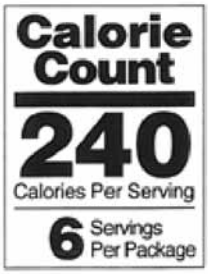
Front-of-Package Labeling Schemes Being Tested by the FDA

Option 1



Option 2

Option 3



Option 4

Option 5

Option 6

Option 7

Recommendations

- The FDA and the USDA should promptly take enforcement actions against manufacturers using misleading front-label nutrition symbols and propose regulations detailing nutrient criteria that must be met before such symbols are used on food packaging. Unlike the FDA's current criteria for "healthy," new criteria should include added sugars and for grain foods, a minimum whole grain requirement. That might entail the FDA's adopting a Daily Value for added sugars, perhaps based on the Dietary Guidelines for Americans (Appendix A-3 in that publication).
- The FDA should promptly complete its consumer research program, in conjunction with related work being conducted by the IOM, and identify the most effective front-of-pack nutrition labeling approach (including nutrient criteria, logo, font size, etc.) for empowering consumers to choose healthier foods.
- The FDA and the USDA should then propose regulations for a mandatory new labeling system.
- The FDA and the USDA should prohibit the use of competing front-of-label nutrition labeling schemes once the national system is implemented.

Part III-10

Food Labeling Chaos

Part IV: Making Ingredient Labels Easier to Read

The Problem

Manufacturers have been required by law to list all ingredients in order of predominance by weight since 1938.[1] However, the format for disclosure of this essential information has not been modernized—ingredients appear on packages much the way they did more than 70 years ago.

Many ingredient labels are difficult to read. They are often printed in small, condensed type, and many manufacturers use all capital letters that studies show are more difficult to read than upper and lower case letters.[2] Furthermore, many manufacturers use full justification, meaning that the left and right margins of each line of the list are flush. This typesetting practice tends to squish letters and words together, making them even harder to read. And, in what may be an attempt to obfuscate the ingredient list even further, some companies print the list in various colors of ink against poorly-contrasting backgrounds or insert the ingredient list in a fold or other area where it will not be visible unless the consumer makes an extra effort to reveal the list or opens the package. See picture on next page.


INGREDIENTS: SUGAR, WHOLE WHEAT FLOUR, WHEAT FLOUR, CHOCOLATE CHIPS (SUGAR, CHOCOLATE LIQUOR, COCOA BUTTER, DEXTROSE, CHOCOLATE LIQUOR PROCESSED WITH ALKALI, SOY LECITHIN, VANILLIN, VANILLA EXTRACT), CORN SYRUP, WATER, HIGH FRUCTOSE CORN SYRUP, PALM OIL, ROLLED OATS, SOYBEAN OIL, EGGS, WHEAT FIBER, MODIFIED CORNSTARCH, TRICALCIUM PHOSPHATE, ARTIFICIAL FLAVOR, MONO- AND DIGLYCERIDES, MOLASSES, SALT, WHEY (MILK), BAKING SODA, NUTRIENT BLEND (CORN SYRUP SOLIDS, NIACIN, VITAMIN A PALMITATE, REDUCED IRON, PYRIDOXINE HYDROCHLORIDE (VITAMIN B6), THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), GUAR GUM, SODIUM PHOSPHATE, CAROB BEAN GUM, GELLAN GUM, SODIUM CITRATE, CALCIUM SILICATE, CARAMEL COLOR, CALCIUM PHOSPHATE. MAY CONTAIN ALMONDS, CASHEWS AND COCONUT.

The small type size, condensed and sans serif font, as well as full justification make this list very difficult to read. (Label is enlarged.)

Difficult-to-read ingredient lists are particularly problematic for consumers suffering from food allergies. Under the Food Allergen Labeling and Consumer Protection Act of 2004,[3] allergens may be identified in the ingredient line or in a separate declaration, "Contains _____" in close proximity to the ingredient declaration. But in both cases, the print size need not be more prominent than that of the ingredient declaration.[4] This Act allows allergen declarations to be printed in the same very

1 FDCA § 403(i), 21 U.S.C. § 343 (i), 21 C.F.R. § 101.4(a).

2 Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, *Action Plan for the Provision of Useful Prescription Medicine Information* 55-56 (Dec. 1996); European Comm., *Guidelines on the Readability of the Labelling and Package Leaflet of Medicinal Programs for Human Use*, 7-9 (Rev. 1) (Jan. 12, 2009).

3 Pub. L. No. 108-282 required the listing of eight food allergens by their common names. After the law was passed, the FDA required a ninth allergen, carmine/cochineal extract, to be disclosed on labels; heretofore, those ingredients have only been listed as "natural coloring." 74 Fed. Reg. 207 (Jan. 5, 2009).

4 FDCA § 403(w)(1), 21 U.S.C. § 343(w)(1).

small type used for the ingredient list. Furthermore, the FDA does not require that the allergen declaration be in bold type—that step remains optional with the manufacturer.[5]

The package folds at the arrows, making it very difficult to read the ingredient list. →

This ingredient list is even more difficult to read because the manufacturer printed the information on a poorly-contrasting background and situated the list so that it is not fully visible until the package is actually opened.

Furthermore, because the FDA does not require the percentage of whole grains to be disclosed and in light of the absence of a DV for added sugars, it is important that consumers be able to quickly refer to the ingredient list to determine the presence and relative amount of such ingredients in a product (e.g., if sugar or high fructose corn syrup is the first ingredient, the product is high in added sugars; if whole wheat flour is somewhere in the middle of the ingredient list, the product probably has only a small amount of whole grains). In addition, because sugar has numerous names that consumers may not identify as a source of added sugar — e.g. lactose, fruit juice concentrates, etc.— sugars should be grouped together in the ingredient listing so that consumers get a truer picture of how many sugary ingredients are actually in the product.

Regulatory and Legislative Status

The FDA has not made any efforts to improve the ingredient label since the 1970s. At that time, the FDA held a series of five nationwide hearings and solicited written statements on food labeling.[6]

Under current FDA regulations, manufacturers are required to use a type size that is at least $^{1}/_{16^{th}}$ inch in height (based on the lower case "o").[7] This is approximately

5 FDA, *Guidance for Industry A Food Labeling Guide* § VI-13 (Apr. 2008), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm; FDA, *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004* (Ed. 4 Final Guidance, Oct. 2006), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.htm.

6 43 Fed. Reg. 25,296 (June 9, 1978). The FDA published an undated summary of comments entitled *Food Labeling Report on the Analysis of Comments*. Ultimately, the FDA, the FTC, and the USDA jointly announced tentative positions on food labeling. 44 Fed. Reg. 75997 (Dec. 21, 1979). No further action was taken.

7 21 C.F.R. § 101.2(c); *FDA Guidance on Food Labeling, supra* note 6, at § VI-3.

4.5-point type,[8] which is a tad more than half the size of the typeface that newspapers commonly used around 1996.[9] Newspapers have been increasing font size over the years.[10] Ingredient lists are supposed to be "prominent," "conspicuous," and likely to be "read and understood," but 4.5-point type is extremely small and does not meet such requirements in accordance with contemporary standards for readability.[11]

This weak requirement contrasts sharply with more modern FDA rules for the display of information on the Nutrition Facts Panel. For example, all Nutrition Facts Panels must:

- Utilize a single easy-to-read type style
- Use upper and lower case letters
- Use at least 1-point of leading (i.e., space between two lines of text); in some cases, at least 4-points of leading are required.
- Letters should never touch
- Most of the required information must be in at least 8-point type. Some information must have a minimum 6-point type.[12]

Some exceptions for small packages may be necessary, and FDA rules provide options in such situations.[13] But, in some cases, if the FDA deletes extraneous information from the Nutrition Facts Panel, space will be freed up on the package that could be used for ingredient lists printed in larger type and easier-to-read formats.

An example appears on the next page.

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8 An inch equals a point size of 72. 1/16 of an inch is approximately 4.5-point type. http://www.unitconversion.org/typography/postscript-points-to-inchs-conversion.html.

9 *Action Plan, supra* note 2 at 55. More than a decade ago, newspapers were usually printed in 8-point type. *Id.*

10 *See, e.g.*, *Redesign Owner's Manual*, Wash. Post, Oct. 19, 2009 at Special Section 3.

11 The FDCA provides that a food is misbranded:

> If any word, statement or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

FDCA § 403(f) 21 U.S.C. § 343(f).

12 21 C.F.R. § 101.9(d)(1); FDA, *Food Labeling Guide*, *supra* note 6, at § VI-2-3.

13 21 C.F.R. § 101.2. The FDA's regulations provide that the ingredient statement (as well as other required statements) may lack the prominence and conspicuousness required by § 403(f) of the FDCA because of the smallness or the style of type, crowding with other written, printed, or graphic material, and obscuring designs or vignettes. 21 C.F.R. § 101.15(a)(6).

Food Labeling Chaos

Current

INGREDIENTS: ENRICHED FLOUR [WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMINE MONOTRATE (VITAMIN B1), RIBOFLAVIN (VITAMIN b2), FOLIC ACID], VEGETABLE SHORTENING (CONTAINS PARTIALLY HYDROGENATED SOYBEN AND/OR COTTONSEED OILS), WHOLE WHEAT, CHEDDAR CHEESE (PASTEURIZED CULTURED MILK, SALT ENZYMES), CALCIUM CARBONATE, SALT, WHEY, AUTOLYZED YEAST, BUTTERMILK SOLIDS, LEAVENING (SODIUM ACID PYROPHOSPHATE, SODIUM BICARBONATE, CORNSTARCH), SUGAR, YEAST, LACTIC ACID, ARTIFICIAL COL0RS (ANNATTO, YELLOW 5, YELLOW 6), SODIUM PHOSPHATE, SODIUM CASEINATE, ONION PODER, ACETIC ACID, XANTHANGUM, POTASSIUM SORBATE
CONTAINS: WHEAT, MILK, AND SOY

Proposed

Ingredient Facts

Major Ingredients: Enriched Flour [wheat flour, niacin, reduced iron, thiamine, mononitrate (vitamin B1), riboflavin (vitamin B2), folic acid] ● Vegetable shortening [contains partially hydrogenated soybean and/or cottonseed oils] ● Whole wheat (5%) ● Cheddar Cheese (1%) (Pasteurized cultured milk, salt, enzymes) ● Calcium carbonate ● Salt ● Whey (milk) ● Autolyzed yeast ● Buttermilk solids ● Leavening (sodium acid polyphosphate, sodium bicarbonate, cornstarch) ● Sugar ● Yeast ● Lactic Acid

Minor Ingredients: Artificial colors (annatto, Yellow 5, Yellow 6) ● Sodium phosphate ● Sodium caseinate (milk) ● Onion powder ● Acetic acid ● Xanthan gum ● Potassium sorbate

Allergy Information: Contains wheat, milk, and soy

The proposed example of a modernized ingredient list is based on the format requirements for the Nutrition Facts Panel. Nutrition and ingredient information should be equally easy to read.

Recommendations

- The FDA, in consultation with the USDA, should publish a Notice of Proposed Rulemaking in the *Federal Register* with the goal of modernizing the format of the ingredient list.
- Requirements for type size, style, spacing, and leading of ingredient lists should be established based on requirements set forth for the Nutrition Facts Panel.
- The use of all capital letters should be prohibited, and left justification should be required.
- Eight-point, non-condensed type should be the minimum for print size, except on small packages.
- Sugar sources in the product should be grouped together in the ingredient list so that consumers could readily identify the ingredients that add sugar, get a better sense as to the relative amount of sugar in the product, and not be fooled by healthy-sounding names, such as “fruit juice concentrate.”
- Ingredients information should be set off in a box by use of hairlines and should be all black or one color type, printed on a white or other highly contrasting background.
- Once FDA regulations are issued, the USDA should approve only those labels that conform to the new requirements.

Part V: Disclosing Caffeine Content

The Problem

Caffeine is a psychoactive drug[1] that is present in a variety of foods and beverages. For several reasons, it is important that the amount of caffeine contained in a serving of a food be clearly disclosed on the label in conjunction with other nutrition and ingredient information. CSPI has urged this action for more than a decade.[2]

In 1997, the American Medical Association passed a resolution calling for the disclosure of the amount of caffeine on product labels.[3] The AMA resolution is supported by a series of public health recommendations. In 1981, the FDA warned "Pregnant women should avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly. . . ."[4] The March of Dimes recommends that women who are, or wish to become pregnant, consume no more than 200 mg of caffeine per day.[5] Health Canada recommends that women of reproductive age limit their caffeine intake to no more than 300 mg a day "based on possible adverse effects on some factors of reproduction and development."[6]

But without the quantity of caffeine per serving listed on food labels, it is difficult for women who are or are considering becoming pregnant to know how much caffeine they are consuming. Although major soft drinks, Lipton Tea, and some energy drinks list caffeine content, many food products do not. Hence, the FDA should promulgate a regulation requiring caffeine content to be listed on the information panel of all foods that contain a significant amount (for example, ≥ 5 mg per serving).

These recommendations are well-grounded in scientific research. Too much caffeine may increase the risk of miscarriage and infertility. In one study, among 1,063 pregnant women interviewed by researchers, 24% of those who consumed at least 200 mg of caffeine a day suffered miscarriages, compared with 10% of those who consumed less than 200 mg.[7] A 1988 study by the National Institutes of Health reported that

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1 Gilbert, R.M. (1984). Caffeine Consumption. In G.A. Spiller (Ed.), *The Methylxanthine Beverages and Foods: Chemistry, Consumption, and Health Effects* (pp. 185-214). New York: Alan R. Liss.

2 CSPI first petitioned the FDA for caffeine content disclosures in 1997. Petition for Amendment of Food Labeling Regulations to Require Quantitative Labeling of Caffeine Content and Request for Review of Health Effects of Caffeine (Docket No. 97P-0039) (July 31, 1997).

3 American Medical Association House of Delegates Resolution 523 (1997) The resolution provides that: " RESOLVED, That the American Medical Association work with the Food and Drug Administration to ensure that when caffeine is added to a product the label reflects this in prominent letters and the amount of caffeine in the product be written on the label." *Id.*

4 HHS, Public Health Service, FDA, *Caffeine and Pregnancy,* FDA Pub. No. 81-1081 (1981).

5 http://wwwmarchofdimes.com/professionals/14332_1192.asp.

6 Health Canada, http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/caffeine-eng.php.

7 *Am. J. Obstet.* doi:1016/j.ajog.2007.10.803.

One single serving size container of Dannon Coffee Yogurt contains 30 mg of caffeine, almost as much as a serving of dark chocolate.

just one cup of coffee a day could cut the odds in half of becoming pregnant. But later studies indicate that if caffeine affects fertility, it takes at least 300 mg per day.[8]

Caffeine can also cause physical dependence in those who regularly consume it.[9] More than 200 mg of caffeine per day can produce increased anxiety, jitteriness, and upset stomach.[10] Consuming caffeine interferes with adenosine, which is believed to be the brain's natural sleep regulator.[11] Those who abruptly stop consuming caffeine after a long period of use can expect withdrawal symptoms, which include headaches, sleepiness, lethargy, and irritability.[12]

For all of those reasons, caffeine content per serving should be listed on the food label so that consumers can limit their caffeine consumption if they so choose.

Over the course of a day, caffeine consumption can add up quickly, far beyond recommended levels. For example, in a single day, a person could consume:

- Three 6 oz. home-brewed cups of Seattle's Best (each with 65 mg, for a total of 195 mg of caffeine).[13]
- One 20 oz. bottle of Coca-Cola with 57 mg.[14]
- One single-serving size container of Dannon Coffee Yogurt with 30 mg.[15]
- Five squares of Hershey's Special Dark Chocolate with 31 mg.[16]

Total ..... 313 mg [17]

8 http://www.otispregnancy.org/pdf/caffeine.

9 James, J.E. (1994). Caffeine, health and commercial interest. *Addiction, 89*, 1595-1599.

10 Griffiths, R.R., & Mumford, G.K. (1995). Caffeine - A drug of abuse? In F. Bloom & DJ. Kupher (Eds.), Psychopharmacology: The Fourth Generation of Progress (pp. 1699-1713). New York: Raven Press Ltd.

11 Dunwiddie, T.V., & Masino, S.A. (2001, March). The role and regulation of adenosine in the central nervous system. *Annual Review of Neuroscience, 24*, 31-55. doi:10.1146/annurev.neuro.24.1.31

12 Hughes, J.R. et. al. (1991). Caffeine self-administration, withdrawal, and adverse effects among coffee drinkers. *Archives of General Psychiatry, 48*(7), 611-617; Silverman, K. (1992, October). Withdrawal syndrome after the double-blind cessation of caffeine consumption. *New England Journal of Medicine, 327*(16), 1109-1114; van Dusseldorp, M., & Katan, M. (1990, June). Headache caused by caffeine withdrawal among moderate coffee drinkers switched from ordinary to decaffeinated coffee. *British Medicine Journal, 300*, 1558-1559. doi:10.1136/bmj.300.6739.1558.

13 Telephone conversation between Hayley Reynolds, CSPI and Seattle's Best Customer Relations (Nov. 24, 2009).

14 As listed on label of 20 oz. bottle of Coca-Cola.

15 Telephone conversation between Hayley Reynolds, CSPI and Dannon Customer Relations (Nov. 18, 2009).

16 *See* Note 20 *supra* and accompanying text.

17 Consumers who have coffee from Starbucks or another coffee shop, may consume far higher levels of caffeine. According to Starbuck's website, each 16 oz. brewed coffee contains 330 mg of caffeine. www.starbucks.com/retail_beverage_detail.asp (last visited Nov. 18, 2009).

This total is above the 200 mg limit recommended by the March of Dimes and the 300 mg limit recommended by Health Canada.[18] Thus, it is important that women have a mechanism to determine the amount of caffeine in various foods so that they can limit their caffeine consumption. It is also important for all consumers to know the amount of caffeine they are consuming to avoid the possible anxiety, jitteriness, withdrawal symptoms, and upset stomach associated with high caffeine consumption.

It is difficult for consumers to determine which types of foods provide significant amounts of caffeine. Some types of healthful-sounding foods contain surprising amounts of caffeine. For example, Dannon Coffee Yogurt shown on the previous page, has 30 mg of caffeine per serving. [19]

Hershey's Special Dark Chocolate fails to disclose that it contains a significant amount of caffeine. A single serving (five squares) contains about 31 mg.[20]

Consumers who eat dark chocolate for its antioxidant content, as promoted on the front of this label, are also getting about 31 mg of caffeine per serving.

In other instances, foods like ice cream can contain more caffeine than colas and many other soft drinks. For example, Starbucks Java Chip Frappuccino ice cream (shown on next page) contains 40 - 50 mg of caffeine per ½ cup serving.[21]

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18 http://wwwmarchofdimes.com/professionals/14332_1148.asp; Health Canada, http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/caffeine-eng.php.

19 Telephone conversation between Hayley Reynolds, CSPI and Dannon Customer Relations on Nov. 18, 2009.

20 http://www.hersheys.com/nutrition/caffeine.asp. The website discloses that 1.45 oz. of chocolate contains 31 mg of caffeine.

21 http://www.starbucksicecream.com/#/faqs/ (last visited Nov. 18, 2009). Mountain Dew Contains 36 mg of caffeine per 8 oz. serving. www.pepsiproductfacts.com (last visited Dec. 15, 2009). Pepsi contains 25 mg of caffeine per 8 oz. serving. *Id.* Coca-Cola Classic contains 23 mg of caffeine per 8 oz. serving www.thecoca-colacompany.com (last visited Nov. 17, 2009).

Food Labeling Chaos

Starbucks Java Chip Frappuccino ice cream contains Starbucks coffee, giving it more caffeine than Mountain Dew, Coca Cola, and Pepsi.

Another Starbucks product, the bottled Frappuccino contains nearly 100 mg of caffeine.

CSPI is not aware of any marketers of coffee, the biggest source of caffeine for most adults, that list caffeine content on labels (see picture on next page). Consumers may drink many cups of coffee per day without knowing how much caffeine they are consuming.[22]

Since CSPI and others proposed caffeine-content labeling, some major companies, such as Coca-Cola and PepsiCo, have begun listing the amount of caffeine on product labels.

But caffeine disclosures need to be standardized in terms of type size and location so that consumers can tell at a glance whether, and how much, caffeine is contained in a food. Some caffeine disclosures, such as the one on Sunkist Orange Soda (pictured on the next page), are in dense type that appears in all capital letters.

Regulatory and Legislative Status

This Vanilla Frappuccino contains 96 mg of caffeine per bottle.

Caffeine may occur naturally in some ingredients added to foods, as when coffee is added to mocha ice cream; or it may intentionally be added as a separate ingredient in the form of pure caffeine or in the form of caffeine-containing ingredients such as guarana and yerba maté, which are often used in energy drinks. Presently, food labels are merely required to list caffeine in the ingredient list. Although companies are required to list guarana, yerba maté, and other caffeine-containing ingredients, they are not required to disclose that those ingredients contain caffeine.

Serious legal questions are raised by the addition of caffeine to foods beyond carbonated cola drinks. The FDA has only deemed caffeine as Generally Recognized as Safe (GRAS) for use as a food ingredient when it is used in cola-type beverages at up to 200 parts per million (48 mg per 8 oz.).[23] In the 1980s, while trying to clarify the status of caffeine in soft drinks as GRAS or subject to a "prior sanction" that would insulate it from regulation as a food additive, the

22 Most caffeine content information for coffee was obtained by CSPI staff in telephone conversations with the companies' customer relations offices on November 24, 2009. Based on a 6 oz. serving, Seattle's Best contains 65 mg; Maxwell House contains 65-75 mg; Folgers contains 59 mg; Peet's contains 100 mg. Information pertaining to Starbuck's Pike Place Roast was obtained by extrapolating from the caffeine content information provided by the company's web site for a 16 oz. serving. If a 16 oz. serving contains 330 mg of caffeine, then there are 20.6 mg of caffeine per ounce. A 6 oz. serving would, therefore, contain 124 mg of caffeine. http://www.starbucks.com/retail/nutrition_beverage_detail.asp.

23 21 C.F.R § 182.1180.

A 6 oz. cup of home brewed coffee may have from 59-124 mg depending on the brand.

Some companies voluntarily list the amount of caffeine.

Caffeine content is listed to the side of the Nutrition Facts Panel, underneath the ingredients.

Although the label for Sunkist Orange Soda discloses the amount of caffeine, it is printed in a hard-to-read font and is almost invisible. Caffeine labeling needs to be standardized so that consumers can tell at a glance how much caffeine is in a product.

Food Labeling Chaos

Although each of these products contains high levels of caffeine, none of them lists the amount.

FDA indicated that "at some future date" the remaining uses of caffeine would be addressed.[24] But the FDA's Center for Food Safety and Applied Nutrition (CFSAN) never resolved the matter.[25]

Since that time, the addition of caffeine to beverages and other foods has exploded. Red Bull was introduced into the United States in 1997 with 80 mg of caffeine per serving. When the FDA failed to require the maker of that product to demonstrate that that level of caffeine was GRAS, the agency opened the floodgates to similar products.

None of the products pictured at the left lists the considerable amount of caffeine – 160 mg to 280 mg per container.[26]

Whether these uses of caffeine are GRAS[27] is beyond the scope of this report. The FDA might decide to ban some uses.[28] In other cases, the FDA might condition GRAS status on the provision of a cautionary statement. But in all cases, caffeine content should be disclosed.

24 52 Fed. Reg. 18,923, 18,925 (May 20, 1987).

25 In contrast, the FDA's Center for Drug Evaluation and Research did take action. In 1988, that division issued a *Final Monograph for Stimulant Drug Products for Over-the-Counter Use* which required a number of warning statements to appear on products containing caffeine as an active ingredient (in amounts that are often found in foods). Two of the warnings are particularly relevant:

> The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat.

21 C.F.R. § 340.50(c). In addition the product must state: "Do not give to children under 12 years of age." Such statements are not required to appear on the labels of food products containing similar, or even larger amounts of caffeine. *Id.*

26 Reissig, C., & Griffiths, R. (Jan. 2009). Caffeinated energy drinks—A Growing Problem. *Drug and Alcohol Dependence, 99*, 1-10. doi:10.1016/j.drugalcdep.2008.08.001. Monster has 160 mg (16 oz.); Jolt Cola has 280 mg of caffeine (23.5 oz.). *Id.* at 3. Stinger has 200 mg of caffeine per 8.4 oz., (telephone conversation between Hayley Reynolds, CSPI and NVE Pharmaceuticals Customer Service Nov. 24, 2009).

27 In a newly released Draft Guidance on criteria for distinguishing liquid dietary supplements from beverages, the FDA implied that it would be addressing caffeine. FDA expressed concern about the safety of "ingredients that have been present in the food supply for many years that are now being added to beverages and other conventional foods at levels in excess of their traditional use levels or in new beverages or other conventional foods." *Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Consideration Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods* (Draft) (Dec. 2009), 74 Fed. Reg. 63759 (Dec. 4, 2009).

28 A November 2009 action by the FDA demanding that manufacturers of alcoholic beverages containing caffeine submit their rationale and supporting data for GRAS status to the FDA is a sign that the agency may enforce its GRAS regulations more strictly. On Nov. 13, 2009, the agency sent warning letters to 30 manufacturers of caffeinated alcoholic beverages, stating: that it was unaware of any basis for concluding that the use of caffeine in alcoholic beverages is GRAS. FDA, *FDA To Look Into Safety of Caffeinated Alcoholic Beverages Agency Sends Letters to Nearly 30 Manufacturers* (Nov. 13, 2009), *available at* http://www.fda.gov/Food/FoodIngredientsPackaging/ucm190366.htm.

The FDA stated in 1987:

> [U]nder section 403(a) of the Act (21 U.S.C. § 343(a)), the agency could require warning labels on caffeine-containing nonalcoholic carbonated beverages if it determines that such products present a potential health hazard to consumers. Although the FDA does not believe that a requirement for such a warning label is warranted at this time, such a requirement can be proposed at any time the available data indicate a need for such action.[29]

If the FDA has the authority to require cautionary statements, it most certainly has the authority to require the declaration of caffeine content, a step CSPI has urged for years.[30] Action by the FDA is even more important today given the growth of caffeine-containing food products that have flooded the marketplace.

Other countries have already acted. For example, the European Union requires that products (other than coffee and tea—a huge loophole) containing caffeine in excess of 150 mg/L state on the label "high caffeine content."[31] Australia now requires formulated caffeine beverages to state on the label: "Not suitable for children and caffeine sensitive persons."[32] Australia also requires that manufacturers advise consumers that products containing guarana are a "source of caffeine."[33] Now is the time for the FDA to act and protect consumers in the United States.

Recommended Reforms

- Caffeine content per serving should be prominently disclosed on food labels, such as on a separate line between the Nutrition Facts Panel and the ingredient list; above the top of the Nutrition Facts Panel where % juice content is declared; or in large, clear type on products (such as cans of coffee) that lack nutrition panels and ingredient lists.
- The terms "guarana" and "yerba maté" (and any other ingredients that are used as a source of caffeine) should be followed by "(a source of caffeine)" in the ingredient list.
- The FDA should require foods containing more than a specified level of

29 52 Fed. Reg. 18,923, 18,925 (May 20, 1987).

30 FDCA §§ 701(a) "the authority to promulgate regulations for the efficient enforcement of this Act. . . .", 403(a), 201(n); 21 U.S.C. §§ 371(a), 343(a), 321(n).

31 Commission Directive 2002/67/EC, O.J. (L 190/20).

32 A formulated caffeinated beverage is defined as "a non-alcoholic water-based flavoured beverage which contains caffeine and may contain carbohydrates, amino acids, vitamins and other substances, including other foods, for the purpose of enhancing mental performance." The product must contain between 145 and 320 mg/L of caffeine. Australia New Zealand Food Authority, Standard 2.6.4-Formulated Caffeinated Beverages.

33 Australia New Zealand Food Standards Code Standard 1.2.3. clause 2.

caffeine to carry the FDA's advice for pregnant women: "Pregnant women should avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly."

Part VI: Stopping Misleading Structure/ Function Claims

In 1990, Congress permitted manufacturers to make health claims for foods that pertained to particular nutrient/disease relationships.[1] An example is: "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."[2]

To prevent abuse, the law requires that the FDA approve health claims prior to marketing and allow only those claims that are supported by "significant scientific agreement."[3] That process can take up to 540 days[4] because the law requires that the FDA follow a transparent rulemaking process that allows for the full participation of scientists, consumers, and all other interested parties. The FDA has approved 12 health claims for conventional foods through this process, and another 6 health claims through an abbreviated process established by Congress in 1997. [5]

Food companies have continually sought ways to make health claims more quickly, with less FDA review. This chapter discusses one of the major ways food companies have tried to achieve that objective and how that has led to marketplace chaos.

The Problem

The primary approach taken by companies has been to make what are referred to as "structure/function" claims, i.e., claims that a nutrient in a conventional food can benefit the normal structure or functioning of a bodily system, without expressly mentioning the role that such nutrient plays in the prevention of any disease. However, the inference is often perfectly clear to the consumer. For example, companies cannot state without prior FDA approval that a nutrient in a food "may help reduce the risk of heart disease," but they can state without FDA approval that the nutrient

1 Until the Federal Food, Drug and Cosmetic Act was amended in 1990, foods were not permitted to claim that they could prevent a disease. If they tried to do so, they were considered unapproved new drugs. In 1985, the FDA first began experimenting with allowing health claims for conventional foods without requiring pre-market approval. The result was a few truthful claims followed by a flood of products claiming to cure almost every ailment under the sun. After several years of such experimentation, the cover story on *Business Week* magazine proclaimed "Can Cornflakes Cure Cancer? Health Claims for Foods are Becoming Ridiculous," Zachary Schiller *et. al. Can Cornflakes Cure Cancer?,* Bus.Wk. Oct. 9, 1989, at 114.

2 21 C.F.R. § 101.75.

3 Although petitions for health claims are filed by an individual company, any company may make the claim once FDA has issued a regulation granting the petition, so long as eligibility criteria are met.

4 FDCA § 403 (r)(4)(A), 21 U.S.C. § 343(r)(4)(A).

5 The food industry obtained a 1997 amendment to the law whereby food companies file a notification with the FDA that they intend to make a health claim based on an authoritative statement of another US government agency or the National Academy of Sciences; the claim becomes lawful if the FDA does not issue a regulation rejecting or modifying the proposed claim within 120 days of receiving the notification. Pub. L. No. 105-115 codified at 21 U.S.C § 343(r)(3)(C).

"helps maintain a healthy heart."

Manufacturers have been permitted to make claims that a food can "affect the structure or any function of the body"[6] since 1938. Until recently, such claims were rare. However, dietary supplement companies were given the right to make such claims by legislation passed by Congress in 1994,[7] and supplement sales soared. That trend was closely observed by the food industry, and over the last several years food manufacturers have increasingly utilized structure/function claims to market conventional foods on the basis of health benefits. In addition to being a successful marketing tool, many companies prefer structure/function claims because in contrast to health claims, the claims can be more succinct and need not be preapproved by the agency.

Furthermore, structure/function claims for conventional foods do not have to satisfy stringent nutrient-content eligibility requirements that FDA established for health claims. Health claims may not be made if the product exceeds disqualifying levels for total fat, saturated fat, cholesterol, or sodium[8] or, if prior to fortification, the food does not contain at least 10% of the Reference Daily Intake of Vitamin A, Vitamin C, iron, calcium, protein, or fiber.[9] This minimum nutrient requirement, known as the "Jelly Bean" rule, prohibits health claims for soft drinks, chewing gums, bottled waters, and other foods and beverages. For health claims, the nutrient that is the subject of the claim must be present at levels that are at least 20% of the Daily Value or in amounts specified by FDA.[10] Finally, approved health claims require that claims be phrased in a particular way and indicate that the disease at issue may be caused by a variety of factors and that the product must be consumed as part of a healthy diet. The FDA has no such requirements for structure/function claims for foods.

Some companies also favor structure/function claims over more explicit health claims for marketing reasons. A national study of public attitudes and actions toward shopping and eating found that many shoppers favored more succinct and positive-sound-

Health Claims Supported by "Significant Scientific Agreement"

For the most part, food companies using health claims approved by FDA under the "significant scientific agreement" standard meet the requirements of the law. But even the strongest law cannot prevent deception if it is not enforced. In the last decade, FDA generally signaled the food industry that it was stepping back enforcement of food labeling regulations. A few food companies making FDA approved health claims took advantage of that political environment and coupled an approved FDA claim based on significant scientific agreement with exaggerated label statements that violated FDA rules. For example, General Mills' Cheerios, which used an FDA approved health claim about oat bran and heart disease, further claimed on its label that the cereal could "Lower Your Cholesterol 4% in 6 weeks." But on May 9, 2009, FDA sent General Mills a warning letter, signaling industry that the agency would not let companies stray so far from FDA approved language. That action by FDA was welcomed by consumer organizations.

6 FDCA § 201(g)(1)(C), 21 U.S.C. § 321(g)(1)(C).

7 Dietary Supplement Health and Education Act, Pub. L. 103-417.

8 21 C.F.R. § 101.14(a)(4).

9 21 C.F.R. § 101.14(e)(6).

10 21 C.F.R. § 101.14(d)(2)(vii).

ing structure/function claims like "supports the immune system" over health claims like "may reduce the risk of cancer."[11]

Through clever wordsmithing, food manufacturers can imply disease prevention, using the softer wording that surveys show many consumers prefer. A study by the industry-funded International Food Information Council (IFIC) concluded that:

> Consumers do not perceive a difference among unqualified textual health claims [e.g. those based on "significant scientific agreement"], structure-function claims, and dietary guidance statements with respect to scientific evidence.[12]

A study conducted by the AARP revealed that more than a third of the respondents could not distinguish between health claims and structure/function claims. When asked to compare "calcium reduces the risk of osteoporosis" and "calcium builds strong bones" 38% of respondents thought the claims meant the same thing.[13]

Similarly, in 1999, the FDA concluded that consumers in numerous focus group studies conducted by the agency could not tell the difference between structure/function claims and health claims.[14] The FDA's own research demonstrated that: "[T]here was no indication that participants differentiated at all between structure/function and health claims."[15]

Because consumers cannot distinguish between structure/function claims and health claims for foods, the FDA should apply the same evidentiary and eligibility standards for their use. This has been a longstanding problem that the FDA has largely ignored.

In a report discussing, *inter alia,* conventional foods sold as so-called "functional" foods, the GAO recommended that the FDA "develop and implement a strategy for identifying and taking appropriate enforcement actions against companies marketing products with unsupported structure/function claims on their labels."[16] More recently, House and Senate Appropriations Committees have also urged the FDA to take enforcement action against false or misleading claims to maintain the integrity of the food label and retain consumer confidence in its accuracy.[17]

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11 Linda Gilbert, *Marketing Functional Foods: How to Reach Your Target Audience*, AgBioForum 272-290 (Winter 2000).

12 International Food Information Council, *Qualified Health Claims Consumer Research Project*, March 2005 at 12, *available at* http://www.ific.org/research/qualhealthclaimsres.cfm.

13 Sandra B. Eskin, AARP Public Policy Institute, *Dietary Supplements and Older Consumers* 4 (Dec. 2001).

14 General Accounting Office, *Food Safety, Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods,"* 23 GAO/RCED-00-156 (July 2000).

15 *Id. quoting* unnamed report of FDA research conducted in August 1999.

16 *Id.* at 27. The FDA issued a guidance document setting out substantiation standards for structure/function claims for dietary supplements, but has not taken such action for structure/function claims for foods. As explained, *infra* notes 40 - 43 and accompanying text, the FDA should not apply substantiation standards for dietary supplement claims to structure/function claims for foods.

17 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2006, S. Rep. No. 109-92, at 153 (2005), H. Rep. No. 109-102, at 83 (2005).

The FDA has failed to implement those recommendations. Supermarket aisles are filled with structure/function claims boasting about the roles that specific nutrients purportedly play in maintaining good health. Many such claims are unsubstantiated, others impermissibly imply disease prevention, and some are simply untrue.

There is no evidence that the product "supports" a child's immune system, although that claim is stated on the front and back of the package label. Moreover, the cereal is about 40% sugar – a quintessential "junk food." The claim was halted by consumer protection officials from the city of San Francisco.

For example, in the fall of 2009, Kellogg's Cocoa Krispies proclaimed that it "now helps support your child's immunity" (a concern of many parents during flu season), because it is fortified with vitamins A, B, C, and E. While a severe deficiency in those vitamins could interfere with the proper functioning of the body's immune system (and any other system), there is no evidence that Cocoa Krispies actually improves children's immune status or wards off disease. Moreover, the cereal is almost 40% sugar, containing 12 g per ¾ cup (31 g) serving.

Kellogg's immunity claim is not only unsubstantiated, it illegally implies disease prevention. The only reason consumers may be concerned about the strength of their immune systems is to ward off disease. A survey conducted by CSPI supports this premise and shows that large numbers of consumers believe that products with "immunity" claims on the label can help prevent disease, including the common cold and the flu.[18] Such claims, therefore, constitute impermissible health claims that have not been authorized by the FDA prior to marketing.

While the FDA has taken no public action, the San Francisco City Attorney objected to the claim. That led Kellogg to announce that it would discontinue the use of immunity claims on its Cocoa Krispies and Rice Krispies cereals.[19]

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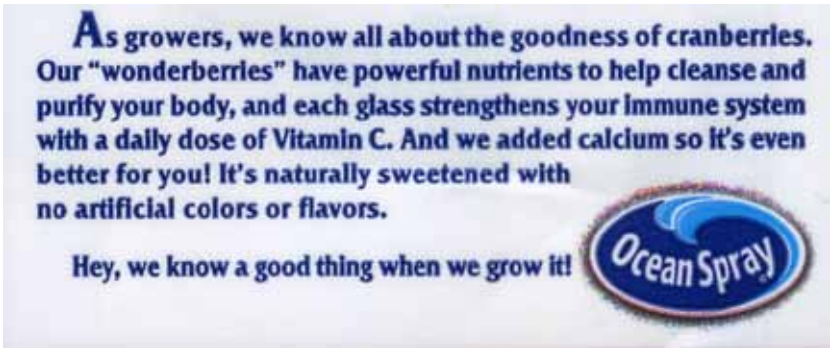
18 Online Caravan Advertisements Survey Prepared for CSPI by Opinion Research Corp. (May 21-22, 2009). For example, of the thousand consumers shown advertisements for a juice making an immunity claim, 37% believed that it helps prevent diseases in general. A third of the consumers thought that it helps prevents colds and the flu. *Id.*

19 Bruce Horovitz, *Kellogg pulls immunity claim from Rice Krispies,* USA Today Nov. 4, 2009, *available at* www.usatoday.com/money/industries/food/2009-11-04-kellogg-immunity_N.htm.

But numerous other immunity claims for foods still exist, and FDA action is needed. For instance, Ocean Spray recently began a major promotional campaign involving advertising and labeling that claims that cranberry juice can help strengthen one's immune system. The label on Ocean Spray Cranberry Juice states that "each glass strengthens your immune system with a daily dose of Vitamin C."



Vitamin C is important for the functioning of the immune system (and every other system). However, consuming Ocean Spray Cranberry Juice Cocktail has no impact on the immune system of healthy persons.

General Mills' Green Giant "immunity blend" frozen vegetables are healthful, but no more likely to improve one's immune system than any other vegetables. Moreover, the packaging promotes a cancer-related fundraising drive, linking the immunity claim with cancer prevention. The FDA does have an approved health claim stating: "Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of

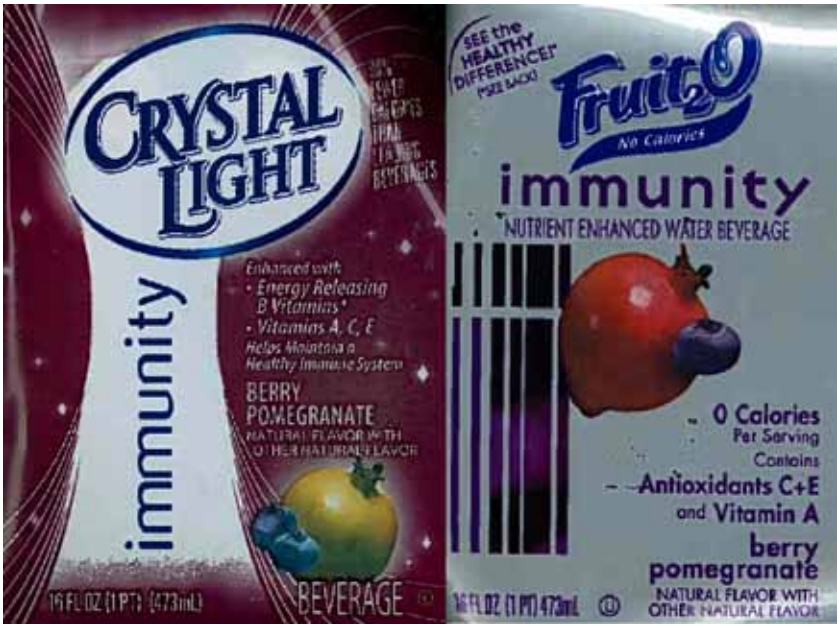
Vegetables are healthful, but General Mills' Green Giant "immunity blend" is no more likely to improve one's immune system than any other vegetables.

The label of Nestlé's Carnation Instant Breakfast misleadingly claims "Antioxidants to help support the immune system."

cancer, a disease associated with many factors."[20] But General Mills has eschewed that authorized claim for a more proprietary claim that attempts to portray the product as a magic bullet that strengthens the immune system and wards off disease.

Another example is Nestlé's Carnation Instant Breakfast. The label boasts "Antioxidants to help support the immune system." Again while severe deficiencies in such nutrients can lead to serious health problems, consumption of this product won't ward off disease by strengthening the average consumer's immune system. Such implied claims are false.

Kraft Foods' Crystal Light Immunity Diet Beverage claims on its label that its "Vitamins A, C, E Helps [sic] Maintain a Healthy Immune System." Similarly, Kraft's Fruit$_2$O Immunity Nutrient Enhanced Water Beverage, now owned by Sunny Delight Beverages Company, claims on the label that it contains vitamin A and antioxidants C and E to "help maintain the immune system."



Kraft admitted that neither of these products, by themselves, will benefit the immune system.

In response to a query from CSPI, Kraft said in 2007: "We do not expect, or claim, that consumption of *Crystal Light* Immunity and *Fruit$_2$O* Immunity will—in and of itself—significantly impact immune function. Consumed as part of a healthy, balanced diet, however, we believe the added Vitamins C, E and A in these products can supplement consumers' intake of these important nutrients and in so doing 'help maintain a healthy immune system,' as the labels state."[21] But that is not what is implied by the statement on the label.

Another example of a product making an immunity claim is Fresh Express Baby Spin-

20 21 C.F.R. § 101.76(e)(1).

21 Email from Bridget A. MacConnell, Kraft Inc., to CSPI (Sept. 7, 2007).

ach. The product is certainly healthful but does not boost the immune system.

The label of Juicy Juice Berry Fruit Juice Beverage claims that it "Helps Support Immunity,"[22] and Dannon DanActive Immunity Probiotic Dairy Drink states "Helps Strengthen Your Body's Defenses." Both are deceptive.

The label of Fresh Express Baby Spinach claims the product is "loaded with natural phytonutrients that help boost immunity."

Companies have made other types of misleading structure/function claims as well. Nestlé markets Juicy Juice Fruit Juice Beverage Brain Development with "DHA—A Building Block for Brain Development." An asterisk on the label indicates that the beverage is intended for use "in children under two years old." The label also informs parents that "The human brain triples in volume between birth and two years, so it's never too early to start good nutrition habits," but fails to mention that the American Academy of Pediatrics recommends that children under six months old not be fed juice at all and that children aged 1 to 6 consume no more than 4 to 6 oz. per day in part to reduce the risk of obesity.[23] The fact that the product is packaged in

Both of these products misleadingly imply that they can strengthen the immune system and ward off disease. Such claims are false and misleading.

Nestlé aims juice drinks with structure/function claims regarding brain development at parents of infants. But infants under six months should not be consuming juice at all according to the American Academy of Pediatrics.

22 The main trend in the children's beverage market is beverages that are all natural, that contain ingredients to strengthen the immune system and that are free from ingredients perceived as unhealthy, according to a report published by *New Nutrition Business*. That report apparently claims that immunity is parents' top health concern worldwide and cites Nestlé's findings that mothers identified immunity as the most important benefit for children ages 2-5. Rod Addy, *Kids' beverages target 'all natural,' 'free-from,' 'immunity,'* AP-Food Technology.Com (Sep. 4, 2009), *available at http://www.ap-foodtechnology.com/Industry-drivers/Kids-beverages-target-all-natural-free-from-immunity.*

23 American Academy of Pediatrics Committee on Nutrition, *The Use and Misuse of Fruit Juice in Pediatrics*, 107 Pediatrics 1210 (May 2001), Reaffirmed 119 Pediatrics 405 (Feb. 2007).

Minute Maid claims that this product is designed "to help protect healthy joints." The information panel states: "Glucosamine helps protect cartilage and joints from the stress of normal daily activities."

1 L bottles is not conducive to limiting serving sizes. Furthermore, a serving of Juicy Juice contains only 16 mg of DHA (as much as ¼ teaspoon of salmon). There is no evidence that this product will facilitate the development of a normal baby's brain.

Minute Maid Active orange juice makes bogus claims "to help protect healthy joints." The label boasts that a serving contains 750 mg of glucosamine HCl.

The form of glucosamine used in this beverage, glucosamine hydrochloride, does not relieve the symptoms of osteoarthritis. The most recent review of the 15 best studies of glucosamine and osteoarthritis concluded that "glucosamine hydrochloride is not effective."[24] In the largest study of glucosamine, funded by the National Institutes of Health, glucosamine hydrochloride did not reduce pain in patients with osteoarthritis of the knee.[25]

Regulatory and Legal Status

Structure/function claims for foods are commonplace, but the FDA has no particular standards for regulating them. Unlike dietary supplements, a disclaimer is not required on the label,[26] and the FDA receives no notification of such claims from the manufacturer.[27] Moreover, the FDA has never issued guidance for the level of substantiation food companies[28] need to make such claims and has ignored recommendations from the GAO to do so.[29]

In remedying this problem, the FDA should not merely follow the model

24 *Arthritis Rheum.* 2007; 56: 2267-77.

25 *N Engl J Med.* 2006 Feb 23; 354 (8):795-808, *available at* http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3051&itool=AbstractPlus-def&uid=16495392&db=pubmed&url=http://content.nejm.org/cgi/pmidlookup?view=short&pmid=16495392&promo=ONFLNS19.

26 Dietary supplements carrying structure/function claims must prominently state: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." FDCA § 403(r)(6), 21 U.S.C. § 343(r)(6).

27 *Id.* FDA receives 30 day post-market notification of structure/function claims for dietary supplements, but not for foods. Post-market notification is not an effective way to stop misleading claims before they appear in the marketplace.

28 In 2000, FDA issued a regulation intended only to prevent supplement manufacturers from making unapproved drug claims under the guise of structure/function claims. 65 Fed. Reg. 1000 (Jan. 6, 2000). Although that regulation applies only to claims on dietary supplements, the FDA said in the preamble to the final regulation that "[F]or consistency, the agency is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods as for dietary supplements." *Id.* at 1034. Regardless, the regulation, does not address the issue of how much substantiation a food manufacturer needs to render a structure/function claim non-misleading.

29 The FDA did issue a substantiation standard for structure/function claims for dietary supplements, 74 Fed. Reg. 304 (2009), but that standard does not, and should not apply to foods, *infra* notes 40-43.

it has used to try to regulate structure/function claims on supplement labels. That approach has been shown to be ineffective to protect consumers from misleading claims. Misleading structure/function claims on dietary supplements abound despite those requirements.

Furthermore, surveys have shown that the disclaimer—"These statements have not been evaluated by the Food and Drug Administration ..."—which appears on dietary supplement labels has been ineffective.[30] Further, the post-market notifications that the FDA may receive of structure/function claims for dietary supplements have not permitted the agency to stop misleading claims before they are made.

Moreover, the FDA is under no obligation to regulate structure/function claims for foods under the weak scheme it has devised for dietary supplements because Congress has established different regulatory schemes for structure/function claims for foods and dietary supplements. In brief, these two product categories present very different health considerations, and Congress has recognized that structure/function claims for each of them should be regulated in different fashions.[31]

For all those reasons, the FDA should treat structure/function claims for foods just like health claims for foods. Studies show that consumers do not typically distinguish structure/function claims from health claims that require FDA approval and must be supported by "significant scientific agreement."[32] The two types of claims should therefore be regulated in the same manner.

Recommendations

- The FDA Should Take Enforcement Action Against Specific Deceptively Labeled Products

Dishonest structure/function claims mislead consumers with regard to serious health matters and threaten the integrity of the food label. Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) states that "a food shall be deemed to be misbranded if its labeling is false or misleading in any particular." Section 201(n) of the FDCA provides, in pertinent part, that:

> [I]n determining whether the labeling . . . is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the

30 AARP *Survey*, *supra* note 13. This nationwide random digital dial survey of 1,480 personage 50 and over found that "only 41 percent of supplement users report having noticed such a disclaimer." *Id.* at 4.

31 The FDA has recognized this distinction in a variety of contexts. For example, structure/function claims for conventional foods must focus on effects derived from "nutritive value," while supplements may focus on nutritive as well as non-nutritive effect. 62 Fed. Reg. 49,859, 49,860-61 (Sept. 23, 1997).

32 GAO Report, *supra* note 14, *at* 23 (July 11, 2000).

> extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . thereof or under such conditions of use as are customary or usual.[33]

In addition, section 701(a) of the FDCA gives the FDA the "authority to promulgate regulations for the efficient enforcement of the Act." All of those provisions provide the FDA with ample authority to act.

The structure/function claims discussed here mislead consumers both expressly and by implication. CSPI, therefore, urges the FDA to order the companies to promptly remove the dishonest claims from product labels.

- The FDA Should Issue an Industry-Wide Letter Clarifying the Substantiation Standard for Structure/Function Claims for Foods

The FDA should warn the food industry of its obligations to comply with the law by issuing an industry letter setting forth the substantiation standard for structure/function claims for foods. The last "Dear Manufacturer" letter the FDA issued on food labeling for foods in January 2007[34] included a cursory discussion of structure/function claims for foods but failed to specify a substantiation standard for such claims. It simply noted that such claims must be truthful and not misleading. The FDA's failure to specify a substantiation standard has effectively granted food manufacturers carte blanche to make any structure/function claims they want.

- The FDA Should Require Structure/Function Claims for Foods to Meet the Same Standard as Health Claims for Foods

Both FDA and food industry studies[35] demonstrate that consumers do not differentiate between structure/function claims and health claims on food labels. To prevent deception, the FDA should subject structure/function claims for conventional foods to the evidentiary standard used for health claims for foods. That standard is "significant scientific agreement."[36]

Applying the same evidentiary standard to health claims and structure/function claims for conventional foods would: 1) preserve order within the food industry, 2) restore integrity to the food label, 3) clarify the limited applicability to foods of FDA's regulations and guidance documents pertaining to dietary supplements, and 4) establish a

33 FDCA § 201(n), 21 U.S.C. § 321(n).

34 *Dear Manufacturer Letter Regarding Food Labeling* (Jan. 30, 2007), http://www.cfsan.fda.gov/~dms/flguid.html. (last visited June 5, 2009).

35 *Supra* notes 12-15 and accompanying text.

36 FDCA § 403(r)(3)(B), 21 U.S.C. § 343(r)(3)(B).

proactive regulatory policy to ensure that all structure/function claims for foods, not just the most egregious examples named here, are scientifically valid. Such steps are consistent with the First Amendment's commercial free speech doctrine, which accords no protection to misleading commercial claims.

- The FDA Should Not Apply its Substantiation Standards for Dietary Supplements to Structure/Function Claims for Conventional Foods

In its 2000 regulation addressing structure/function claims for dietary supplements,[37] the FDA stated in passing that such claims must be "supported by adequate scientific evidence,"[38] noting that "[I]n response to a request for substantiation for the statement, the agency would expect manufacturers to provide a requester with contrary as well as supporting studies."[39] The FDA later stated in both its *Guidance* document on substantiating structure/function claims for dietery supplements and the *Federal Register* notice announcing its availability that the *Guidance* "does not extend to substantiation issues that may exist in other sections of the Act." [40] Thus the FDA's *Guidance* for substantiating structure/function claims for supplements does not—and, for the reasons explained below, should not—apply to structure/function claims for foods.[41]

In its *Guidance* document, the FDA said that its substantiation standard for dietary supplements "is consistent with the Federal Trade Commission's [FTC] standard for *advertising* of supplements and other health related products . . ." (emphasis added) which requires that claims be based on "competent and reliable scientific evidence."[42] But advertising is not the same as labeling. Consumers expect ads to be filled with pitches and exaggerations, but depend on food labels for accurate information about product quality and content.[43]

Thus, it would be inappropriate for the FDA to apply the FTC's advertising substantiation standard to food labeling claims. Further, the FTC's approach to supplement

37 *Final Rule on Structure/Function Claims, supra* note 28.

38 As opposed to "significant scientific agreement."

39 65 Fed. Reg. at 1032.

40 FDA, *Guidance for Industry, Substantiation for Dietary Supplement Claims Made under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act,* (Dec. 2008), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm; 74 Fed. Reg. 304 (Jan. 5, 2009).

41 CSPI maintains that the claims discussed here are false and misleading, and constitute misbranding, even if the FDA applied the "competent and reliable scientific evidence" standard. That enforcement approach would still require companies to maintain "competent and reliable" substantiation for their claims including studies that are contrary to, as well as supportive of the claims in question. If the FDA requested the companies to provide their substantiation, it is likely that many firms would be hard-pressed to produce quality studies that satisfy the "competent and reliable" substantiation standard. However, as discussed herein, we believe the FDA should require that structure/function claims for foods meet the same significant scientific agreement standard as health claims for foods.

42 *Guidance*, *supra note 40, at 3-4* The availability of the Guidance document was announced on Jan. 5, 2009, shortly before the end of the previous administration. 74 Fed. Reg. 304 (2009).

43 *Korber Hats v. FTC,* 311 F.2d. 358, (1st Cir. 1962) ("Consumers accept labelling [sic] statements literally while perhaps viewing with a more jaundiced eye the vaunted claim of the advertising media.") *Id.* at 361.

advertising claims, while enforced by that agency on numerous occasions over the last decade, has overall been a failure; misleading claims in supplement advertising abound despite repeated attempts by the FTC to stop them. The latest court decision weakened the FTC's "competent and reliable" scientific evidence standard even further.[44] The extension of the FDA's structure/function claims substantiation policy for supplements to conventional foods would merely accelerate the spread of the dishonesty that has plagued the dietary supplement industry to the much larger food industry.[45]

- The FDA Should Issue a Safe Harbor List of Permissible Structure/Function Claims

The FDA should facilitate industry compliance with our recommended regulatory approach by establishing a "safe harbor" of permissible claims. Such a list could include claims such as: "Calcium builds strong bones" on foods with at least a specified amount of calcium[46] and that do not exceed the disqualifying levels for nutrients such as saturated fat.[47] The list could also include approved health claims that have been reworded as structure/function claims. This step would help ensure that manufacturers use only those structure/function claims that are scientifically sound.

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44 See *FTC v. Lane Labs*-USA Inc. (Civ. Act. No. 00-cv-3174 (D.NJ) (Aug. 11, 2009). The Federal District Court's holding makes the FTC's advertising substantiation standard even less appropriate for label claims that consumers rely on for dependable information. The Court held that FTC's determination that the defendant did not rely on competent and reliable evidence to support its claims was erroneous when the company "provided credible expert testimony for the claims it made and the substantiation it provided in support of those claims." *Id.* The FTC is appealing the decision.

45 It is noteworthy that under the FDCA, Congress addressed structure/function claims for foods and dietary supplements in different manners, *compare*, 21 U.S.C. § 201(g)(1)(C) with 21 U.S.C. § 403 (r)(6)(A).

46 *See* 21 C.F.R. § 101.54 (nutrient content claim for "good source").

47 21 C.F.R. § 101.14(a)(4). See discussion *supra* note 8.

Part VII: Prohibiting Qualified Health Claims for Foods

The Problem

The second way companies have sought to avoid statutory requirements that health claims for foods be based on "significant scientific agreement" is to persuade the FDA to authorize health claims based on any amount of scientific evidence, so long as the claim is accompanied by a disclaimer that the evidence is uncertain. Such claims are referred to as "qualified health claims."

The Grocery Manufacturers of America had pressured the FDA to follow that approach for foods after the U.S. Court of Appeals decision in *Pearson v. Shalala*.[1] That case held that under the First Amendment the FDA must consider permitting qualified health claims (QHCs) for dietary supplements. From 1999 to 2002, the FDA refused to apply the *Pearson* case to health claims for foods in light of the fact that the Nutrition Labeling and Education Act expressly required that health claims for foods be based on "significant scientific agreement," a requirement justified by volumes of legislative history supporting the need for a strong standard.

In contrast, no such body of legislative history existed for demonstrating that dietary supplement claims needed to be strictly regulated, and Congress did not set out any specific standard in the Act that a court could review. Nonetheless, food industry trade associations continued to pressure the FDA, and after the Bush White House appointed a new chief counsel, the agency's policy was turned on its head. In 2002, by administrative fiat, the FDA simply declared that the Court's holding in *Pearson* did apply to conventional foods.

The FDA's decision to ignore its statutory mandate and authorize qualified health claims for conventional food was based on an overly broad reading of *Pearson*. The FDA is under no legal obligation to apply the *Pearson* case to the food industry. The Court never considered whether its holding applied to foods, and no food company has sued the agency over the matter.

The FDA also circumvents statutory requirements that specify that health claims should only be developed through notice and comment rulemaking. Instead, the FDA merely sends authorization letters to food companies that admit, in essence, that the claims requested by the companies violate the "significant scientific agreement" standard written into the law, but state that the agency will exercise its prosecutorial discretion and not take enforcement action to halt them. The FDA refers to such health claims as "qualified health claims" because to purportedly protect consumers, the agency requires that the claims be qualified by a disclosure indicating

1 Pearson v. Shalala, 164 F.3d 650 (D.C Cir. 1999).

that the scientific evidence underpinning the claim is uncertain.[2]

FDA's policy decision has led to some rather bizarre FDA-authorized qualified health claims for conventional foods.

An example involving tomatoes and cancer is:

> Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.[3]

An example involving green tea is:

> Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.[4]

Such claims have been highly criticized by leading health, medical, and consumer organizations.[5] The American Medical Association stated that it opposed qualified health claims because the FDA did not have the legal authority to allow them, that the new FDA policy would lower scientific standards for label claims, and that such claims would confuse consumers. Opposition was also voiced by the American Public Health Association, the American Cancer Society, the American College of Preventative Medicine and others.[6]

While few food manufacturers use qualified health claims,[7] perhaps because of the wordy FDA-required disclaimers, the agency's policy has still caused many problems for consumers. Some companies take advantage of the lax regulatory environment

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2 Even assuming that *Pearson* did apply to foods, the Court held that if the FDA had evidence that the disclaimer statements failed to protect consumers, it could hold companies to the "significant scientific agreement" standard. The FDA's own consumer research, in fact, shows that disclaimers fail to protect consumers from being misled. Hence, the agency is under no obligation to authorize such claims. See *infra* notes 43-47 and accompanying text`.

3 FDA, *Qualified Health Claims: Letter Regarding Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers (American Longevity Petition)* (Docket No. 2004Q-0201)(Nov. 8, 2005), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072767.htm.

4 FDA, *Letter Responding to Health Claim Petition dated January 27, 2004: Green Tea and Reduced Risk of Cancer Health Claim* (Docket No. 2004Q-0083)(June 30, 2005), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072774.htm.

5 *E.g.*, Mike Mitka, *Food Fight Over Product Label Claims, Critics Say Proposed Changes Will Confuse Consumers,* 290 JAMA 871 (Aug. 20, 2003), *available at* http://jama.ama-assn.org/cgi/reprint/290/7/871.

6 Letter from Am. Cancer Soc'y *et al.* to Sen. Herb Kohl (Sept. 25, 2007).

7 Paula Fitzgerald Bone *et al.*, *Qualified Health Claims on Package Labels*, 28 J. Pub. Pol'y Mktg. 253 (Fall 2009).

created by the FDA's handling of this matter and choose to make only the positive portion of the qualified claim authorized by the agency, leaving out the required disclaimer. Others may make the complete claim in small print on labels, but use the FDA's authorization of the qualified health claim as the basis for full-page advertisements or Internet sites that contain statements going far beyond the FDA-authorized language, *infra* notes 21-32 and accompanying text. Then there are companies that do not use the qualified health claim at all, but bootstrap on the publicity that surrounds an FDA action to authorize such a claim and simply emphasize on labels and in ads the presence of the ingredient that is the subject of the claim, *infra* notes 18-20 and accompanying text.[8]

At the end of the day, the FDA's policy of authorizing qualified health claims for foods has led not only to problems for consumers, but also diminished respect for the agency's scientific determinations, once regarded as a "gold standard," both here and abroad.[9]

A. Some companies fail to comply with the specific requirements of FDA authorization letters

The FDA's practice of authorizing qualified health claims by informal communications with food companies has led some manufacturers and trade associations to push the envelope and make only portions of a qualified health claim authorized by the FDA. Although the FDA takes the position that manufacturers must use the exact wording specified by the FDA for a qualified health claim,[10] some companies simply ignore the agency. For example, the FDA issued a letter of enforcement discretion permitting a qualified claim that limited evidence suggested that consuming olive oil might reduce the risk of heart disease. The claim states:

> Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat

8 Some of those statements constitute impermissible, unapproved nutrient content claims. *Infra* notes 19-20 and accompanying text.

9 Discussion between CSPI and the DG Sanco officials of the European Commission at the meeting of the Transatlantic Consumer Dialogue, Brussels, Belg. (June 9, 2008).

10 The FDA routinely states in its letters authorizing qualified health claims that companies must use the exact language specified by the agency. For example in the FDA's *Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease* (Docket No. 2003Q-0401) (September 8, 2004), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072963.htm. The agency stated:

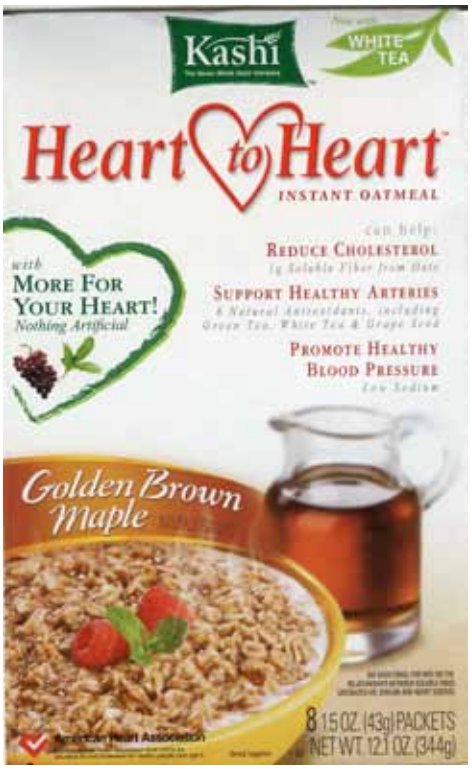
> Thus, FDA will consider exercising enforcement discretion *for the following qualified health claim:* Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and *DHA* omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content]. . . . *FDA intends to consider exercising enforcement discretion for the above qualified claim* when all other factors for enforcement discretion identified in Section IV of this letter are met. .

Id. at 25 (emphasis added).

Food Labeling Chaos

Authorized Language Incomplete Language

The product on the left, produced by Filippo Berrio, carries the FDA-authorized language in its entirety. However, the bottle on the right, produced by Olitalia, fails to use the key qualifying language indicating that any health benefits may occur only if the olive oil replaces a similar amount of saturated fat in the diet and overall caloric consumption is not increased.



This cereal hypes the presence of green tea to support healthy arteries. However the FDA's QHC for green tea relates to cancer, not heart disease.

and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.[11]

As illustrated above, Olitalia, does not use the entire claim that the FDA authorized. Instead, the company uses only the part of the FDA authorized claim that is positive, but ignores the FDA word-ing-requirement that possible health benefits are contingent upon not increasing calories and not substituting olive oil for foods that contain significant amounts of saturated fat.

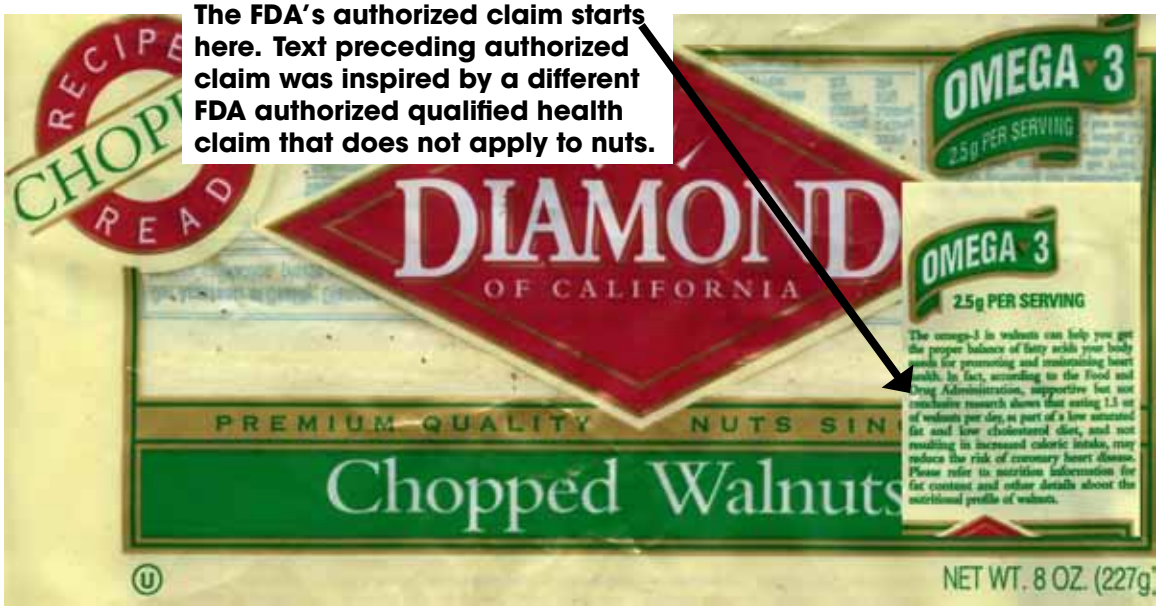
In another case, Kashi oatmeal hypes the presence of green tea, the subject of an FDA qualified health claim for cancer. The product label, however, claims that green tea can purportedly support healthy arteries, a matter not addressed in the FDA authorized claim for this ingredient.

In still another example, a company misleadingly embellishes the language authorized by the FDA. In this case, the FDA issued a letter of enforcement discretion permitting Diamond of California to make the following claim on its walnuts:

11 FDA, *Letter Responding to Health Claim Petition dated August 28, 2003: Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease* (Docket No. 2003-0559)(Nov. 1, 2004), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072963.htm.

> Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content.[12]

In its letter announcing that it would not take enforcement action against such a claim, the FDA specifically stated that Diamond could not refer to the alpha-linolenic acid (ALA) omega-3s in the nuts as contributing to any possibility that walnuts could reduce the risk of coronary heart disease. The FDA explained that Diamond's request for a qualified health claim did not identify a specific substance in the walnuts responsible for the purported benefits, and the FDA had insufficient information to do so.[13]



Diamond prefaced the QHC authorized by the FDA with language about the benefits of omega-3 in an effort to "end run" the FDA's conclusion that there was insufficient evidence to demonstrate that the health benefits of walnuts are attributable to the food's omega-3 content.

After issuing its qualified health claim for walnuts, the FDA authorized a separate qualified health claim for two types of omega-3s—docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA)—that might reduce the risk of coronary heart disease. That FDA action created so much positive publicity about omega-3s that Diamond wanted to brag about omega-3 fatty acids, in addition to the qualified health claim-

12 FDA, *Qualified Health Claims: Letter of Enforcement Discretion - Walnuts and Coronary Heart Disease* (Docket No 02P-0292) (Mar. 9, 2004), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072910.htm.

13 *Id.* at 3.

authorized by the FDA specifically for walnuts.[14] Therefore, Diamond brazenly—and misleadingly—prefaced the FDA's authorized qualified claim for walnuts with language about the heart benefits of omega-3s even though such information was not part of the FDA's authorization letter to the company.

Diamond's actions are particularly misleading because ALA,[15] the type of omega-3 fatty acids found in walnuts, is neither included in the FDA's qualified health claim for walnuts nor in the FDA's qualified health claim for omega-3 fatty acids.[16] Nevertheless, Diamond tries to dupe consumers into believing that its walnuts contain the kind of omega-3 fatty acids that the FDA says might provide heart benefits.[17]

Then there are producers who are ineligible to use a qualified health claim and instead simply highlight the presence of a nutrient that is the subject of a qualified health claim. A prime example is the FDA's authorization of a qualified health claim for EPA and DHA omega-3 fatty acids. The authorization of that qualified health claim, even though it is rarely used on labels, is responsible for much marketplace chaos.

Like Diamond, the egg industry wanted to take advantage of the qualified health claim for omega-3 fatty acids even though eggs were not eligible for such claims. In fact, the FDA specifically denied a petition for a qualified health claim for omega-3 eggs, because of their high level of cholesterol.[18] To circumvent the FDA's policy, egg producers simply began to include the term omega-3 in a prominent position on egg cartons.[19]

The simple disclosure of omega-3 content (as well as any other nutrient) in terms of milligrams per serving is permissible under the FDCA and FDA policy so long as the disclosure does not imply that the food is high or rich in omega-3s.[20] But some com-

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14 Food industry trade publications cited the FDA's decision to allow qualified health claims for omega-3s as a reason why the "omega-3 market continues to explode." *Omega 3's: The Supply Side,* Nutraceuticals World, Oct. 2007, at 78. In 2005 alone, omega-3 fatty acids showed up in 120 new food and beverage products. *Foods & Beverages with Omega 3's*, Nutraceuticals World, Oct. 2007, at 62.

15 Although ALA has some benefits, it pales in comparison to the other types of omega-3s that are of aquatic origin, i.e., from fish and algae. Nevertheless, supermarket aisles are filled with cereals, pasta, frozen waffles, and other products containing primarily ALA (from non-aquatic sources such as flax), implying that they reduce the risk of heart disease that is associated with the consumption of DHA and EPA omega-3 fatty acids.

16 FDA, Omega-3 Letter, *supra* note 10.

17 CSPI filed a complaint about the Diamond walnuts with the FDA on Apr. 25, 2007, but no action has been taken, and the product remains on the market with the labeling discussed in our complaint.

18 FDA, *Eggs with Enhanced Omega-3 Fatty Acid Content and a Balanced 1:1 Ratio of Omega-3/Omega-6 Fatty Acids and Reduced Risk of Heart Disease and Sudden Fatal Heart Attack* (Apr. 5, 2005), *available at* http://www.cfsan.fda.gov/~dms/qhceggs.html (last visited Nov. 14, 2009).

19 The American Egg Board stated at that time that it "is committed to research to increase the omega-3 content of egg and egg products," *available at* http://www.aeb.org/Assets/PDF/AmericanEgg Board_Nov.06 PDF. at 1 (last visited June 6, 2007).

20 21 C.F.R. § 101.13(i)(3).

panies place such factual information in large letters, or surround it by graphics that imply the product is rich in omega-3s.

Eating Right Eggs marketed under Safeway's brand use a red sunburst to emphasize the omega-3 content of eggs, but the eggs are high in cholesterol and ineligible to make a qualified health claim, even if only implied, about omega-3 and heart disease.

Here is another example of this misleading technique as used by another major food retailer.

Whole Foods Eggs Boast "OMEGA-3" in large, upper-case letters, implying that the product is rich in Omega- 3s. Judging from the numbers on the label, most of the omega-3s are probably of the less-valuable ALA type.

The authorization of a qualified health claim for omega-3 fatty acids also coincided with the launch of a number of plainly illegal health claims for eggs. The website for

Country Hen eggs states that "Omega-3s can also help reduce blood pressure, blood clots, heart disease, arrhythmia and cancer."[21] The FDA has never approved such claims.

County Hen's website goes far beyond the qualified health claim authorized by FDA and makes several unauthorized claims. The FDA has expressly stated that eggs, because of their high cholesterol content, must not make claims related to heart disease and has never permitted claims about eggs and cancer.

CSPI filed a formal complaint[22] with the FDA in 2007, in part on the grounds that producers were implicitly claiming that their eggs were rich in omega-3s by using large typeface and other techniques to highlight statements on food labels. The FDA has taken no enforcement action. [23]

B. The FDA's authorization of qualified health claims for foods has led to misleading claims in advertising and other sources of consumer information

Some companies do not use the FDA's qualified health claims at all, but use the FDA's authorization of such claims as an excuse to make blatantly misleading advertising and public relations claims that deceive consumers. Each FDA authorization letter stating it will not take enforcement action against health claims that fail to meet the "significant scientific agreement" standard required by law signals an "anything goes" regulatory environment that contributes to the dissemination of a variety of nutrition

21 http://www.countryhen.com/about.php (last visited Oct. 7, 2009).

22 Complaint letter from CSPI regarding eggs products illegally labeled with omega-3 claims (June 21, 2007).

23 CSPI's complaint also addressed other problems caused by the FDA's authorization of a qualified health claim for omega-3s, including the agency's failure to permit qualified health claims in the absence of a Daily Value for the nutrient that is the subject of the claim. As a result, consumers have no idea whether they are consuming a significant amount of omega-3s, even on products that the FDA authorized to carry the qualified health claim. *See*, Omega-3 letter, *supra* note 10. "[T]he scientific evidence . . . does not support the establishment of a recommended daily dietary intake level. . . ." *Id.* at 22.

misinformation. The problem is exacerbated by the fact that the Federal Trade Commission, which regulates food advertising, has no pre-market procedure for reviewing advertising claims. Thus, deceptive claims can only be stopped after the fact, often through a time-consuming process that sometimes involves litigation that can take years to complete.

For example, the FDA's authorization of a preliminary health claim for a reduced heart-disease risk due to certain omega-3 fatty acids helped give "omega-3s" a positive connotation, spurring the use of statements such as "100 mg omega-3s" on products not eligible to make the qualified health claim on labels. Food industry trade publications cited the FDA's decision to allow qualified health claims for omega-3s as a reason for the increased popularity of adding the substance to foods.[24]

> "As a practical matter, an approved QHC from FDA probably helps… marketing efforts which is the practical value to the company of getting a QHC."
>
> *— Alan S. Levy*
> *Chief Consumer Studies Branch, FDA*

Research shows that when consumers become aware that a product contains an ingredient that is the subject of a qualified health claim they are more likely to buy a product containing that ingredient because they are predisposed to associate a health benefit with it. When consumers read claims that implicitly characterize the level of omega-3 fatty acids in the product as being high, they may infer that the food is useful in reducing the risk of heart disease.[25]

The chief of the Consumer Studies Branch of the FDA's Center for Food Safety and Applied Nutrition summarized the results of research on how consumers are influenced by a relevant content claim for a dietary ingredient specified in a qualified health claim and how this effect, in turn, influences advertising and related marketing efforts:

> Consumers will tend to become more responsive to relevant content claims as they become more familiar with the diet/disease relationship being invoked by the QHC, but the speed and magnitude of the response is likely contingent on the amount and successfulness of marketing efforts to popularize the diet/disease relationships. As a practical matter, an approved QHC from FDA probably helps these marketing efforts, which is the practical value to the company of getting a QHC.[26]

After the FDA authorized qualified health claims for nuts on July 14, 2003, and

24 *Omega 3's: The Supply Side,* Nutraceuticals World, Oct. 2007, at 78. According to trade press reports "The rate of product launches continues to outpace other nutrients," and omega-3s are "still at the beginning of a growth curve." Adam Ismail, *Omega 3's Potential in Foods,* Nutraceuticals World (June 2009), *available at* http://www.nutraceuticals-world.com/articles/2009/06/omega-3s-potential.

25 E-Mail from Alan S. Levy, Chief, Consumer Studies Branch, CFSAN, FDA to Ilene Ringel Heller, Senior Staff Attorney, CSPI (June 13, 2007, 4:05 PM EDT) (on file with CSPI).

26 *Id.*

This ad suggests that almonds should be added to steakhouse salad with blue cheese dressing. But adding nuts to a meal that already contains steak and blue cheese dressing simply means adding more saturated fat. Just 1 tablespoon of blue cheese dressing has more than 4 g of artery-clogging saturated fat.

walnuts on March 9, 2004, "a tremendous amount of media buzz" was generated. One industry expert explained that "The qualified health claim has given people permission to put nuts back into their diet"[27] and revived an industry that was "somewhat depressed because of nutrition policy about fat."[28] By the summer of 2004, Diamond of California's walnut sales increased 30% over the previous year, according to Nutrition Business Journal.[29] But even those who don't use the FDA qualified health claim are benefiting and "see good things happening to sales."[30]

It is no surprise then that companies use the publicity surrounding the FDA's authorization of a qualified health claim, which by definition is based on weak scientific evidence, to make misleading claims. Had the FDA not opened the door to qualified health claims, such problems would have been much less likely to occur.[31]

The FDA's QHCs for nuts recognize that nuts are high in fat and calories and that to be a healthful component of a diet must be consumed only in controlled portions.[32] The advertisement at left for almonds obscures another key element of the FDA's qualified health claim for nuts, i.e. that nuts, when added to the diet, must be part of a healthful diet that is low in saturated fat.

Ads by some manufacturers obscure the fact that not all nuts are eligible for the QHC. (See following page.) Although Planters' (Kraft Foods) NUT-rition Heart Healthy Mix carries the qualified health claim on its label, other products in its NUT-rition product line, including the South Beach Diet variety shown in the ad do not. This variety is not eligible to make the QHC claim because it contains cashews and macadamia nuts which FDA conclud-

27 *Health Claims and Branded Ingredients Play Role in Marketing,* Nutrition Bus. J. 14 (July/Aug. 2004), *quoting* Sam Cunningham of Cunningham Consulting which specializes in services to the nut industry.

28 *Id.*

29 *Id.*

30 *Id.*, *quoting* Cunningham (emphasis added).

31 *See,* James E. Tillotson, PhD, MBA, Professor, Tuft's Friedman School of Nutrition Science and Policy, *quoted in Winning the Claim Game—Confused by label claims for health benefits on everything from walnuts to corn oil? Here's how to read the fine print.* Tufts Univ. Health & Nutrition Letter, Aug. 2007, special supplement. "Everybody wants a claim, because it moves product. How valid it is really doesn't seem to matter much . . . .It's kind of a gold badge – if it's on there, people think the product is good . . . . *Id.* at. 1. The standards of proof for the validity of health messages have tobogganed steadily downhill since 1990. You could get a claim for arsenic." *Id.* at 2.

32 The FDA's qualified health claim for nuts states that: "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts such as [peanuts, almonds, pistachios, pecans, walnuts or hazelnuts] as part of a diet low in saturated fat and cholesterol may reduce the risk of coronary heart disease. See nutrition information for fat content." *FDA, Qualified Health Claims: Letter of Enforcement Discretion - Nuts and Coronary Heart Disease* (Docket No. 02P-0505 July 14, 2003), *available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072926.htm.*

ed had too much saturated fat to qualify. Nevertheless, Planter's promotes its South Beach Diet variety in this advertisement as part of its "NUT-rition Built for a Healthy Lifestyle" line of products.

Although the South Beach Diet variety of Planters' NUT-rition nuts is not eligible for the QHC, the ad was part of the promotional campaign that followed in the wake of the FDA's authorization of QHCs for other kinds of nuts.

Regulatory and Legal Status

As previously stated, the FDA embarked on an initiative to approve qualified health claims because of food industry pressure to apply *Pearson*[33] to conventional foods. That court decision required the FDA to determine whether claims for dietary supplements that did not meet the "significant scientific agreement" standard for health claims could be made non-misleading by the addition of a disclaimer explaining the state of the scientific evidence. From 1999 to 2002, the FDA, seeking to prevent the spread of deceptive labeling, maintained that the *Pearson* decision applied only to dietary supplements, not foods.

It is noteworthy that health claims for foods and supplements are subject to different statutory provisions in the Act. Congress specifically spelled out that health claims for foods must be based on "significant scientific agreement" and only permitted such

33 Pearson, *supra* note 1.

claims after a full notice and comment rulemaking process.[34] That requirement was based on a rich legislative history demonstrating the abuses that occurred in the absence of a strict legal standard.[35]

In contrast, Congress did not examine abuses within the dietary supplement industry and did not set out specific requirements for dietary supplement health claims.[36] Given the two different legislative histories and statutory frameworks for making health claims for foods and supplements, the results of the FDA's consumer research showing that disclaimers are ineffective,[37]and the chaos that has been created in the marketplace since the *Pearson* case, a new court reviewing the issue would likely uphold an FDA decision to cease exercising its enforcement discretion to permit qualified health claims for foods.

In 2002 and 2003, with the Bush administration fully in place, the FDA changed course and announced in guidance documents that the *Pearson* decision applied to food as well as supplements.[38] Under this policy that runs counter to the statute, the FDA issues letters indicating whether it will exercise its enforcement discretion to permit claims that are not legal under the FDCA because they are not supported by significant scientific agreement and have not been promulgated pursuant to notice and comment rulemaking that allows for full input by the general public and scientific community.[39]

CSPI and Public Citizen filed suit against the FDA on the grounds that the agency set up a new regulatory scheme for qualified health claims that violates the substantive and procedural requirements of the law enacted by Congress in 1990. Those requirements specified that the FDA could only permit health claims for foods if the agency

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34 FDCA § 403(r)(3)(B)(i), 21 U.S.C. § 343(r)(3)(B)(i).

35 *See* H.R. Rep. No. 101-538 (June 13, 1990).

36 *See* Cong. Rec. S 16607 (daily ed. Oct. 24, 1990). Congress did not consider the implications of permitting health claims for dietary supplements. Supplements were added to the NLEA on the Senate floor by the Metzenbaum-Hatch amendment. *Id.* at S 16608 (statement of Sen. Metzenbaum). The matter was not raised during the hearing process. The hearings focused solely on food. E.g., *Hearing Before the Senate Comm. on Governmental Affairs on Health and Nutrition Claims in Food Advertising and Labeling,* 101st Cong. 2d Sess. (No. 101-1224 June 25, 1990), *Hearing Before the House Subc. on Health and the Environment of the Comm. on Energy and Commerce on a Bill to Amend the Federal Food, Drug, and Cosmetic Act to Prescribe Nutrition Labeling for Foods,* 101st Cong. 1st sess.(No. 101-65 Aug. 3, 1989); *Hearing Before a Subcomm. of the House Comm. on Gov't Operations on FDA Proposals to Permit the Use of Disease-Specific Health Claims on Food Labels,* 100th Cong. 1st Sess. Dec. 10, 1987).

37 Brenda M. Derby, Alan S. Levy, *Working Paper Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Sept. 2005). This is discussed in more detail in notes 47 and accompanying text.

38 FDA, *Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements* (Dec. 20, 2002); FDA, *Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for Health Claims on the Labeling of Conventional Human Food and Human Dietary Supplements* (July 10, 2003).

39 Even assuming, *arguendo*, that the FDA correctly applied *Pearson* to qualified health claims for foods, nothing in the holding of that case requires the agency to abandon notice and comment rulemaking in favor of an information letter authorization process that largely excludes the public and scientific community from providing public comment on proposed claims, as Congress generally intended.

found through notice and comment rulemaking, that the claim was supported by "significant scientific agreement."[40] Just days before a reply to the complaint was due, the FDA issued an ANPR seeking comments on alternatives for regulating qualified health claims for both supplements and conventional foods.[41] The case was then dismissed on procedural grounds[42], including, *inter alia,* that the matter was not ripe for judicial review because the FDA had not yet reviewed any qualified health claims under its Guidance.[43]

While the FDA's ANPR has never led to a proposed, let alone final rule, the FDA's statements in the preamble (made prior to any public comment) have become the basis of a *de facto* new law, which was issued via administrative fiat, that is expressly contrary to the requirements for health claims for conventional foods enacted by Congress in 1990. If the FDA sincerely questioned whether the *Pearson* case applied to foods, it should have sought guidance from Congress rather than taking it upon itself to in effect, amend portions of the statute through exercises of enforcement discretion.

"FDA's own consumer research concluded that QHC 'failed the key communications test.'"

Even assuming that the rationale for the *Pearson* decision was applicable to conventional foods, the FDA is not required to follow the disclaimer approach set out in that case. The *Pearson* decision set forth a number of exceptions. The Court stated that if the FDA had empirical evidence demonstrating that consumers would be "bewildered" by the disclaimers and that the disclaimers "would fail to correct for deceptiveness," the agency would not be obligated to permit qualified health claims.

The agency is, in fact, in possession of such research. The FDA's own consumer research study completed in 2005 concluded that qualified health claims "failed the key communications test" and that consumer perceptions of products' health benefits were not diminished by disclaimers indicating greater scientific uncertainty for a claim.[44]

40 FDCA § 403(r)(3)(B)(i), 2 USC § 403(r)(B)(i).

41 68 Fed. Reg. 29448 (Nov. 25, 2003).

42 CSPI v. FDA, Civ. Act. No. 03-1962 (D.D.C. July 30, 2004).

43 The courts have upheld government prohibitions on deceptive labeling of foods against First Amendment challenges. *See, e.g.*, Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. 1998) (A 540-day review by FDA of health claims was not unconstitutional prior restraint "in the context of evaluating, pursuant to defined standards, whether commercial health claims are truthful and non-misleading."); U.S. v. General Nutrition, Inc., 638 F. Supp. 556, 562 (W.D.N.Y. 1986) (upholding FDA prohibition of certain nutritional claims on the product label); American Frozen Food Institute v. Mathews, 413 F. Supp. 548 (D.D.C. 1976), *aff'd* 555 F.2d 1059 (D.C. Cir. 1977) (Upheld FDA regulations that "constitute the conclusion by the Commissioners that labeling which fails to meet the requirements of the regulation is misleading); *see also*, U.S. v. Harkonen, No. C 08-00164 MHP, slip op. at 12 (N.D. Cal. 2009) ("It is undisputed that the government has the right to regulate false and misleading statements … [I]t is clear to the court that the speech at issue is not outside the bounds of the FDCA's regulatory reach as being wholly protected by the First Amendment as a matter of law."); Kraft Inc. v. FTC, 970 F.2d 311 (7th Circ. 1992) (FTC did not violate First amendment when it determined without extrinsic evidence that manufacturer of processed cheese slices misrepresented that each slice contained the same amount of calcium as 5 oz. of milk).

44 *Effects of Strength of Science Study, supra* note 37.

The FDA's conclusions were supported by the FTC. In its official comment to the FDA, the FTC stated that:

- None of the tested disclaimers communicated serious limitations in the scientific evidence.
- Most consumers either overestimated or underestimated the certainty of the science supporting qualified health claims.[45]

In 2006, the FDA announced that a second consumer survey on qualified health claims had been approved by the Office of Management and Budget.[46] Although the study is completed, it has not been released.

In 2007, key health, medical, and consumer groups, including the American Cancer Society, American Diabetes Association, American Heart Association, American College of Preventive Medicine, American Public Health Association, American Medical Association, and others asked Congress to approve language prohibiting the FDA from using FY 2008 appropriations to authorize qualified health claims for foods.

On July 30, 2007, the House of Representatives approved such language, but it was weakened by the Senate. The final congressional language expressed the House and Senate's concern that the "FDA may have exceeded its statutory authority when the agency decided to begin allowing the use of qualified health claims for conventional foods in 2003." The Appropriations Committees requested that the Government Accountability Office conduct an investigation of the FDA's actions and evaluate consumer understanding and the usefulness of qualified health claims. That investigation, to date, has not been completed. Pending completion of the GAO investigation, the Committees urged the FDA "not to use funds . . . to review requests for qualified health claims for conventional foods or to issue letters permitting such claims through exercises of enforcement discretion. . . ."[47]

But the FDA ignored Congress. In a June 30, 2008 letter to CSPI and other organizations, FDA Commissioner Andrew C. von Eschenbach, M.D. stated that the FDA would continue work on a petition for reconsideration of a previously authorized qualified health claim and "has no plans to issue a notice or announcement indicating that it will no longer issue letters of enforcement discretion for qualified health claims on conventional foods.[48] Subsequently, in a "midnight" guidance statement issued

45 Comments of the Federal Trade Commission to the FDA in the Matter of Assessing Consumer Perceptions of Health Claims (Docket No. 2005N-0413) (Jan. 17, 2006).
46 71 Fed. Reg. 69,134 (Nov. 29, 2006).

47 153 Cong. Rec. H15741 (daily ed. Dec. 17, 2007) (statement of Rep. Obey).

48 Letter from FDA Comm'r Andrew C. von Eschenbach to Bruce Silverglade, CSPI (June 30, 2008). On August 18, 2008, the FDA refused to modify its prior decision on green tea and a reduced risk of cancer. Letter to Sin Hang Lee, Fleminger, Inc.: *Petition for Reconsideration: Letter Responding to Health Claim Petition Dated January 27, 2004: Green Tea and Reduced Risk of Cancer Health Claim* (Docket No. 2004Q-0083 Aug.19, 2008).

shortly before President Obama took office in January 2009,[49] the FDA formally announced that it would continue to authorize qualified health claims for supplements and conventional foods.[50] No new petitions have been filed for qualified health claims for conventional foods, although there is a petition pending for qualified health claims for infant formula.[51]

Recommendations

- The FDA should release its second consumer research study on whether the disclaimers in qualified health claims for conventional foods protect consumers from being misled, and hence, whether the agency is under any legal obligation under the First Amendment (and the *Pearson* case) to authorize them.
- The FDA should delete language relating to conventional foods from the Bush Administration's January 2009 "midnight" guidance document[52] and specify that, until a court or Congress says otherwise, companies are prohibited from making qualified health claims on conventional foods that do not meet the significant scientific agreement standard.
- The FDA should delete language relating to conventional foods from its 2003 ANPR and specify that conventional foods not meeting the significant scientific agreement standard are prohibited from making qualified health claims.

49 FDA, *Evidence-Based Review System for the Scientific Evaluation of Health Claims* –Final (Jan. 2009).

50 *Id.* This Guidance replaced the Interim Evidence Based Ranking System for Scientific Data. *Id.* at 26, note 3.

51 *Petition for Qualified Health Claim for 100% Whey-Protein Partially Hydrolyzed Infant Formula and a Reduced Risk of Atopic Dermatitis in Healthy Infants,* submitted by Nestlé Nutrition (Nestlé Infant Nutrition/Gerber Product Co.) (May 14, 2009), *available at* http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2009-Q-0301.

52 *Supra* note 49.

Food Labeling Chaos

Part VIII: Halting Deceptive "0 Trans Fat" Claims

The Problem

The FDA recognized in 2003 that about 80% of dietary trans fat comes from partially hydrogenated vegetable oils.[1] Artificial trans fatty acids are formed when vegetable oils (rarely animal fats) are reacted with hydrogen to increase their melting points, shelf lives, and stability. In the process, some of the unsaturated fatty acids in the oils are converted into saturated and trans monounsaturated fatty acids.

Trans fat (naturally occurring or artificial) raises LDL-cholesterol, lowers HDL-cholesterol, and has other physiological effects, making it the most potent type of fatty acid in terms of increasing the risk of coronary heart disease.[2] In July 2002, the National Academy of Sciences Institute of Medicine, at the request of the FDA, reviewed the scientific evidence on trans fat and concluded that trans fat is at least as harmful to health as saturated fat[3] and increases the risk of heart disease.[4] A 2004 FDA Food Advisory Committee concluded that, gram for gram, trans fat is *more harmful* than saturated fat.[5]

The FDA recognized the dangers of trans fatty acids and, in 2003, required that trans fatty acid content be disclosed on the Nutrition Facts Panel (the rule gave companies until January 1, 2006, to change labels).[6] After the FDA required manufacturers to list trans fat on the Nutrition Facts Panel, many companies reformulated their products so that they could declare "0" on the line of the Nutrition Facts Panel where the trans fat content is disclosed. Some companies reformulated their products by replacing partially hydrogenated vegetable oils with more-healthful unsaturated fats. Other companies, however, replaced partially hydrogenated oils with saturated fats, which are almost as unhealthful as trans fat.

Moreover, the latter companies sometimes make prominent "0 g trans fat" claims on the front of the package label, implying that the product is healthful, when the products actually contains substantial amounts of saturated fat.

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1 68 Fed. Reg. 41,434, 41,470 (July 11, 2003). Calculated from data in Table 1.

2 Ascherio, AM, Katan MB, Zock PL, *et. al* trans fatty acids and coronary heart disease. New Engl J Med. 1999;340:1994-8.

3 Food and Nutrition Board of the Institute of Medicine, *Letter Report to the Dietary Reference Intakes for* Trans *Fatty Acids* (July 10, 2002) at 34.

4 *Id.*

5 Food Chem. News at 27, (May 3, 2004).

6 68 Fed. Reg. at 41,433. CSPI has petitioned the FDA to ban artificial trans fat completely. CSPI, *Petition for Rulemaking to Revoke the Authority for Industry to Use Partially Hydrogenated Vegetable Oils in Foods* (May 18, 2004).

The FDA considers products containing more than 4 g of saturated fat per serving to be high in saturated fat and disqualifies such products from making health claims.[7] In addition, the FDA front-panel disclosure requirements for nutrient content claims are triggered by saturated fat content in excess of 4 g.[8] The FDA limits "cholesterol free" claims to foods with 2 g or less of saturated fat[9] per serving and limits "healthy" claims to foods with 1 g or less of saturated fat,[10] because saturated fats, like trans fats, raise serum cholesterol levels.

Edy's Dibs Bite Sized Frozen Snacks boast "0 g trans fat!" per serving but contain 16 g of saturated fat (80% of the Daily Value).

The following products illustrate the deceitful "0 g trans fat" marketing technique:

"0 g trans fat" claims on such products, often printed in large type, surrounded by banners, or followed by exclamation points, imply that the level of unhealthful fats is low and are deceptive in light of the product's saturated fat content.

7 21 C.F.R. § 101.14(a)(4).

8 21 C.F.R. § 101.13(h).

9 21 C.F.R. § 101.62(d).

10 21 C.F.R. §§ 101.65(d), 101.62(c)(2).

Gorton's Crispy Battered Fish Fillets prominently proclaims "0 grams trans fat" in a sunburst on the front of the package, but contain 4.5 g of saturated fat (23% of the Daily Value), an amount that the FDA considers to be "high."

Hot Pockets Meatballs and Cheese with Sauce in a Crust emphasize "0 g Trans Fat per serving," but that serving has 7 g of saturated fat, 35% of the Daily Value.

Regulatory and Legislative Status

When the FDA issued its long-awaited final rule requiring the Nutrition Facts Panel to list the amount of trans fatty acids, it withdrew proposed regulations pertaining to nutrient content claims for trans fat and qualifying criteria for other related claims.[11] The FDA proceeded from the premise that because it was premature to develop a DV for trans fat, it could not establish a definition for "trans fat free," "reduced trans fat" and "reduced saturated fat and trans fat" nutrient content claims. Further, and inexplicably, the agency claimed that it could not establish a limit for the permissible amount of trans fat in foods bearing nutrient content claims for saturated fat (as well as disqualifying levels for health claims and disclosure statements for nutrient content claims).

Instead, the agency took a step backward. It issued an ANPR, merely soliciting information and data that could be used to establish new nutrient content claims for trans fat; qualifying criteria for trans fat in existing nutrient content claims for saturated fat, cholesterol, lean and extra lean claims; and health claims that included messages about cholesterol-raising lipids. In addition, it sought comments on disclosure and disqualifying criteria to "help consumers make heart-healthy food choices." Finally, the FDA requested comments on whether it should consider statements about trans fat alone or in combination with saturated fat and cholesterol as a footnote to the Nutrition Facts Panel, or as a disclosure statement in conjunction with claims about how to use information about cholesterol-raising lipids to make healthy food choices.[12]

Ironically, the agency had already prohibited nutrient content claims for "saturated fat free" unless a serving of the food contains less than 0.5 g of saturated fat and less than 0.5 g of trans fat per RACC and per labeled serving. In contrast, disqualifying levels of trans fat are not included in FDA's regulations governing "low in saturated fat" or claims relating to cholesterol.[13] Rather than building on the agency's precedents for saturated-fat claims, and completing its proposed rules for trans fat claims, the FDA said that it merely planned to "continue to evaluate the emerging science and revisit the need for" the proposed rules it had just withdrawn.[14]

Moreover, in the interim, the agency signaled to the food industry that it would accept an "anything goes" policy. The FDA stated that it would consider requests for the exercise of its enforcement discretion to permit statements about the fat content of a product that are "demonstrably true, balanced, adequately substantiated and not misleading."[15] As of 2006, the FDA had not received any requests from companies

11 68 Fed. Reg. at 41,434.

12 68 Fed. Reg. 41507, 41509 (July 11, 2003).

13 21 C.F.R. § 101.62.(c) and (d).

14 68 Fed. Reg. at 41,509.

15 *Id.*

for the agency to exercise its enforcement discretion and permit such claims.[16] Yet, numerous manufacturers began making such claims, some of which were deceptive because the products, while no longer containing trans fats, were not low in saturated fat. Such steps by some companies mislead consumers and unfairly disadvantage honest competitors who actually reduced trans fats to 0 g in their products and replaced them with more healthful fats. In brief, the FDA's bungling of the issue created marketplace chaos and an unlevel competitive playing field.

On March 14, 2006, CSPI filed a complaint letter with the FDA concerning products that highlight "0 grams of trans fat" although they were not low in saturated fat. In an April 14, 2006, response, the FDA concluded that the claims identified by CSPI (and illustrated in this report) do not characterize the level of trans fat, but are merely "factual statement[s]" about the amount or a percent of a nutrient in a product and are permissible under FDA rules codified at 21 C.F.R. § 101.13(i)(3).

Nothing could be further from the truth. The "0" trans fat claims illustrated earlier, surrounded by banners, exclamation points, and sunbursts clearly indicate a low level of trans fat and imply that the food is heart-healthy. The FDA has grossly mischaracterized these embellished "0" trans fat proclamations as mere statements of fact about the amount of a nutrient. The agency should recognize them for what they are, blatantly deceptive, unapproved implied nutrient content claims.

Furthermore, the exemption that Congress made for simple statements of fact about the amount of a nutrient is limited. Congress instructed the FDA to only "permit statements describing the amount and percentage of nutrients in food *which are not misleading* and are *consistent with the terms defined* in section 403(r)(2)(A)(i)."[17] Statements like "0 trans fat!" are misleading if a food is not low in saturated fat. In addition, they are not consistent with the terms defined in section 403(r)(2)(A)(i). Thus, FDA erred by relying on the narrow exemption set out by Congress to deny CSPI's complaint. [18]

Recommendations

The FDA's conclusion that "0 trans fat claims" highlighted by banners, large type, and exclamation points are merely factual statements of the amount of a nutrient is plainly wrong. Rather, such statements clearly constitute implied nutrient content claims that

16 Letter from Barbara Schneeman, Dir. Office of Nutritional Products, Labeling, and Dietary Supplements, to Michael Jacobson, Exec. Dir. of CSPI (Apr. 14, 2006).

17 Pub. L. No. 101-535, 21 U.S.C. 343 note (b) regulations (1)(A)(iv), 101 STAT. 2361(emphasis added).

18 The FDA also erred because Section 403(r)(1) of the Act only exempts statements of nutrient amounts from nutrient content claim requirements if the statement appears in the Nutrition Facts Panel. The legislative history of the Act explains that statements like "0 trans fat" (which appear on the Nutrition Facts Panel) are not exempt from FDA's nutrient content claim requirements if they appear elsewhere on the package of the product. H. Rep. No. 101-538 (101st Cong. 2d Sess.) at 19 (June 13, 1990).

have not been approved by the agency. The FDA should recognize that when such claims are made on the labels of products that are not low in saturated fat they are misleading. To remedy this problem, the FDA should:

- Review its enforcement policy and promptly issue an industry-wide warning letter stating that products that emphasize "0 trans fat" on the front panel when such foods contain per serving more than 5% of the DV for saturated fat (i.e., are not "low" in saturated fat) and cholesterol are in violation of the law. Simultaneously, the agency should send warning letters to manufacturers of products that are making "0 g trans fat" claims on products that are not low in saturated fat.
- The FDA should propose rules setting forth conditions for making nutrient content (and health) claims for products low in trans fats that are based on existing rules for claims for products that are "low saturated fat." Such rules should ban "0" or "no" or "low" trans fat claims (and health claims), unless a serving of the food is also low in saturated fat and cholesterol.
- The FDA immediately should revoke the Generally Recognized as Safe status of partially hydrogenated oils, as requested in our 2004 petition. Partially hydrogenated oils are unnecessary, as evidenced by industry's gradual abandonment of them in favor of less-harmful oils. Eliminating the use of partially hydrogenated oil would mitigate the need for all of the activities in which the FDA is currently engaged regarding the labeling of trans fat.

Part IX: Stopping Misleading Ingredient Claims

The Problem

Health experts have advised consumers to increase their consumption of fruits, vegetables, and whole grains.[1] It is no surprise, therefore, that the supermarket is filled with package labels claiming that a food is "made with" whole grains, fruits, or vegetables, or that emphasize the presence of such healthful ingredients through the use of pictures, banners, or other techniques.

While the law requires companies to comply with specific FDA regulations for claims about *nutrients* such as fats, cholesterol, sodium, fiber, vitamins, and minerals,[2] the law does not cover claims about *ingredients*, such as whole wheat, spinach, broccoli, oranges, or strawberries.

In addition, while the FDA has the authority,[3] the agency does not generally require companies to disclose the percentage of characterizing ingredients in a food. Congress required in 1990 that the percentage of actual fruit or vegetable juice in diluted juice drinks be disclosed "with appropriate prominence on the information panel."[4]

As a result, consumers can easily be deceived by labels that claim "made with whole wheat" or that depict real fruit, implying that the product contains substantial quantities of those ingredients. While ingredients must be listed in order of predominance[5] elsewhere on the label,[6] ingredient lists are sometimes difficult to read, as discussed in greater detail in Part IV. Moreover, it is often not possible to determine the amount of an ingredient in a product simply by noting its position on the ingredient list.

A. Misleading Ingredient Claims for Whole Grains

The Dietary Guidelines for Americans and the USDA's Food Pyramid recommend that consumers "make half your grains whole."[7] This means that when consumers

1 *See* HHS, USDA *Dietary Guidelines for Americans 2005*, at 23-24.

2 For example, products that contain 10 to 19% of the Daily Value for a particular vitamin or mineral can claim to be "good" sources of that nutrient. Products that contain 20% or more of the Daily Value for fiber can claim to be an "excellent source" of that substance. 21 C.F.R. § 101.54.

3 21 C.F.R. § 102.5.

4 Pub. L. No. 101-535 NLEA § 7(2); codified at FDCA § 403(i)(2), 21 U.S.C. § 343(i)(2).

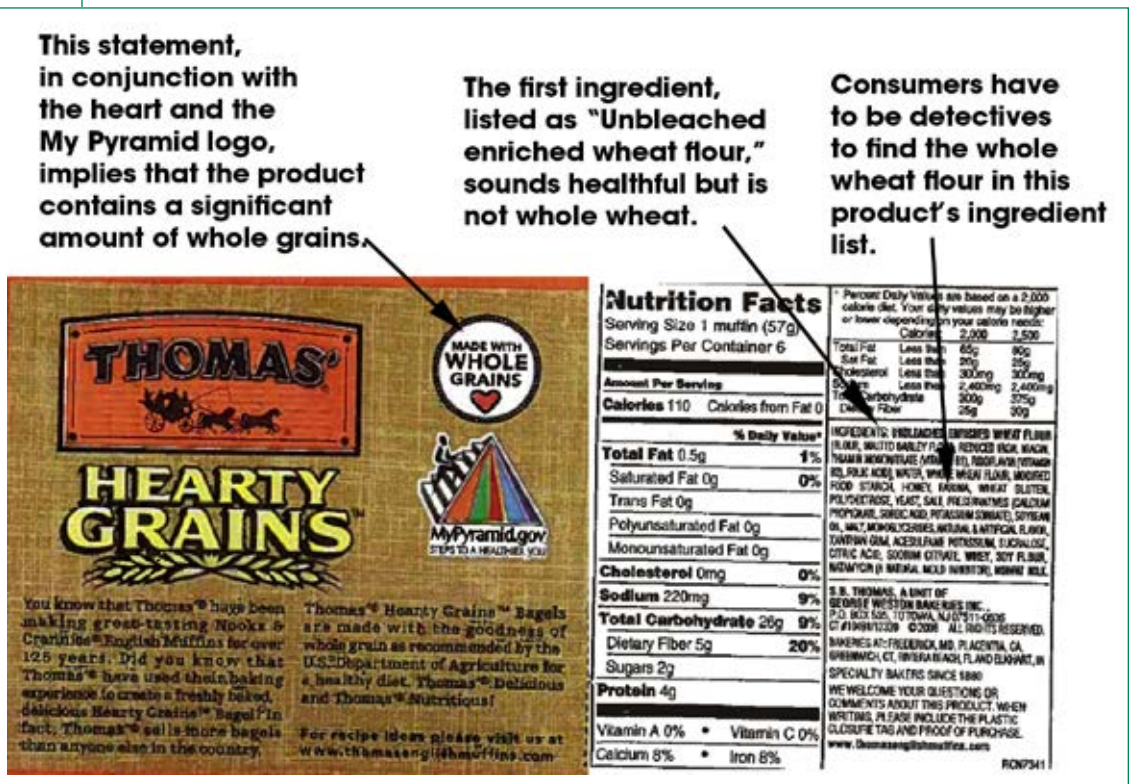
5 21 C.F.R. § 101.4.

6 Williams v. Gerber Products Co., 523 F.3d 934 (9th Cir. 2008). ("We do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield for liability for the deception.") *Id*. at 940.

7 *Dietary Guidelines for Americans*, *supra* note 1 at 36 ("Consuming at least half the recommended grains servings as whole grains is important for all ages, at each calorie level, to meet the fiber recommendation.")

eat grain foods ranging from bread to pizza, they should try to choose 100% whole grains or products in which at least 50% of the grain content consists of whole grains. Numerous manufacturers try to exploit consumers' interest in eating more whole grain by making claims that misleadingly imply that their products are rich in whole grains when they primarily consist of ordinary refined wheat flour.

For example, the label of Thomas' Hearty Grains English Muffins states "made with whole grains" and "made with the goodness of whole grain." The first (primary) ingredient, however, is "Unbleached enriched wheat flour." While that may sound healthful, it is not whole grain. Whole wheat flour is the third ingredient, indicating that the product contains relatively little. The name of the product, "Hearty Grains" and the dark brown color of the carton adds to the confusion.



Although the label says "made with whole grains," the primary ingredient is ordinary white flour. There is more water in the product than whole grain.

Another example is Keebler's Zesta Saltine Crackers, which proclaim "Made with Whole Wheat." Again, whole wheat flour appears as the third item—just before salt—in the ingredient list. Caramel coloring is used to darken the crackers and simulate the use of whole wheat flour. The label emphasizes the dark color of the crackers because consumers often associate darker-colored baked products with high whole wheat content.[8] The primary ingredient, however, is ordinary refined flour.

8 *See* FDA, USDA, Eating healthier and feeling better using the Nutrition Facts Label (Aug. 2006) ("Whole grain foods can't always be identified by color. . . .") *Id.*

Keebler's Town House Bistro "Multigrain" crackers (pictured on the following page) claim to be made with "hearty ingredients like toasted whole wheat" but are made primarily with ordinary refined wheat flour.

Regulatory and Legislative Status

Some companies have recognized the need for a new regulatory framework. General Mills petitioned the FDA in 2004 to develop definitions for "excellent source," "good source," and "made with" as descriptors for the whole grain content of foods.[9] The FDA denied the petition in 2005 on the basis that it needed to assess whether whole grain claims are implied nutrient content claims for fiber and whether such claims should be classified as dietary guidance, nutrient content claims, or health claims before it could reach a decision.[10]

In 2006, the FDA issued a draft guidance permitting companies to disclose whole grain content as the number of grams of whole grains per serving.[11] The agency said statements such as "10 grams of whole grains" are permissible "factual statements" provided that they are not misleading and do not imply that the food is high in whole grains.[12] FDA's draft guidance discourages companies from making some misleading claims, like "excellent source" of whole grain, but does not address problems such as "made with whole grain" claims that are misleading. Nor does it acknowledge that claims like "Contains 10 grams of whole grain" imply large amounts or high percentages of whole grains and are deceptive for products that contain significant amounts of refined grains.

The USDA's policy is also flawed. The USDA permits statements such as "made with whole wheat," so long as the

The label of Zesta saltine crackers proclaims "Made with Whole Wheat" on the front of the box, but the primary ingredient is ordinary flour.

9 Whole Grain Descriptive Claims Citizen Petition Submitted on Behalf of General Mills, Inc. (May 11, 2004) (Docket No. 2004P-0223/CP1).

10 Letter from Margaret O'K Glavin, Associate Comm'r for Regulatory Affairs, FDA to Stuart M. Pape, Patton Boggs, LLP Re Docket No. 2004P-0223/CP1 (Nov. 8, 2005).

11 FDA, *Draft Guidance: Whole Grain Label Statements, Guidance for Industry and FDA Staff* (Feb. 17, 2006), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059088.htm.

12 FDA cited 21 C.F.R. § 101.13(i)(3) which governs claims about nutrient content.

The label of Keebler's Town House Multigrain Crackers boasts on the side of the package that they are made with "toasted whole wheat," but the small print in the ingredient list indicates that the product contains more sugar than whole wheat.

product contains 8 g of whole wheat and does not specifically identify the component (e.g. crust, noodles, etc.) that is made with whole wheat. For example, a product such as a pot pie would be permitted to state "made with whole grain" even if the crust was primarily made from refined grains. Like the FDA, the USDA does not ac-

knowledge that such a claim may imply that the amount of whole grains as a percentage of total grains in the product is greater than may actually be the case. However, under USDA policy, if a product characterizes the grain in a component, for example, "made with whole grain pie crust,"[13] at least 51% of the grain component must be whole grain and the product must contain a significant amount (8 g) of whole grain as well."[14] Thus, under the USDA's approach, a chicken pot pie with a "whole grain crust" would need to consist of 51% whole grains (and contain a significant amount of whole grains per serving), while a vegetable pot pie under FDA jurisdiction could state the number of grams of whole grain per serving even if the percentage or amount of whole grains were small.[15]

The stamp on the left may be misleading because it does not indicate the percentage of whole grain in the product.

Federal policies that permit disclosures such as "10 grams of whole grain per serving" do not help consumers follow the Dietary Guidelines' advice to "make half your grains whole." That advice encourages consumers to eat a minimum *proportion* of their grains as whole grains. Without knowing how many grams of refined grain are in a food that claims to contain X grams of whole grain, consumers cannot determine whether half or more of the grains are whole.[16]

Disclosures such as "10 grams of whole grain" also make it difficult to compare foods because the total grain content of foods varies so widely. For example, 10 g of whole grain could be 60% of the grain in a slice of bread, but only about 33% of the grain in a breakfast cereal with a 30 g serving size or only about 18% of a 2 oz. serving of pasta. Even when consumers try to compare one cereal to another, they likely will have trouble sizing up a claim such as "10 grams of whole grain," because 10 g could comprise 33% of the grain in a breakfast cereal with a 30-gram serving size but just 18% of the grain in a breakfast cereal with a 57 g serving size.

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13 USDA, *Food Safety and Inspection Service, Statement of Interim Policy Guidance, Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grains Claims* (Oct. 17, 2005).

14 The USDA indicated that a significant amount of whole grain would be at least a .5 oz. equivalent of whole grain ingredient, i.e., at least 8 g of dry whole grain ingredient, but that is not the sole criterion for a claim. Whole grains must also comprise at least 51% of the grain content of the product.

15 The FDA and the USDA need to coordinate their policies to avoid absurd results. For example, a whole grain pizza crust would be required to be 100% whole grain under the FDA's *Guidance*, but only 51% of the grains would need to be whole for a pepperoni pizza with a whole grain crust that is regulated by the USDA.

16 The *Dietary Guidelines* also recommends that consumers eat at least 3 servings of whole grains a day. However, that advice was designed to give consumers a rule of thumb regarding the number of servings of whole grains that they should consume. It is less applicable than the advice to "make half your grains whole" because some people consume more – and others fewer – than 6 servings of grain a day. Urging people to consume at least 3 servings of whole grains could mislead people to assume that more is always better. In fact, encouraging people to consume more calories than they should from grains, whole or refined, could promote weight gain.

For foods that contain both whole and refined grains, consumers cannot figure out how the whole grain content compares to the refined grain content of the food, though the ingredient label provides some help. Without that information, people trying to consume more whole grains might unwittingly consume excess refined grain in a misguided effort to consume more whole grains.[17]

The Whole Grains Council has developed a "stamp" of approval for products that contain at least 8 g of whole grain and another for those that are 100% whole grain.[18] But the stamp for products that are less than 100% whole grain may be misleading because it does not indicate what percentage of the grain in a product is whole. Eight grams might imply that a product is rich in whole grains, but, as noted above, such a product might be only 18% whole grain. Any whole grain disclosure is misleading if it fails to also reveal the refined grain content of the food. The FDA should consider that an omission of material fact.

The stamp on the left of the previous page can also be misleading because the Whole Grains Council permits its logo to be used on products with considerable amounts of saturated or trans fat and sugar, such as cookies so long as the products contain 8 g of whole grain per labeled serving.[19]

In October 2009, The National Academy of Sciences Institute of Medicine released recommendations for school lunches that urged FDA to "take action to require labeling for the whole grain content of food products." The IOM explained that "[t]he lack of such labeling is a major barrier to menu planners who are striving to achieve a one-to-one ratio of whole grains to refined grains, as recommended by Dietary Guidelines."[20] The IOM recommended a "temporary criterion for whole-grain-rich foods."[21] One element of that criterion is that a serving of a food contain 8 g of whole

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17 The FDA's draft *Guidance* also fails to help people follow the *Dietary Guidelines*' advice to consume at least 3 servings of whole grains a day because the disclosures use grams rather than servings. There is no easy way to convert grams into servings because the amount of grain in a serving varies from food to food.

18 On Jan. 5, 2005, the Whole Grains Council introduced stamps including the words "good source" and "excellent source." Presentation by Cynthia Harriman, Dir. of Food and Nutrition Strategies Oldways & the Whole Grains Council at the Food and Drug Law Institute (Oct. 31, 2006).

19 Whole Grains Council, *Stamp FAQ* – Manufacturers *available at* http://www.wholegrainscouncil.com/node/31/print.

20 Virginia A. Stallings et. al., ed., IOM, *School Meals: Building Blocks for Healthy Children.* Recommendation 6, S-1. (2009).

21 IOM stated that at least *one* of the following conditions must be met:

- The whole grains per serving must be greater than or equal to 8 g;
- The product bears the FDA-approved health claim for whole grain: "Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol may help reduce the risk of heart disease." The FDA requires that such foods contain 51% whole grain by weight, but does not require that 51% of the of the grain in the product be whole. The two measurements are different.
- Products must list whole grains first in the ingredient list.

Id. at 7-13, 7-14.

grain. The Whole Grains Council portrayed that as tantamount to an endorsement of its program.[22]

But the IOM admitted that such a temporary criterion would likely result in a whole grain intake that is lower than that recommended by the Dietary Guidelines. IOM said it was not reasonable to set more stringent standards at this time for a variety of reasons, including the "limited information on product packaging regarding the whole grain content of food products."[23]

Recommendations

Presently, consumers have no effective way to determine whether a product can help them "make at least half of their grains whole" because labels do not disclose both whole grain and refined grain content. Ingredient lists are confusing and difficult to read—in many cases, the only way to determine that a product is primarily whole grain is if the label states "100% whole grain" or if the only grain ingredients are whole grains. But FDA regulations allow manufacturers to list ordinary flour, which is often the first ingredient in breads, crackers, muffins, etc., as "Enriched flour (wheat flour)." That declaration may sound very similar to some consumers as a declaration akin to whole wheat.

To prevent deceptive whole-grains claims:

- The FDA should withdraw the portions of its 2006 *Draft Guidance* document dealing with whole grain claims;
- The FDA and the USDA should propose regulations requiring that the amount of whole grain (as a percentage of total grain) be disclosed conspicuously at the top of the Nutrition Facts Panel;
- The FDA and the USDA should require that the percentage of whole grains be disclosed prominently in immediate conjunction with any statements mentioning whole grains on the front, back, or side labels of the product.
- Both agencies should issue a new industry guidance document clarifying that statements such as "8 g of whole wheat per serving" impermissibly imply that a product is rich in whole wheat and are misleading because they fail to disclose the percentage of grains that are whole.

B. *Misleading Ingredient Claims for Fruits and Vegetables*

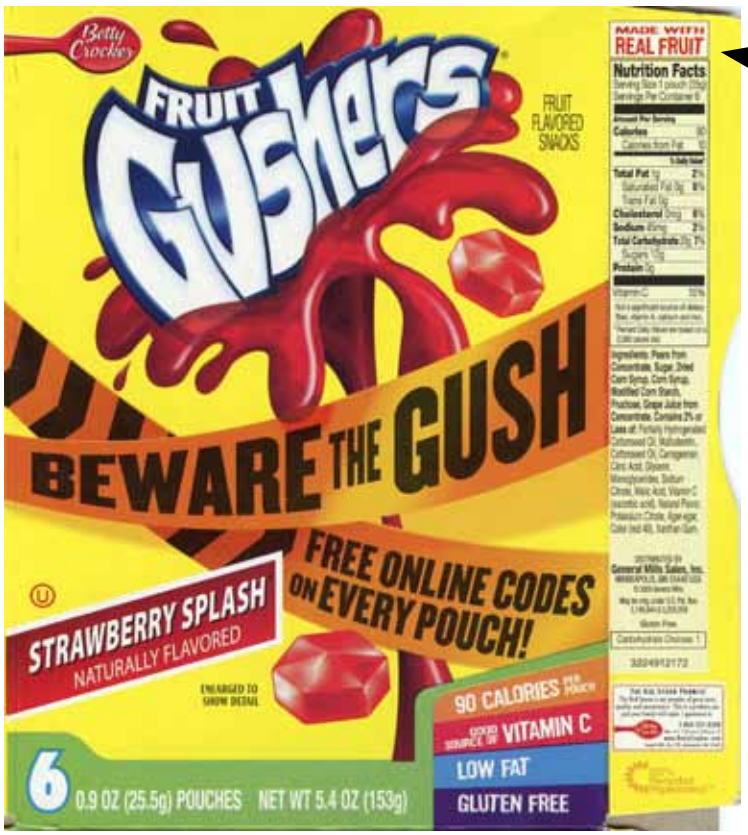
Similar to whole-grain deceptions, some food manufacturers exploit consumers' interest in eating more fruits and vegetables through the use of misleading statements and

22 *IOM Calls for Whole Grain Labeling,* The Gourmet Retailer, Oct. 30, 2009, *available at* http://www.gourmetretailer/content_display/news/elece59e59 (last visited Nov. 19, 2009).

23 *IOM Report, supra* note 20 at 10-18.

Food Labeling Chaos

Gerber Juice Treats Fruit Medley do not contain juice from most of the fruits pictured on the front and back of the package. But they are loaded with added sugars.



Betty Crocker "Strawberry" Fruit Gushers claim to be "Made with REAL FRUIT" but do not contain any strawberries. Rather, the ingredient panel lists pears from concentrate and lots of refined sugars from a variety of sources.

pictures on product labels. Some labels depicting healthful fruits and vegetables can create the misperception that the product contains more fruits and vegetables than is actually the case.

For example, the label of Gerber Juice Treats Fruit Medley for Preschoolers bears pictures of fresh oranges, raspberries, cherries, peaches, grapes, and pineapple. The product, however, contains no cherry, orange, or pineapple juice, and less than 2% raspberry and apple juice concentrates

The label of Knorr Chicken flavor Broccoli Fettuccini & Broccoli in a Chicken Flavored Sauce gives the impression that broccoli is a major ingredient. The product, however, has more salt than dried broccoli.

(although no apples are pictured) and peach juice — and is colored with annatto extract and elderberry juice to help create the impression of a greater abundance of actual fruit. The primary ingredients, listed in small print in capital letters, are corn syrup and sugar. The Dietary Guidelines for Americans considers juice concentrates to be a form of added sugars.[24] A single 1 oz. serving of the Juice Treats provides 17 g of added sugars (approximately 4 teaspoons), almost the maximum amount a 2-to-3-year-old preschooler should have in an entire day.

Similarly, Betty Crocker "Strawberry Splash Fruit Gushers" claim on the side label to be "Made with REAL FRUIT." The product however, contains no strawberries at all. The "REAL FRUIT" promoted on the side of the label turns out to be pears from concentrate. The product is almost half sugar containing 12 g of sugars per 25 g serving. In addition, the "strawberry" color comes from Red No. 40 dye.

Some manufacturers also misleadingly portray the amount of vegetables in their products. For instance, Knorr Chicken Broccoli fettuccini noodles contains more salt than

24 *Dietary Guidelines supra* note 1 at 38 Table 14. The *Dietary Guidelines* suggest that children 2-3 years old consuming a 1000-calorie diet have no more than 20 g (5 teaspoons) of added sugars. *Id.* at 55.

The front label of Snyder's of Hanover "Eat Smart Veggie Crisps" misleadingly portrays the product as a healthful potato chip. The back of the Veggie Crisps label promises that consumers of the product will "enjoy the simple goodness of garden fresh vegetables."

dried broccoli despite the fact that the term "broccoli" is highlighted in large letters on a prominent banner on the front label.

Snyder's of Hanover "Eat Smart Veggie Crisps" (pictured on the next page) is described on the front of the package as "A bountiful blend of potato, spinach and tomato chips." The product, however, contains more potassium chloride than spinach and practically none of the vitamins and minerals found in spinach or tomatoes.

Regulatory and Legislative Status

The FDA has the authority to halt deceptive fruit/vegetable labeling, including the authority to impose percentage-ingredient labeling for fruits, vegetables, and other key ingredients[25] for most foods—but it has failed to do so. The agency's "common or usual name" regulations require manufacturers to include the percentage of any characterizing ingredient or component when the proportion of that substance "has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case."[26] But few manufacturers follow that general principle, and the FDA—on its own accord—has only issued regulations to implement it in a few cases.[27]

In contrast, the European Union, Australia, New Zealand, and even Thailand have taken much broader measures. Those countries generally require the disclosure of the percentage of key ingredients contained in a particular food.

In the EU, such disclosures are referred to as Quantitative Ingredient Declarations (QUID).[28] The EU's 1997 directive requires QUID "where the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer."[29] For example, the amount of strawberries in "strawberry yogurt" and the amount of vegetables in "spring rolls" must be disclosed.[30]

The following examples illustrate the importance of such disclosures for consumers

25 Standardized foods such as cheese and flour must comply with FDA content regulations that specify the amount of required ingredients and set forth permissible optional ingredients. E.g., 21 C.F.R. §§ 133.102 137.105.

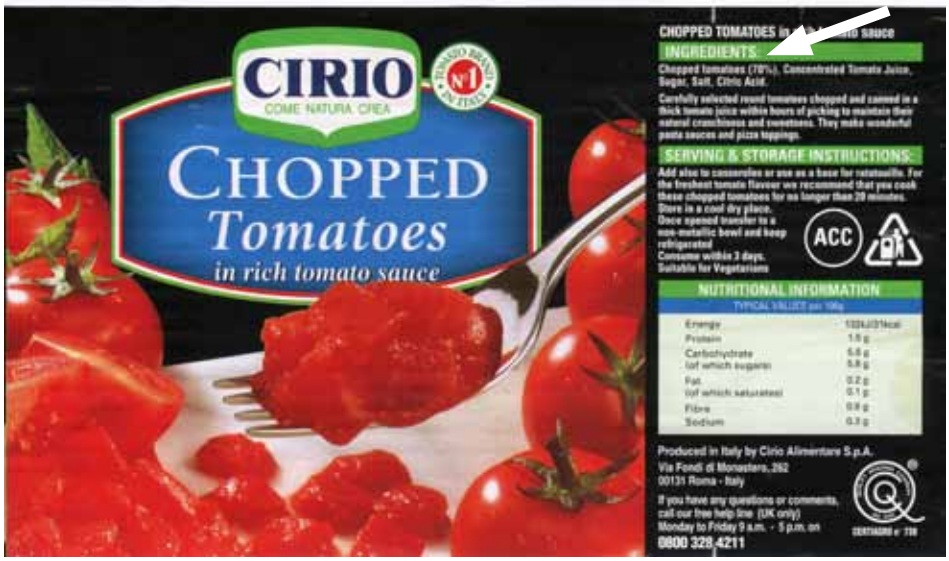
26 21 C.F.R. § 102.5.

27 The FDA requires that peanut spreads indicate the percentage of peanuts in the spread; olive oil blends indicate the percentage of olive oil; and seafood cocktail include the percentage of seafood ingredients present in the cocktail. 21C.F.R. §§ 102.23, 102.37 and 102.54.

28 *See* Directive 97/4/EC of the European Parliament and of the Council amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs, art. 1 (Jan. 27, 1997).

29 *Id.* at art. 7(2)(a).

30 Ministry of Agriculture, Fisheries and Food, *Draft Guidance Notes,* July 1997, United Kingdom, §§ 13 & 15. The guidance notes are for purposes of providing informal, non-statutory guidance on QUID and should not be taken as an authoritative statement or interpretation of the law.



Both products have tomatoes and water as the leading ingredients. An American consumer would have no way of knowing which product contains a higher percentage of tomatoes. In the EU, however, percentage-ingredient labeling reveals that the can of chopped tomatoes actually has more tomatoes (70%) than the can of whole peeled tomatoes (60%).

trying to increase their consumption of fruit, vegetables, and other healthful ingredients. The can of chopped tomatoes actually contains more tomatoes than the can of whole tomatoes. Consumers in the EU are provided that information while consumers of similar products in the US are kept in the dark.

The EU also requires QUID "where the ingredient or category of ingredients concerned is emphasized on the labeling in words, pictures or graphics."[31] For example,

UK consumers can determine that Kellogg's Nutri-Grain Morning Bars - Apple contain only 5% apples, but consumers of similar Kellogg products, like Nutri-Grain Twists - Strawberries (and Cremé), sold in the U.S. are left guessing about the actual amount of fruit (if any) in the product.

if a package like Gerber Juice Treats features pictures of raspberries on the label, the amount of that ingredient must be disclosed.

In the EU the quantity of an ingredient must be stated "where the ingredient or category of ingredients concerned is essential to characterize a foodstuff and to distinguish it

31 Directive 97/4/EC at Article 7(2)(b).

from products with which it might be confused because of its name or appearance."[32]

The EU directive requires that the percentages of key ingredients "shall appear either in or immediately next to the name under which the foodstuff is sold or in the list of ingredients in connection with the ingredient or category of ingredients in question."[33]

It should be emphasized that information about the percentage of valuable or characterizing ingredients is not provided by the Nutrition Facts Panel. That panel provides information on *nutrients*, such as calories, sodium, fats, vitamins, and mineral content, but in many cases only a trained dietitian could analyze that data to determine whether one product has substantially more fruits, vegetables, or other healthful ingredients than another. Furthermore, the ingredients panel lists ingredients in order of predominance, but the average consumer (and most nutritionists) cannot translate that order into percentages of ingredients. Thus, percentage-ingredient labeling is necessary to both prevent deception and help consumers choose more healthful foods.

Recommendations

- The FDA should require that the percent by weight of key ingredients that bear on health such as fruits or vegetables be disclosed on the principal display panel in conjunction with any claim or in parentheses after the listing of the relevant ingredient in the ingredient declaration.
- Products stating made with whole grains should disclose what percent of total grains are whole.
- "Key ingredients" should be considered to include those mentioned in the name of the food, or emphasized on the label by words, pictures, or graphics.
- The FDA should coordinate its policy with the USDA so as to include meat or poultry products, including stews and pot pies.

32 Directive 97/4/EC at Article 7(2)(c).

33 *Id.* at art. 7(5).

Part X: Controlling Misleading "Natural" Claims

The Problem

The United States market for "natural" foods grew by 10% to $12.9 billion from 2007 to 2008 and "All Natural" was the second-most-common claim on new food products launched in 2008.[1] Products claiming to be natural, particularly those aimed at parents of young children, have a competitive edge in the marketplace, according to recent trade reports.[2]

Some consumers may interpret claims such as "All Natural" or "100% Natural" as indicating a more nutritious or wholesome food product than is actually the case. Thus, while not an explicit health or nutrient-content claim, "natural" claims are worthy of attention by the FDA and the USDA as part of a comprehensive program to improve food labeling and protect consumers from deceptive marketers.

The FDA and the USDA regulate the term "natural" differently. The USDA has had a formal enforcement policy since 1982 and approves each label individually prior to marketing. Recently, it issued an Advance Notice of Proposed Rulemaking to clarify this complicated issue. The FDA has sent a number of warning letters to companies over the years, but has never issued formal rules on the matter and takes enforcement action only after the fact. Unfortunately, both agencies have allowed deceptive claims to remain in the marketplace.

A. FDA

For example, Hunt's, a division of ConAgra Foods, markets its tomato sauce as "100% Natural," despite the fact that it contains added citric acid.[3] As indicated by FDA warning letters, the agency does not consider added citric acid an appropriate ingredient for a food labeled as "All Natural."[4] Further, the product consists of reconstituted tomato paste, instead of whole tomatoes crushed soon after picking.[5]

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1 Monica Eng, *Organic v. natural a source of confusion in food labeling,* Chi. Trib. July 10, 2009, *available at* www.chicagotribune.com/health/chi-natural-foods-10-jul10,0,834771.story.

2 According to a recent trade report, *Marketing Kids' Healthy Beverages*: "Across all food categories, the message that a food or food component is naturally and intrinsically healthy is one of the most appealing to consumers . . . ." The report is available from New Nutrition Business at www.new--nutrition.com. Health conscious parents increasingly choose such products for their children. *See,* Mike Stones, *Big growth forecast for US children's healthy drinks market,* food navigator-usa.com (Sept. 24, 2009) quoting Julian Mellentin.

3 For the purposes of this Part, we presume that all added citric acid is factory made.

4 *See, e.g.,* Warning letter from Henry Fielden, Dist. Dir. Cinn., FDA to Karl A. Hirzel, Hirzel Canning Co. (Aug. 29, 2001). *See also infra* note 13.

5 The Council of Better Business Bureaus National Advertising Division (NAD) found that an earlier version of the claim shown above, "packed full of Hunt's 100% natural vine-ripened tomatoes," should be discontinued because consumers would reasonably take away the impression that the final tomato sauce was made directly from vine-ripened tomatoes, rather than pre-processed tomato puree (i.e., tomato paste and water) as is the case. NAD, Con Agra Foods Hunt's Tomato Sauce, Case No. 4945 (Dec. 8, 2008).

Part X-2

Food Labeling Chaos

The claim "packed full of premium vine-ripened tomatoes," in conjunction with the "100% Natural" claim on the front of the label is misleading because the product comes from concentrate.

Hunt's Tomato Sauce claims to be "100% natural" but contains added citric acid and is reconstituted.

This so-called "All Natural" product contains added citric acid.

Products containing added citric acid are not "All Natural" according to the FDA.

"All Natural" Snapple Tea includes citric acid and is not "natural" under FDA policy. The FDA sent a warning letter in 1992, but the owners of the company today appear to have ignored or are not aware of that warning. The letter stated "The term 'all natural' is false or misleading on products containing the added chemical preservatives, ascorbic acid, *or added citric acid*" (emphasis added).[6]

Some products containing high-fructose corn syrup also claim to be natural. High-fructose corn syrup is made through a complex chemical industrial process in which

6 Letter from Edward T. Warner, Dist. Dir. N.Y., FDA to Mr. Leonard March, Chairman of the Board Snapple Natural Beverage Co. (Mar. 9, 1992).

cornstarch molecules are chemically or enzymatically degraded to glucose and oligosaccharides, and then some of the glucose molecules are converted to fructose. Though glucose and fructose certainly occur in nature, the chemical conversions of cornstarch should not be considered natural.

Thus, Minute Maid "All Natural" Cranberry Apple Juice Cocktail is actually not all natural because it contains high-fructose corn syrup, as well as added citric acid.[7]

Minute Maid should not call its beverage all natural: it contains high-fructose corn syrup and added citric acid.

Some products should not be called natural because they are artificially colored. For example, Snapple's Kiwi Strawberry Juice Drink contains vegetable juice concentrate as a coloring agent. The FDA has concluded that the term natural may not be used if a product uses color additives of any type.[8] In this case, a consumer would reasonably assume that the color of the drink comes from its strawberry and kiwi ingredients, not added coloring. The drink also contains added citric acid, another violation of FDA policy.

Other products may not expressly state "All Natural," but imply that they are natural when they are not. Minute Maid Premium Original 100% Pure Squeezed Orange Juice, shown on the next page, boasts in large type on the side of the label that it has "natural orange goodness," "natural goodness," and is "naturally delicious." Only in small print on the front does the company admit that the juice is made "FROM CONCENTRATE."[9]

The product is called "All Natural" but it is colored with vegetable juice concentrate and contains citric acid.

7 *See infra* notes 12-22 and accompanying text for a discussion of the FDA's policy on whether foods containing high-fructose corn syrup can be labeled "All Natural."

8 For example, when beet juice is used to color pink lemonade, it is a color additive, and the product cannot be labeled as "all natural." 21 C.F.R. § 70.3(f).

9 Natural Claims can be implied less directly as well. Consumers, for example, may assume that a shelf of fresh fruit or vegetables in the produce section of the supermarket is all natural, but often the produce is coated with waxes to prevent moisture loss during shipment and storage. The FDA has previously recognized this issue, and requires disclosures, but the policy rarely appears to be enforced. 21 C.F.R. § 101.4 (b)(22); FDA, *Produce Safety, Safe Handling of Raw Produce and Fresh-Squeezed Fruit and Vegetable Juices* 11, *available at* http://www.fda.gov/food/resourcesfor you/consumers/ucm114299.htm (last visited Dec. 4, 2009).

Minute Maid Premium Original 100% Pure Squeezed Orange Juice discloses in small print on the front of the package that it is made "FROM CONCENTRATE" but loads the side label with claims of "natural goodness."

B. USDA

While the USDA has defined the term "natural,"[10] it has made case-by-case exceptions to its general policy resulting in various problems. For example, the use of the term "natural" on poultry products sometimes has been used in a misleading manner. Hormel's "Natural Choice 100% Natural Deli Turkey" lists the following ingredients: "turkey breast meat, water, salt, turbinado sugar, carageenan (from seaweed), baking soda, natural flavoring and lactic acid starter culture (not from milk)." That kind of highly processed product barely resembles the natural turkey that a consumer would cook and slice at home.

The USDA also permits other poultry and meat products to be labeled "100% Natural" or "All Natural" even if they contain added chicken or beef broth which can raise the water and sodium content of the product to decidedly unnatural levels. So-called "enhanced" poultry or beef products are flavored with a watery and usually salty marinade or injection and should not be considered "100% Natural." The added water content deceptively inflates the weight of the product and can lead consumers to pay a premium for water.[11] Further, the added sodium makes the product less healthful than truly natural poultry, because excess sodium increases blood pressure and the risk of heart attack or stroke.[12]

Some products, such as Tyson's 100% All Natural Chicken Wing Sections, contain up to 12% chicken broth, or, as the label states "up to 12% Natural Chicken Broth."

Safeway brand boneless/skinless chicken thighs and breasts have 330 mg of sodium per/100 g and Shady Brook Farms young turkey breast with broth contains 304 mg of sodium per 100 g. Both products contain up to 15% added broth.

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10 The USDA generally considers a product to be natural if: (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 C.F.R. § 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. FSIS, USDA, *Food Standards & Labeling Policy Book* (Aug. 2005).

11 Current USDA policy permits the net weight of poultry to include "solutions that are added to the meat or poultry, or into which the meat or poultry is placed for flavoring, seasoning and tenderizing. . . " Letter from Robert C. Post, Ph.D. Dir., Labeling and Consumer Protection Staff, USDA to Steven B. Steinborn, Hogan & Hartson LLP (Mar. 24, 2006).

12 USDA, HHS, *Dietary Guidelines for Americans 2005* at Ch. 8, *available at http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter8.htm.*

Although this product claims to be "100% Natural" and minimally processed, in fact, it contains ingredients, such as carrageenan (extracted from seaweed), baking soda, and lactic acid starter culture, not normally found in roast turkey prepared at home.

USDA permitted Tyson to label this product "100% All Natural" even though it contains up to 12% chicken broth which increases the sodium content of the food and inflates the net weight. Other brands have as much as 15% added broth.

Regulatory and Legislative Status

A. FDA

Although use of the term "natural" has been a hot topic since the 1970s, FDA has never issued a comprehensive definition of the term for processed foods. Its long-standing policy is that:

> [N]atural means that nothing artificial (including artificial flavors) or synthetic (including all color additives regardless of source) has been included in or has been added to a food that would not normally be expected to be in the food. Additionally, . . .we do not restrict the use of the term "natural" except on products that contain added color, synthetic substances and flavors as provided for in Title 21 of the Code of Federal Regulations (CFR), section 101.22.[13]

Over the years, the FDA has issued warning letters declaring that use of the term "all natural" is inappropriate if the product contains citric acid, calcium chloride, ascorbic acid, or potassium sorbate.[14] In addition, a 1940 letter from the FDA to a food producer indicates that at least at that time the term should not be used "for canned grapefruit juice subjected to the usual heat treatment." The agency stated that "this term should be reserved for fresh juice or juice which has been kept without intervention of any process of heat treatment."[15]

Over the years, the FDA has considered adopting a more comprehensive policy regarding the regulation of "natural" claims, but never moved forward:[16]

- In 1991, the FDA requested comments on how natural should be defined.[17]
- In 1993, the FDA concluded that "if the term 'natural' is adequately de-

13 Letter from Geraldine A. June, Supervisor Product Evaluation and Labeling Team, Food Labeling and Standards Staff, Office of Nutrition, Labeling and Dietary Supplements, FDA, to Audrae Erickson, President, Corn Refiners Ass'n (July 3, 2008).

14 E.g., Warning Letter to Hirzel Canning Co., *supra* note 3 (Chopped tomato products not natural because products contain calcium chloride and citric acid); Warning letter from Robert L. Hart, Acting Dist. Dir. N.Y., FDA to Richard Classey, Oak Tree Dairy Farm (Aug. 16, 2001) (Oaktree All Natural Lemonade misbranded because it contains potassium sorbate; All Natural Oaktree Real Brewed Ice Tea misbranded because it contains citric acid); Warning letter to Thomas E. Nieman, Federal Foods, Inc. from John Feldman, Dist. Dir. Minneapolis Dist. FDA (Aug. 12, 1994) (Cat food misbranded because ascorbic acid is not natural. Citric acid is a chemical preservative).

15 FDA, TC-142—March 7, 1940, *reprinted in* Kleinfeld, Dunn and Kaplan, *Federal Food, Drug and Cosmetic Act* 624 (1978).

16 In contrast, the government of Canada has developed a comprehensive policy on natural claims for both labelling and advertising. See Health Canada's Guide to Food Labelling and Advertising which offers numerous examples of processes that disqualify a food from making a "natural" claim. http://www.inspection.gc.ca/english/fssa/labeti/guide/ch4ae.shtml (last visited Dec. 9, 2009).

17 56 Fed. Reg. 60421, 60466-67 (Nov. 27, 1991).

fined, the ambiguity surrounding use of this term that results in misleading claims could be abated."[18] Nevertheless, because of the complexity of the issue, resource limitations, and other agency priorities, the FDA did not undertake a rulemaking at that time.[19]

- In 2004, the FDA rejected a petition asking the FDA to clarify the use of the term "100% Natural" because of concerns that manufacturers were using "big letters" to promote products as 100% natural when those products contained artificial partially hydrogenated oils associated with cardiovascular disease. In denying that petition, the FDA said that the petitioner did not provide any information that the FDA had not already reviewed in 1993.[20]
- "Natural" claims are not even an enforcement priority during establishment inspections.[21]

"FDA confused matters when it . . . stated that the agency would make determinations on a case-by-case basis, as opposed to adopting a consistent, uniform policy."

The FDA recently added confusion to the use of the term "natural" with respect to high-fructose corn syrup. In a 2008 letter to the Corn Refiners Association, the FDA stated that a product containing high-fructose corn syrup may be labeled natural when "none of the fixing agent (glutaraldehyde) would come in contact with the high dextrose equivalent corn starch hydrolysate."[22] But the FDA confused matters when it also stated that the agency would make determinations on a case-by-case basis, as opposed to adopting a consistent, uniform policy. The FDA said:

> Consistent with our policy on the use of the term "natural," we have stated in the past that the determination of whether an ingredient would qualify for use of the term "natural" is done on a case-by-case basis. Further, ingredients with the same common or usual name may be formulated in different ways, where a food containing the ingredient formulated one way may qualify for the use of the term "natural" and another food containing the ingredient with the same common or usual name, which has been formulated in a different way may not be eligible for the use of the term "natural."[23]

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18 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

19 *Id.*

20 Letter from Margaret O'K Glavin, Associate Comm'r for Regulatory Affairs, FDA to Antonio Zamora (Dec. 14, 2005).

21 Letter from John B. Foret, Dir. Div. of Compliance and Enforcement, Office of Nutritional Products, Labeling and Dietary Supplements, FDA to Michael F. Jacobson, Ph.D (regarding the use of the claim natural on the labels of Ben and Jerry products containing artificial flavorings and other man-made ingredients) (Sept. 19, 2002). Letter responded to a complaint filed by CSPI with FDA on July 30, 2002.

22 Letter to Corn Refiners Ass'n, *supra* note 12; Laura Crowley, *HFCS is natural, says FDA in a letter,* Foodnavigator-usa.com/content/view/print/144787.

23 *Id.*

B. USDA

Since 1982, the USDA, which regulates meat and poultry products, has limited "natural" labeling to those foods that contain no artificial ingredients and are minimally processed.[24] Recently, however, the USDA issued an Advance Notice of Proposed Rulemaking to assist the Department in defining the conditions under which it would permit meat and poultry products to be labeled as natural.[25] This latest action follows the submission of a petition by Hormel Foods on October 9, 2006, requesting that the Department institute rulemaking to establish a codified definition for natural. In particular, Hormel seeks a regulation that would prohibit exceptions for specific chemical preservatives and synthetic ingredients. A public hearing was held on the petition in December 2006.

In its ANPR, the USDA explained that:

> The comments indicated there is an overall lack of consensus on both the general or common understanding of what the claim "natural" means to the industry and to the public and on the approach that FSIS [Food Safety Inspection Service] should take to address issues associated with the use of "natural" on claims on the labels of meat and poultry products.[26]

Recommended Reforms

The FDA should:

- Issue a letter to industry summarizing the contents of past warning letters that had concerned the use of the word "natural" and state that the agency will be taking similar enforcement actions.
- Prohibit the use of the term "natural" on products that include high-fructose corn syrup, regardless of whether glutaraldehyde was used as the fixing agent.
- Restrict "natural" claims to foods that do not contain artificial ingredients and are minimally processed (and that are not deceptive for any other reason). The latter term, "minimally processed," is admittedly difficult to define, but the government needs to provide a uniform standard on which consumers can rely.

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24 USDA, FSIS, *Labeling Policy Memo 55* (1982), superseded by Food Standards Labeling Policy Book (Aug. 2005).

25 74 Fed. Reg. 46,951 (Sept. 14, 2009). The USDA should also address other controversies raised by terms such as "Naturally Raised." Defining such terms could help consumers choose meat and poultry products that were produced with animal welfare in mind. This issue, however, is beyond the scope of this report.

26 *Id.* at 46,952.

The USDA should:

- Finalize regulations under its recent Advance Notice of Proposed Rule-making concerning the term "natural." The Department should propose rules to prevent "natural" claims on poultry or beef that have been flavored by a watery and salty marinade or injections. In addition, the USDA should require much more prominent labeling of the added-water content of those products.
- Determine that high-fructose corn syrup is not a natural ingredient and that products containing it may not be labeled natural.

Part X-10

Food Labeling Chaos

Part XI: Compilation of Recommendations

Improving the Nutrition Facts Panel

- The declaration of calories per serving should appear in a larger font, on a contrasting background on the Nutrition Facts Panel. Instead of saying "Amount Per Serving," labels should state "Amount Per ½ Cup Serving."
- Little-used information, such as calories from fat and the NFP footnote allowing consumers to convert Daily Values based on a 2,000-calorie a day diet to a 2,500-calorie a day diet, should be eliminated to simplify the label and create additional space for more important information.
- Products that may reasonably be consumed by one person at a single eating occasion should be considered a single serving and their labels should disclose nutrition information for the entire package. Dual columns that also show nutrition information for the Reference Amount Customarily Consumed should be prohibited.
- The FDA and the USDA should update certain RACCs in light of current consumption data.
- A Daily Value should be established for added sugars, and the %DV and added sugar content per serving (in terms of teaspoons and grams) should be required on the Nutrition Facts Panel.
- The FDA should also clarify that the definition of fiber only includes intact fibers from whole grains, beans, vegetables, fruit, and other foods.
- The FDA should define "low sugar" and prohibit health claims for products that are not low in sugar, prohibit the use of the term "healthy" on such products, and restrict "fat free" and "low fat" claims on products that are not low in sugar.
- The USDA should adopt the same requirements for foods under its jurisdiction, including the disclosure of trans fats, and finalize its proposed rule requiring nutrition labeling on single-ingredient meat and poultry products.

Standardizing Front-of-Package Nutrition Labeling

- The FDA and the USDA should promptly take enforcement actions against manufacturers using misleading front-label nutrition symbols and propose regulations detailing nutrient criteria that must be met before such symbols are used on food packaging. Unlike the FDA's current criteria for "healthy," new criteria should include added sugars and for grain foods, a minimum whole grain requirement. That might entail the FDA's

adopting a Daily Value for added sugars, perhaps based on the Dietary Guidelines for Americans (Appendix A-3 in that publication.)

- The FDA should complete its consumer research program, in conjunction with related work being conducted by the Institute of Medicine, and identify the most effective front-of-pack nutrition labeling approach (including nutrient criteria, logo, font size, etc.) for empowering consumers to choose healthier foods.
- The FDA and the USDA should then propose regulations for a mandatory new labeling system.
- The FDA and the USDA should prohibit the use of competing front-of-label nutrition labeling schemes once the national system is implemented.

Making Ingredient Labels Easier to Read

- The FDA, in consultation with the USDA, should publish a Notice of Proposed Rulemaking in the *Federal Register* with the goal of modernizing the format of the ingredient list.
- Requirements for type size, style, spacing, and leading of ingredient lists should be established based on requirements set forth for the Nutrition Facts Panel.
- The use of all capital letters should be prohibited, and left justification should be required.
- Eight-point, non-condensed type should be the minimum for print size, except on small packages.
- Sugar sources in the product should be grouped together in the ingredient list so that consumers could readily identify the ingredients that add sugar, get a better sense as to the relative amount of sugar in the product, and not be fooled by healthy-sounding names, such as "fruit juice concentrate."
- Ingredient information should be set off in a box by use of hairlines and should be all black or one color type, printed on a white or other highly contrasting background.
- Once FDA regulations are issued, the USDA should approve only those labels that conform to the new requirements.

Disclosing Caffeine Content

- Caffeine content per serving should be prominently disclosed on food labels, such as on a separate line between the Nutrition Facts Panel and the ingredient list; above the top of the Nutrition Facts Panel where % juice content is declared; or in large, clear type on products (such as cans

of coffee) that lack nutrition panels and ingredient lists.

- The terms "guarana" and "yerba maté" (and any other ingredients that are used as a source of caffeine) should be followed by "(a source of caffeine)" in the ingredient list.
- The FDA should require foods containing more than a specified level of caffeine to carry the FDA's advice for pregnant women: "Pregnant women should avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly."

Stopping Misleading Structure/Function Claims

The FDA Should Take Enforcement Actions Against Specific Deceptively Labeled Products

Dishonest structure/function claims mislead consumers with regard to serious health matters and threaten the integrity of the food label and public confidence in food manufacturers and the FDA. Section 403(a)(1) of the Food, Drug, and Cosmetic Act states that "a food shall be deemed to be misbranded if its labeling is false or misleading in any particular." Section 201(n) provides for the disclosure of material facts in light of representations made on the label. Section 701(a) gives the FDA the "authority to promulgate regulations for the efficient enforcement of [the FDCA] …" All of those provisions provide the FDA with ample authority to act.

The FDA Should Issue an Industry-Wide Letter Clarifying the Substantiation Standard for Structure/Function Claims for Foods

The last "Dear Manufacturer" letter the FDA issued on food labeling (in January 2007,[1]) included a cursory discussion of structure/function claims, but failed to specify a substantiation standard for such claims; it simply noted that such claims must be truthful and not misleading. The FDA's failure to specify a substantiation standard has effectively granted food manufacturers carte blanche for structure/function claims.

The FDA Should Require Structure/Function Claims for Foods to Meet the Same Standard as Health Claims

Both the FDA and food industry studies demonstrate that consumers do not differentiate between structure/function claims and health claims on food labels. To prevent deception, the FDA should, therefore, subject structure/function claims to the same evidentiary standard used for health claims. That standard is "significant scientific agreement." Such steps are consistent with

1 Dear Manufacturer Letter Regarding Food Labeling (Jan. 30, 2007), http://www.cfsan.fda.gov/~dms/flguid.html. (last visited June 5, 2009).

the First Amendment's commercial free-speech doctrine, which accords no protection to misleading commercial claims.

The FDA Should Not Apply Its Substantiation Standards for Dietary Supplements to Structure/Function Claims for Conventional Foods

The FDA stated in both its Guidance for substantiating structure/function claims for dietary supplements and the *Federal Register* notice announcing its availability that the *Guidance* "does not extend to substantiation issues that may exist in other sections of the Act." Thus the FDA's *Guidance* does not – and, for the reasons explained in this report should not – apply to structure/function claims for foods.

The extension of the FDA's structure/function claims substantiation policy for supplements to conventional foods would merely accelerate the spread of the dishonesty that has plagued the dietary supplement industry to the much larger food industry.

The FDA Should Issue a Safe Harbor List of Structure/Function Claims

The FDA should facilitate industry compliance with our recommended regulatory approach by establishing a "safe harbor" of permissible claims.

Prohibiting Qualified Health Claims for Foods

The FDA Should:

- Release its second consumer research study on whether the disclaimers in qualified health claims for conventional foods protect consumers from being misled, and, hence, whether the agency is under any legal obligation under the First Amendment (and the *Pearson* case on dietary supplements) to authorize them.
- Delete language relating to conventional foods from the Bush Administration's January 2009 "midnight" guidance document and specify that, until a court or Congress says otherwise, companies are prohibited from making qualified health claims on conventional foods that do not meet the significant scientific agreement standard.
- Delete language relating to conventional foods from its 2003 Advance Notice of Proposed Rulemaking and specify that conventional foods not meeting the significant scientific agreement standard are prohibited from making qualified health claims.

Halting Misleading 0 g Trans Fat Claims

The FDA Should:

- Review its enforcement policy and promptly issue an industry-wide warning letter stating that products that emphasize "0 trans fat" on the front panel when such foods contain per serving more than 5% of the DV for saturated fat (i.e., are not "low" in saturated fat) and cholesterol are in violation of the law. Simultaneously, the agency should send warning letters to manufacturers of products that are making "0 g trans fat" claims on products that are not low in saturated fat.
- Propose rules setting forth conditions for making nutrient content (and health) claims for products low in trans fats that are based on existing rules for claims for products that are "low saturated fat." Such rules should ban "0" or "no" or "low" trans fat claims (and health claims), unless a serving of the food is also low in saturated fat and cholesterol.
- Revoke the Generally Recognized as Safe status of partially hydrogenated oils, as requested in the 2004 petition submitted by CSPI. Partially hydrogenated oils are unnecessary, as evidenced by the industry's gradual abandonment of them in favor of less-harmful oils. Eliminating the use of partially hydrogenated oil would mitigate the need for all of the activities in which the FDA is currently engaged regarding the labeling of trans fat.

Stopping Misleading Ingredient Claims

- The FDA should require that the percent by weight of key ingredients that bear on health, such as fruits or vegetables, be disclosed on the principal display panel in conjunction with any claim or in parentheses after the listing of the relevant ingredient in the ingredient declaration.
- Products stating "made with whole grains" should disclose what percentage of total grains are whole.
- "Key ingredients" should be considered to include those mentioned in the name of the food, or emphasized on the label by words, pictures, or graphics.
- The FDA should coordinate its policy with the USDA so as to include meat or poultry products, including stews and pot pies.

Controlling Misleading "Natural" Claims

The FDA should:

- Issue a letter to industry summarizing the contents of past Warning Letters that addressed the use of the word "natural" and state that the agency

will be taking similar enforcement actions.

- Prohibit the use of the term "natural" on products that include high-fructose corn syrup, regardless of whether glutaraldehyde was used as the fixing agent.
- Restrict "natural" claims to foods that do not contain artificial ingredients and are minimally processed (and that are not deceptive for any other reason). The latter term, "minimally processed," is admittedly difficult to define, but the government needs to provide a uniform standard on which consumers can rely.

The USDA should:

- Finalize regulations under its recent Advance Notice of Proposed Rule-making concerning the term "natural." The Department should propose rules to prevent "natural" claims on poultry or beef that has been flavored by a watery and salty marinade or injections. In addition, the USDA should require much more prominent labeling of the added-water content of those products.
- Determine that high-fructose corn syrup is not a natural ingredient and that products containing it may not be labeled natural.

CENTER FOR
Science IN THE
Public Interest

From: s22
To: s22
Subject: RE: Lyme MC [SEC=UNCLASSIFIED]
Date: Tuesday, 17 May 2016 9:40:00 AM

Thanks s22

Regards
s22

From: s22
Sent: Tuesday, 17 May 2016 9:28 AM
To: s22
Subject: Lyme MC [SEC=UNCLASSIFIED]

Hi s22 – thought you may interested in reading the following from a "for information only' ministerial that was sent to Min Ley:

Cheers
s22

MC16-021306

For Info – 20 Days – [SL] – [OHP]
Pls link to MC16-014465, MC16-011469, MC16-011469, MC16-010316, MC16-004512.

From: Minister Ley
Sent: Friday, 13 May 2016 3:21 PM
To: Health Referrals
Subject: For Info: Demand a retraction of defamatory remarks [SEC=UNCLASSIFIED]

From: s22 [mailto:s22@comcast.net]
Sent: Thursday, 12 May 2016 2:08 AM
To: s22 @cdc.gov
Cc: s22 @cdc.gov; s22 @cdc.gov; s22 @cdc.gov
Subject: Re: Demand a retraction of defamatory remarks [SEC=No Protective Marking]

May 11, 2016

National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027
Attn: s22, MD, MPH, s22

Dear Dr s22

I am in receipt of Dr Sin Lee's second letter addressed to you on May 1, 2016 and have posted his letter to the Change.org site.
https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-

cdc-idsa-and-aldf/u/16542176

As a Lyme disease patient, I would like to know more of the research project which you approved and whose purpose was "to evaluate the accuracy of a new diagnostic test for Lyme disease, utilizing nested PCR and DNA sequencing", as stated in Dr. Lee's second letter to you. It is encouraging indeed to learn that the CDC actually had agreed to help initiate a PCR-based test for Lyme and related borreliosis for early diagnosis. I would be glad to publish in this forum any correspondence between the CDC and Dr. Lee on this matter because there seems to be a public health issue here; the public has a right to know.

1. I would gladly post a retraction of your remarks as Dr Lee demands;

2. You are welcome to point out the "inconsistent results" of Dr Lee's publication.

3. Have an open debate to justify the CDC's position to not consider Dr Lee's proposal of instituting a national proficiency test program to survey the competencies of all diagnostic laboratories testing for Borrelia burgdorferi, B miyamotoi, B mayonii and other strains of pathogenic borreliae in human patients.

Infections by B miyamotoi and B mayonii cannot be diagnosed by the current two-tiered serology tests so we can no longer maintain the status quo of a dysfunctional system by suppressing innovations.

Sincerely,

s22
Hudson, NH

Dr Lee's letter to the CDC:

Dr s22
s22

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)
s22 @cdc.gov

cc: s22 @comcast.net May 1, 2016
Re: Demand a retraction of defamatory remarks

Dear Dr s22

In an open email correspondence dated March 13, 2016 https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/15826757, I requested that you point out the "*inconsistent results*" you allegedly found in a peer-reviewed publication in which the authors reported DNA sequencing-based evidence of a novel relapsing fever borrelia strain detected in a CDC-supplied archived serum sample originally collected from a patient who had been treated for neurologic Lyme disease [1]. Since you have not answered my email, I must assume that you cannot substantiate your base-less and disparaging allegation. As the lead author of the above referenced publication, I demand that you publish a retraction and openly apologize for having made such defamatory remarks to smear the reputation of the authors of the

publication.

As the s22 of the CDC NCEZID, you approved a research project, the purpose of which was "to evaluate the accuracy of a new diagnostic test for Lyme disease, utilizing nested PCR and DNA sequencing" under CDC Material Transfer Agreements No. NCEZID-R137154-00 and No. NCEZID-R147284-00, listing me, Sin Hang Lee, MD as the Investigator. I submitted two reports dated September 4, 2013 and November 21, 2013, respectively to the NCEZID, stating in both reports the following conclusion:

"Since Lyme disease-related borrelioses are now known to be caused by Borreliae other than Borrelia burgdorferi sensu stricto, PCR primers designed to amplify the 16S ribosomal RNA gene DNA of various members of the Borrelia burgdorferi sensu lato complex and Borreliae of the relapsing fever group are also used in this testing protocol. Molecular diagnosis of a Borrelia requires a 100% ID match of the nested PCR amplicon with the standard 16S ribosomal RNA gene DNA in the region selected for DNA sequence alignment analysis."

Using the same protocol for testing patient materials, another novel Lyme disease borrelia has been detected and reported in an article entitled "Lyme disease caused by *Borrelia burgdorferi* with two homeologous 16S rRNA genes: a case report"
https://www.dovepress.com/lyme-disease-caused-by-borrelia-burgdorferi-with-two-homeologous-16s-r-peer-reviewed-article-IMCRJ

These published results indicate that there are as yet unrecognized borrelia strains causing "Lyme disease" in the United States. Based on information available in the public domain, Lyme and related borreliosis in the U.S. can be caused by *Borrelia burgdorferi* sensu stricto, *B miyamotoi*, *B mayonii* and at least two unnamed borrelia strains reported from my laboratory, one of which has a GenBank Seq ID KM052618.

I understand you might try to discredit other innovative technologies which are in competition to the invention being patented by s22 and s22 of the NCEZID under Pub. No. WO 2013110026 A1 entitled "Compositions and methods relating to Lyme disease". However, as the director of the NCEZID, you also need to not ignore the scientific and technical advances made since the first description of Lyme disease in the mid-1970s before the DNA sequencing and PCR technologies were invented in the best interest of Lyme disease patients. Based on the conclusion of the project studies I reported to the CDC NCEZID in 2013, you knew or should have known that genus-specific PCR amplifications can detect all known strains, including *Borrelia burgdorferi* sensu stricto, *B miyamotoi*, and *B mayonii* and probably many unknown strains of pathogenic borreliae in human patients. I implore you to immediately implement a national proficiency test program to survey the competencies of all diagnostic laboratories offering Lyme disease testing in this country for their ability in detecting these microbes in simulated blind-coded samples, as routinely performed for all infectious agents by the College of American Pathologists, to stimulate innovative development of the diagnostic tools for reliable diagnosis of all Lyme-related borrelial infections at the early stage of the disease for timely appropriate treatment to prevent tissue damage and "chronic Lyme disease" whose existence we can no longer deny.

I am looking forward to reading your response.

Sincerely,

Sin Hang Lee, MD
Director
Milford Molecular Diagnostics laboratory
Shlee01@snet.net

Reference

[1] Lee SH, Vigliotti JS, Vigliotti VS, Jones W, Shearer DM. Detection of Borreliae in Archived Sera from Patients with Clinically Suspect Lyme Disease. Inter J Mol Sci. 2014; 15:4284-4298.

s22
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Zoonoses, Foodborne and Emerging Infectious Diseases
s22

BMC Research Notes

SHORT REPORT Open Access

Early Lyme disease with spirochetemia - diagnosed by DNA sequencing

Sin Hang Lee[1*], Veronica S Vigliotti[1†], Jessica S Vigliotti[1†], William Jones[1†], Jessie Williams[2†], Jay Walshon[2†]

Abstract

Background: A sensitive and analytically specific nucleic acid amplification test (NAAT) is valuable in confirming the diagnosis of early Lyme disease at the stage of spirochetemia.

Findings: Venous blood drawn from patients with clinical presentations of Lyme disease was tested for the standard 2-tier screen and Western Blot serology assay for Lyme disease, and also by a nested polymerase chain reaction (PCR) for *B. burgdorferi* sensu lato 16S ribosomal DNA. The PCR amplicon was sequenced for *B. burgdorferi* genomic DNA validation. A total of 130 patients visiting emergency room (ER) or Walk-in clinic (WALKIN), and 333 patients referred through the private physicians' offices were studied. While 5.4% of the ER/WALKIN patients showed DNA evidence of spirochetemia, none (0%) of the patients referred from private physicians' offices were DNA-positive. In contrast, while 8.4% of the patients referred from private physicians' offices were positive for the 2-tier Lyme serology assay, only 1.5% of the ER/WALKIN patients were positive for this antibody test. The 2-tier serology assay missed 85.7% of the cases of early Lyme disease with spirochetemia. The latter diagnosis was confirmed by DNA sequencing.

Conclusion: Nested PCR followed by automated DNA sequencing is a valuable supplement to the standard 2-tier antibody assay in the diagnosis of early Lyme disease with spirochetemia. The best time to test for Lyme spirochetemia is when the patients living in the Lyme disease endemic areas develop unexplained symptoms or clinical manifestations that are consistent with Lyme disease early in the course of their illness.

Background

Lyme disease is a tick-borne human infection which is an imperative differential diagnosis for internal medicine physicians offering primary care to ambulatory patients in the endemic counties of the United States. Hematogenous dissemination of the *Borrelia burgdorferi* spirochetes from the initial skin site of a tick bite is believed to cause secondary skin lesions and extracutaneous manifestations in Lyme disease [1]. Borrelia spirochetemia, when validated, provides reliable objective evidence for the diagnosis of early Lyme disease, based on which timely appropriate treatment is instituted to avoid tissue damage and to prevent the infection from going into chronic phase. However, *B. burgdorferi* spirochetemia is transient, and the culture techniques which require at least 9 mL of plasma sample and may take several weeks to recover [2] are not practical as a routine diagnostic tool. Pathogenic *Borrelia burgdorferi* cells are known to exist in non-dividing or slowly dividing forms which may not generate a visible positive growth in artificial media at all [3]. The diagnosis of early Lyme disease has been a challenging task for the primary contact physicians practicing in the endemic areas [4].

The polymerase chain reaction (PCR) technologies for the study of the most conserved genospecies-specific *Borrelia burgdorferi* sensu lato16S ribosomal RNA gene, or 16S rDNA, have been used in epidemiology research [5,6]. Using a pair of specific TEC1 and LD2 primers for PCR, the chances of non-specific amplification of 16S rDNA derived from spirochetes unrelated to Lyme disease are minimized [7]. However, little attempt has been made to transfer this procedure into clinical laboratory practice because the method is not robust enough for routine diagnostic applications. We have recently refined this research tool with a nested PCR technology for DNA

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Full list of author information is available at the end of the article

detection, followed by automated direct DNA sequencing for validation of the genospecies-specific *B. burgdorferi* sensu lato 16S rDNA in patient body fluids to further augment the sensitivity and specificity of the procedure as a clinical laboratory test [8]. Since the base sequence of the PCR-amplified spirochete DNA in this procedure is routinely validated by online sequence alignment algorithms with the GenBank database with a 100% identities match with an exclusive unique sequence for the molecular diagnosis to be established, there are no false positive results due to molecular misidentification. The nested PCR technology has increased the sensitivity of the commonly used one-round PCR NAAT for Lyme spirochete DNA by 100-1000 fold [8]. This report summarizes our experience in using this routine clinical laboratory test for molecular diagnosis of *B. burgdorferi* spirochetemia in an endemic suburban town during a summer season.

Methods

From May 1 to November 30, 2009, 463 paired samples of EDTA-anticoagulated venous blood and venous blood without additives from patients suspected of having Lyme disease were received by the Milford Hospital-affiliated Milford Medical Laboratory to be tested for Lyme disease.

Of these 463 pairs of blood samples, 130 were collected on the order of the physicians working in the hospital emergency room (ER) and walk-in clinic (WALKIN) because clinical manifestations of the patients were suggestive of Lyme disease with or without the history of a recent tick bite. Milford is a suburban town in Connecticut in which Lyme disease is endemic.

Milford Hospital is a community hospital. Its ER and WALKIN have about 40,000 patient visits a year. The local residents and practicing physicians are aware that Lyme borreliosis should always be a differential diagnosis during the months from spring to fall when a patient presents with a recent onset of fatigue, skin rash, fever, muscle aches, neck pain, joint pains or lymphadenopathy, without a clear etiology. These symptoms and signs which may vary from patient to patient are recognized as common clinical presentations in early Lyme disease in the United States [9].

The remaining 333 pairs of blood samples were from patients referred by their primary care private physicians in the area for possible Lyme disease.

The 130 ER/WALKIN patients had an age range between 14 and 84 years old with a median age of 42. In comparison, the 333 patients referred from the private physicians' offices had an age range between 11 and 89 with a median age of 51.

For every pair of the blood samples received, the plasma was separated from the EDTA-blood for nested PCR/DNA sequencing for the detection of *B. burgdorferi* 16S rDNA, which was performed at the Milford Medical Laboratory, a clinical laboratory approved by the Department of Public Health, State of Connecticut, under the Clinical Laboratory Improvement Act of 1988 to perform high-complexity laboratory testing, including PCR and DNA sequencing for the molecular identification of *Borrelia burgdorferi*. The latter methodology was published elsewhere [8]. Briefly, a 100 μL aliquot of the patient plasma was mixed with 200 μL 0.7 M ammonium hydroxide in a 1.5 mL Eppendorf tube for DNA extraction. The mixture was heated at 95-98°C for 5 min with closed cap, followed by 10 min with open cap. After the tube was cooled to room temperature, 700 μL of 95% ethanol and 30 μL of 3 M sodium acetate were added to the mixture. The mixture was centrifuged at 13,000 rpm (~16,000 *g*) for 5 min and the supernatant discarded. The precipitate was re-suspended in 1 mL of cold 70% ethanol. Then the suspension was centrifuged at 13,000 rpm for 5 min. After all liquid was discarded, the pellet was air-dried and re-suspended in 100 μL TE buffer with heating at 95-98°C for 5 min. The heated suspension was finally centrifuged at 13,000 rpm for 5 min. One μL of the supernatant was used for primary PCR to be followed by nested PCR amplification without further purification, using a ready-to-use HiFi® DNA polymerase LoTemp® PCR mix (HiFi DNA Tech, LLC, Trumbull, CT) in a total volume of 25 μL. A trace of the primary PCR products without purification was transferred by a micro glass rod to another 25 μL LoTemp® PCR mix containing a pair of heminested (nested) primers for nested PCR amplification.

The primary PCR primers used were nucleotides LD1 (5'-ATGCACACTTGGTGTTAACTA) and LD2 (5'-GAC TTATCACCGGCAGTCTTA) [5]. The nested PCR primers were nucleotides TEC1 (5'-CTGGGGAGTATGC TCGCA AGA) [7] and LD2 [5]. The thermocycling steps were programmed to 30-cycles at 85°C for 30 seconds, 50° C for 30 seconds, and 65°C for 1 minute after an initial heating for 10 minutes at 85°C, with a final extension at 65°C for 10 minutes for both primary and nested PCR in a TC-412 Thermal Cycler (Techne Incorporated, Burlington, NJ). All positive nested PCR products showing a band of expected target size on gel electrophoresis were subjected to direct automated DNA sequencing, using TEC1 nucleotide as the sequencing primer.

The serum sample was submitted for Lyme disease antibody screen by the 2-tier immunoglobulin M (IgM) and immunoglobulin G (IgG) enzyme-linked immunosorbent assay (ELISA) and Western Blot for the detection of antibodies against sonicated whole-cell *B. burgdorferi* by Quest Diagnostics Incorporated, Wallingford, CT, a recognized commercial reference clinical laboratory, according to the CDC guidelines [10].

Publication of general analytical data extracted from hospital records with concealed patient identities was

approved by the Milford Hospital Institutional Review Board.

Results

As previously reported, nested PCR amplification of the conserved segment of *B. burgdorferi* sensu lato 16S rDNA for signature sequence analysis generated a 293 base-pair (bp) amplicon with the TEC1 and LD2 primers. After confirming a 100% identities match with a unique specific DNA sequence for *B. burgdorferi* sensu lato 16S rDNA stored in the GenBank database using the online Basic Local Alignment Search Tool (BLAST), the molecular identification of the nested PCR product as a genomic DNA of *B. burgdorferi* was established beyond a reasonable doubt. BLAST analysis of a 50-60 bp sequence downstream of the LD2 primer-binding site was more than adequate to achieve a very low E-value, which indicates that the chance of molecular misidentification is infinitesimal. A segment of the electropherogram containing the signature nucleotide sequence (Figure 1) was incorporated in the laboratory report for completion of an evidence-based molecular diagnosis of Lyme borrelia spirochetemia.

Our experience confirmed that PCR is not a specific tool for DNA identification, especially for the diagnosis of Lyme disease. From this series of 436 patients, 3 plasma samples were found to contain non-target DNA which led to generation of PCR products of a molecular size similar, but not identical, to that of the *B. burgdorferi* 16S rDNA. These non-Lyme disease DNA molecules were amplified by the PCR primer pair designed for *B. burgdorferi* DNA replication. However, in the absence of a fully matched *B. burgdorferi* target DNA template, these unintended and non-target DNA molecules were amplified by the partially matched primers during the highly sensitive nested PCR process. One of such non-target PCR amplicons was only 6-bp shorter than the expected 293-bp *B. burgdorferi* 16S rDNA fragment, as observed on gel electrophoresis (Figure 2). Only DNA sequencing could confirm that it was really a 287-bp 16S rDNA fragment of an environmental bacterium (Figure 3). As indicated in the GenBank database, the primer binding sites selected for PCR amplification of the most conserved 16S ribosomal RNA gene of the genospecies of *Borrelia burgdorferi* sensu lato also bear great similarities in DNA sequence with the 16S ribosomal RNA genes of other bacterial species (Figure 4).

There was an obvious difference in the test results between the 333 blood sample pairs from the patients referred to the laboratory by the individual private

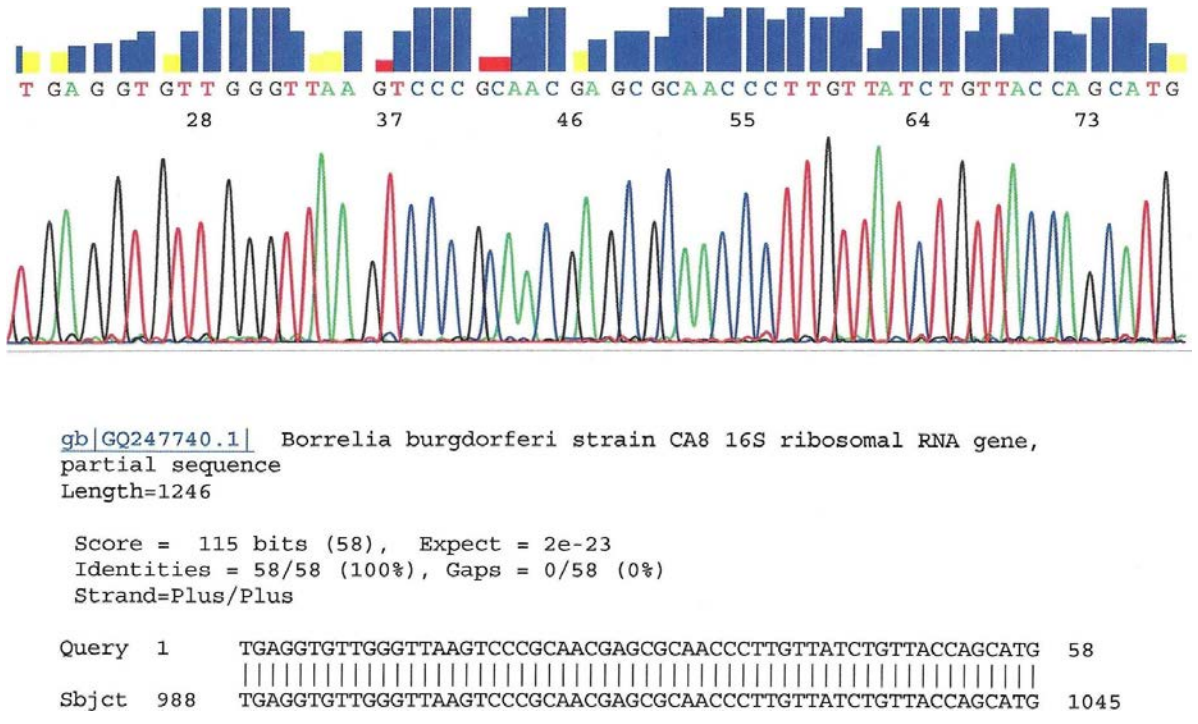

Figure 1 DNA sequencing of *Borrelia burgdorferi* 16S rDNA detected in the plasma of a spirochetemic patient. This 58-base sequence was excised from an electropherogram generated by an ABI 3130 genetic analyzer. The template was the nested PCR amplicon generated by the TEC1 and LD2 primers. The sequencing primer was TEC1. BLAST alignment analysis validates the molecular diagnosis of hematogenous dissemination of Lyme disease in this patient. ABI, Applied Biosystems, Foster City, CA.

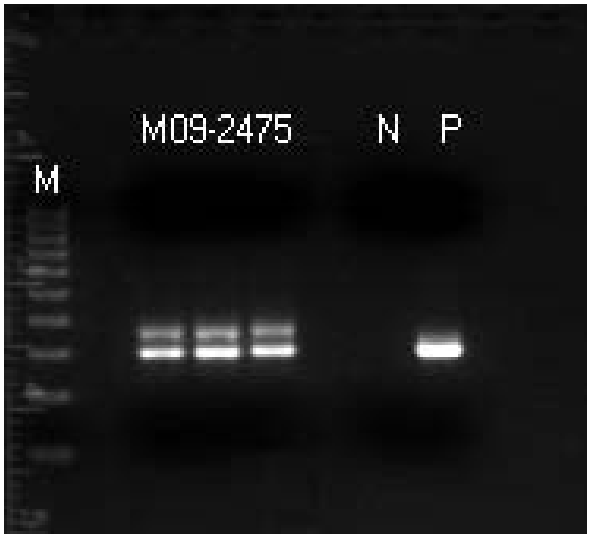

Figure 2 Gel electrophoresis of nested PCR products of DNA from the plasma of a patient suspicious of Lyme disease (M09-2475). The sample was amplified by the TEC1 and LD2 primers and one major band had the molecular weight indistinguishable from the *B. burgdorferi* DNA control. P = *B. burgdorferi* 16S rDNA nested PCR amplicon control; molecular size 293 base pairs. M09-2475 = Nested PCR products of questionable DNA isolated from a patient's plasma. The nested PCR was performed in triplicate to ensure technical accuracy. M = Molecular ruler. N = Negative control to rule out reagent contamination.

practitioners and the 130 blood ample pairs from the patients seen by the physicians at the ER and WALKIN. Of the blood samples from the former group of 333 patients, 28 (28/333), namely 8.4%, were found to be positive for the 2-tier IgM and IgG ELISA screen and further confirmed by Western Blot for the detection of antibodies against sonicated whole-cell *B. burgdorferi*. But all of the 333 companion plasma samples in this group were negative for *B. burgdorferi* nested PCR NAAT, indicating that there was no evidence of spirochetemia in these patients (Table 1).

Of the blood sample pairs collected from the 130 patients visiting the ER and WALKIN, 2 (2/130), namely 1.5%, were found to be positive for the 2-tier Lyme disease serology test, and 7 (7/130), namely 5.4%, were found to contain *B. burgdorferi* 16S rDNA. Of the 2 patients in this group, whose serum was positive for the 2-tier antibody test for Lyme disease, 1 was also found to have circulating *B. burgdorferi* DNA in the companion plasma. The other sero-positive patient did not have evidence of *B. burgdorferi* spirochetemia when the 2-tier Lyme disease antibody test became positive. In other words, among the 7 ER/WALKIN patients presenting with spirochetemia, 6 had *B. burgdorferi* DNA in their blood without the characteristic antibodies while 1 patient had both *B. burgdorferi* DNA and the characteristic Lyme disease antibodies in the blood (Table 2).

At the spirochetemic stage, 3 of the 7 patients had skin rashes. Two of the 3 skin lesions presented with a "bull's eye" appearance, considered typical of Lyme disease, and 1 was described as "hives". Most of the spirochetemic patients (5/7) stated that the duration of their chief complaint symptoms and signs lasted for about 24 hours before they decided to seek immediate medical attention. Two (2/7) of the patients had multiple joint pains or headaches for about 3 weeks before visiting the ER/WALKIN after noticing an additional chest pain or a

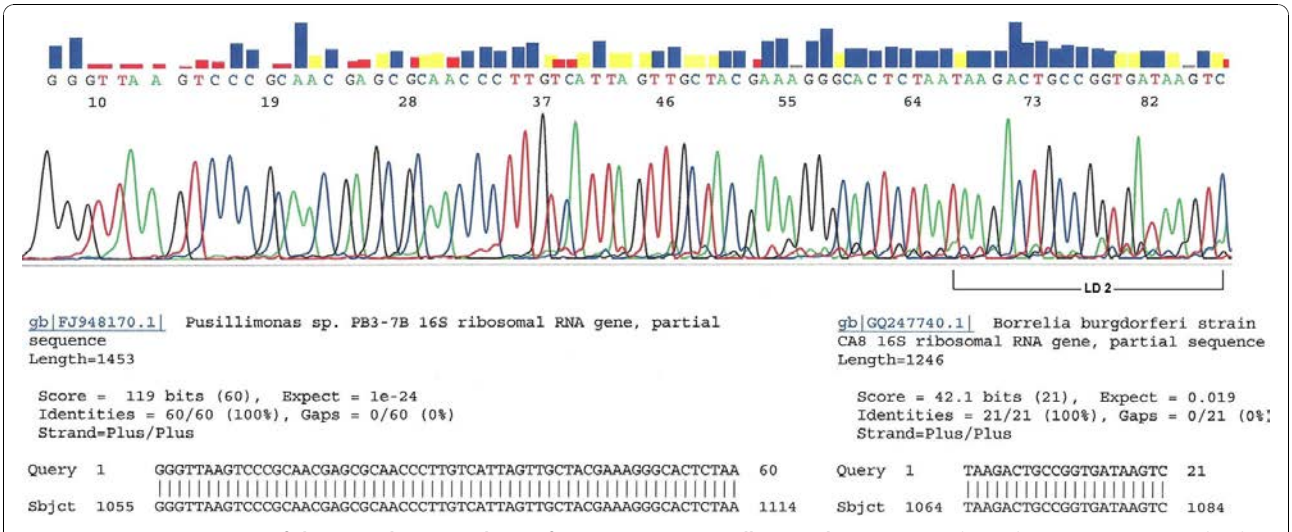

Figure 3 DNA sequencing of the nested PCR products of case M09-2475, as illustrated in Figure 2. The 21-base LD2 PCR primer-binding site for *B. burgdorferi* is marked on the right. A 60-base sequence on the left is validated to be that of a *Pusillimonas* 16S rDNA based on GenBank database. This is a typical example of environmental bacterial 16S rDNA in patient's blood masquerading as *B. burgdorferi* 16S rDNA.

Alignment of the DNA sequences of the two PCR primer binding sites with 10 adjoining bases of *B. burgdorferi* sensu lato 16S rDNA **(a)** against those of an environmental bacterium **(b)** (see Figure 3)

(a) ctggggagtatgctcgcaagagtgaaactcaX------gggactcagataagactgccggtgataagtc

(b) ctggggagtacggtcgcaagattaaaactcaX000000ggcactctaatgagactgccggtgacaaacc

Figure 4 Two partial DNA sequences retrieved from the National Center for Biotechnology Information database. **(a)** GenBank Locus GQ247740, a 293-base long signature sequence for *B. burgdorferi* 16S rDNA. TEC1 (left) and LD2 (right) PCR primer sites underlined. **(b)** GenBank Locus FJ948170, a 287-base long sequence of 16S rDNA for numerous environmental bacteria. TEC1 and LD2 primer sites underlined. Note 6 mismatched bases printed in red bold face. X——————— = 231 bases in a sequence specific and unique for *B. burgdorferi* 16S rDNA. X = 225 bases in a sequence nonspecific for environmental bacterial 16S rDNA. 000000 = 6 slots with no nucleotide bases. In the absence of a fully matched *B. burgdorferi* DNA, the PCR primers may bind to a partially matched non-target bacterial DNA templates which are not infrequently present in normal human blood. Only DNA sequencing can distinguish the 287 base-pair PCR amplicon of a common environmental bacterial 16S rDNA from a 293-base *B. burgdorferi* 16S rDNA.

skin rash. At the time of the initial visit, none of the spirochetemic patients registered a fever. On 4 patients for whom a CBC was ordered, 3 (3/4) showed slight leukocytosis with an increased percentage of neutrophils. One patient who had a concomitant chronic liver disease showed evidence of leukopenia. None of the 7 spirochetemic patients recalled a history of recent tick bites. As stated above, only one of the 7 spirochetemic patients (1/7) was found to be positive for the 2-tier serology test at the time of the initial visit. Follow-up information obtained from the primary care physicians of the patients confirmed that all presenting clinical symptoms and signs ascribed to Lyme borreliosis resolved completely after treatment with oral doxycycline, without recurrences in the ensuing 6-11 months. Only one of the 6 spirochetemic patients who were serologically negative at the initial visit was re-tested for possible rising antibody titers of Lyme disease, and the serology re-testing result was also negative. The major relevant clinical findings of the 7 spriochetemic patients were summarized in Table 3.

Discussion

Accurate diagnosis of early Lyme disease plays a pivotal role in "curing" the infection with appropriate antibiotic treatment, and in preventing the infection from going into chronic phase which may cause debilitating tissue damage. However, the clinical manifestations of early Lyme disease are highly variable and often not easily distinguished from those caused by other illnesses. The commonly used 2-tier serology laboratory test which usually only turns positive during convalescence of the infection is reported to be negative or non-diagnostic in 75% of the "clinically confirmed" cases of early Lyme disease [4]. Testing for *B. burgdorferi* spirochetemia has been suggested to be the laboratory approach to diagnose early Lyme disease at the stage of hematogenous dissemination of the bacteria, which is believed to

Table 1 Comparison of nested PCR and 2-tier serology in detection of Lyme disease among 333 patients referred by private practitioners from offices

	Two-tier Serology		Total
	+	-	
Nested PCR +	0	0	0
Nested PCR -	28	305	333
Total	28	305	333

+ = positive.

- = negative.

Laboratory detection of Lyme disease among 333 patients referred from private offices:

Confirmed case prevalence = 28/333 = 8.4% (2-tier serology only).

Sensitivity of nested PCR = 0% (0/28).

Sensitivity of 2-tier seropositivity = 100% (28/28).

Table 2 Comparison of nested PCR and 2-tier serology in detection of Lyme disease among 130 patients visiting emergency room and walk-in clinic

	Two-tier Serology		Total
	+	-	
Nested PCR +	1	6	7
Nested PCR -	1	122	123
Total	2	128	130

+ = positive.

- = negative.

Laboratory detection of Lyme disease among 130 ER/walkin patients:

Confirmed case prevalence = (7+1)/130 = 8/130 = 6.2% (DNA sequencing or 2-tier serology).

Sensitivity of nested PCR = 87.5% (7/8).

Sensitivity of 2-tier seropositivity = 25% (2/8).

Table 3 Clinical summary of 7 early Lyme disease patients with spirochetemia

Age/Sex	Chief Complaint	Duration	Temp °F	CBC Results?	Hx Tick Bite?	Skin Lesion?	Serology	Follow up Serology
1) 43/M	Hives; Thoracic Spine Pain	24 hr	98.0	Not Done	NO	YES	ELISA = +, WB IgM = +	NONE
2) 39/F	Bilateral Leg Pain, Headache	24 hr	98.1	7.2 WBC; Elev Neut%	NO	NO	ELISA = - WB = -	NONE
3) 15/F	Shoulder Pain; Bilateral Leg Pain	24 hr	96.8	4.8 WBC; Elev Neut%	NO	NO	ELISA = -	ELISA = - 2 wks later
4) 43/M	Bull's eye rash	24 hr	98.3	Not Done	NO	YES	ELISA = -, WB = -	NONE
5) 22/M	Painful Inguinal Lymphadenopathy	24 hr	98.6	Not Done	NO	NO	ELISA = -, WB = -	NONE
6) 52/M	Multiple Joint Pain/Chest Pain	3 weeks/72 hr	97.7	10.8 WBC; Elev Neut%	NO	NO	ELISA = -	NONE
7) 55/F	Headache, Bull's eye rash	? 3 weeks	98.5	3.5 WBC; Decreased Neut%	NO	YES	ELISA = -	NONE

precede the appearance of the diagnostic antibodies [1,2,4]. However, the traditional microbiology blood culture techniques are not practical for the diagnosis of Lyme disease because it takes several weeks to recover a positive growth of the Lyme spirochetes in the liquid media. Attempts to culture *B. burgdorferi* spirochetes from patients' blood as a diagnostic tool have largely resulted in disappointments [11]. Non-dividing or slowly dividing *Borrelia burgdorferi* cells which do not generate a discernible positive culture in artificial liquid media are known to cause infections in animals [3]. The other alternative to detect this fastidious infectious agent in a patient's blood is to test for its genetic fingerprint materials, namely by a NAAT.

Several PCR-based nucleic acid amplification tests have been used for the detection of *B. burgdorferi* DNA in the blood samples of patients suffering from Lyme disease. However, their sensitivity is generally too low to be useful for clinical application [12-15] in part due to a lack of consistency of the *Borrelia burgdorferi* genetic materials targeted for PCR amplification by these methods. The lack of rigorous validation of the PCR products has also caused false positive results which can lead to inappropriate treatment with potentially serious complications [16,17]. Adoption of a NAAT procedure for the diagnosis of Lyme disease must proceed with caution.

Since all bacteria contain a 16S ribosomal RNA gene, or 16S rDNA, which differs from one another in their respective unique hypervariable regions, three oligonucleotide PCR primers, known as LD1, LD2 [5,6], and TEC1 [7], have been introduced to amplify a highly conserved region of the *B. burgdorferi* sensu lato 16S rDNA for its molecular fingerprint identification. In combination with the nested PCR and direct automated DNA sequencing technologies, these genospecies-specific PCR primers are useful in generating reliable materials for sequence alignment analysis using the online GenBank database as the standard for validation of the *B. burgdorferi* sensu lato 16S rDNA [8]. The potential value of their clinical application in confirmation of early Lyme disease spirochetemia has been demonstrated by the results presented in this report.

One potential pitfall in targeting a highly conserved bacterial16S rDNA of the genospecies of *B. burgdorferi* sensu lato for molecular diagnosis of Lyme borrelia spirochetemia is that some environmental bacterial 16S rDNA fragments, which may be present in normal human blood samples [18,19], can be amplified by the chosen PCR primers, especially when the nested PCR technology is employed to increase the detection sensitivity (Figures 2, 3, 4). This kind of potential false positive result generated by a non-specific PCR can be eliminated by routine direct DNA sequencing of all putative PCR-positive materials with their signature sequences validated through online GenBank sequence alignment algorithms (Figure 1).

In one residential suburb where Lyme disease is endemic, we found that 5.4% of the ER/WALKIN patients presenting with Lyme disease-like clinical manifestations were shown to have *B. burgdorferi* spirochetemia while none (0%) of the patients referred to the laboratory from their private doctors' offices with the same differential diagnosis had evidence of spirochetemia when tested by the same procedure. In comparison, only 1.5% of the ER/WALKIN patients in the same group were positive for the 2-tier antibody serology test for Lyme disease while 8.4% of the patients referred from the private doctors' offices were positive for the 2-tier serology test. These findings seem to indicate that the best time for detecting spirochetemia in early Lyme disease is when the onset of the clinical manifestations is noticed by the patient. Such immediate medical attention is probably only available at the ER or WALKIN in most endemic regions. Waiting for a scheduled appointment to the regular private doctor's office may miss the window of opportunity in DNA detection at the time when the Lyme disease bacteria are circulating in the blood, but only briefly.

In our series, 6 of the 7 (85.7%) PCR-detected, DNA sequencing-confirmed Lyme spirochetemic patients did not develop the 2-tier Lyme disease antibodies at the time of initial laboratory testing. Since these patients were all suspected of suffering from Lyme borreliosis based on clinical manifestations alone, they were prescribed a short course of preventive doxycycline while waiting for the laboratory test results. The antibiotics would be discontinued when the 2-tier serology screen test and the PCR test results were both found to be negative. All ER/WALKIN patients were referred back to their regular primary care physicians for follow up, and most private healthcare practitioners did not order additional serology tests for these patients. Therefore, it is not known if these 6 sero-negative, proven spirochetemic patients would turn sero-positive for the 2-tier serology test during their long-term convalescence. If no further follow-up serology tests were ordered, or if the subsequent 2-tier antibody tests turned out to be negative as a result of the initial partial treatment [20,21], these 6 Lyme disease patients would have been classified as having "no evidence of Lyme disease", except for the DNA evidence of Lyme spirochetemia. These clinical observations emphasize the importance of public education in the diagnosis of Lyme borrelial spirochetemia. Early Lyme disease is essentially a patient-initiated laboratory diagnosis under the guidance of an alert physician. The patients generally control the window of

opportunity for the detection of spirochetemia which is transient and brief. The time points of spirochetemia may vary from patient to patient.

Conclusion

We found DNA evidence of *B. burgdorferi* spirochetemia in 7 of 130 (5.4%) ER/WALKIN patients with clinical manifestations of early Lyme disease. During the same period, we found no DNA evidence of spirochetemia in 333 patients who were referred from private physicians' offices for Lyme disease tests. In comparison, 28 of the 333 (8.7%) patients from the private physicians' offices were positive for the 2-tier Lyme disease antibody test whereas only 2 of the 130 (1.5%) ER/WALKIN patients were positive for the 2-tier serology test. Only 1 of the ER/WALKIN patients was positive both for the *B. burgdorferi* DNA and for the 2-tier antibody test at the same time. Based on these findings, we conclude that molecular testing for detection of *B. burgdorferi* spirochetemia should be a supplement to the standard 2-tier serology assay for all ER/WALKIN patients with clinical manifestations of early Lyme disease. Relying on a serology test alone may miss the diagnosis of 85.7% of the early Lyme disease, which can be confirmed by a blood NAAT for spirochetemia.

Abbreviations

TEMP: temperature; CBC: complete blood count; WBC: white blood count; ELEV NEUT: elevated neutrophils; Hx: history; ELISA: Enzyme-linked immunosorbent assay; WB: Western Blot; +: positive; -: negative

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Authors' contributions

SHL conceived of the study, participated in its design and coordination and helped draft the manuscript. VSV, JSV and WJ participated in study conception, data acquisition, and laboratory data analyses. JW and JW participated in study conception, design, and clinical evaluation of patients. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Is HPV Vaccine Safety an Illusion Maintained by Suppression of Science?

By Norma Erickson

Breaking News: On January 14, 2016, Dr. Sin Hang Lee sent an open letter of complaint to the Director General of the World Health Organization, Dr. Margaret Chan, charging members of GACVS, the CDC, the Japanese Ministry of Health, Labor and Welfare, and others with manipulation of data and suppression of science in order to maintain the illusion of HPV vaccine safety in the face of valid contradictory evidence.

According to Dr. Lee's letter, a series of emails recently uncovered via a Freedom of Information request submitted in New Zealand revealed evidence that Dr. Robert Pless, chairperson of the Global Advisory Committee on Vaccine Safety (GACVS), Dr. Nabae Koji of the Ministry of Health of Japan, Dr. Melinda Wharton of the CDC, Dr. Helen Petousis-Harris of Auckland University, New Zealand, and others (including WHO officials) may have been actively involved in a scheme to deliberately mislead the Japanese Expert Inquiry on human papillomavirus (HPV) vaccine safety before, during and after the February 26, 2014 public hearing in Tokyo.

The complaint letter states that the emails provided clearly demonstrate this group of WHO officials and government employees charged with the responsibility of advising the expert committee from the Japanese government on HPV vaccination safety knew before the February 26, 2014 Tokyo public hearing that one of their own experts showed scientific evidence that HPV vaccination does increase cytokines, including tumor necrosis factor (TNF), particularly at the injection site compared to other vaccines. Yet, they chose to suppress this information at the public hearing.

Of course, this piece of scientific data which was known to all members of the group is also missing from the GACVS Statement on the safety of HPV vaccination issued on March 12, 2014. Unfortunately for medical consumers, this is the same GACVS statement currently being used to assure health officials, political decision makers and medical professionals around the world there is nothing to worry about when it comes to the safety of HPV vaccines.

Dr. Lee concluded his letter of complaint by clearly stating that there is at least one known mechanism of action explaining why serious adverse reactions occur more often in people injected with HPV vaccines than other vaccines, and why certain predisposed individuals may suffer a sudden unexplained death as a result. It appears this is part of the information the 'experts' deemed necessary to suppress.

Dr. Lee states:

> *Those whose names appear in my complaint and any who blindly dismiss valid safety concerns in order to continue promoting HPV vaccinations should be held accountable for their actions. There is no excuse for intentionally ignoring scientific evidence. There is no excuse for misleading global vaccination policy makers at the expense of public health interests. There is no excuse for such a blatant violation of the public trust.*

Note: Read Dr. Lee's letter of complaint here.

Attachments to letter:

- GACVS Terms of Reference
- GACVS Statement on the continued safety of HPV vaccination on March 12, 2014
- WHO GACVS emails from February 18, 2014 to February 27, 2014 in chronological order
- Original FOIA – Attachment obtained in New Zealand – available upon request

Read this article in Spanish here.

The Case Reports of Adverse Reactions to HPV Vaccines
Ignored by the Government

Dr. Sin Hang Lee presents 13 references on serious adverse reactions after HPV vaccination, either as a full article or as published abstract of a full article, after an incomplete search of the medical literature. Most health care providers who reported these cases are concerned about damage to the central nervous system with papilledema and transient loss of vision being a common finding. A group of physicians in Connecticut, including a neuropathologist who reviewed the brain biopsy of a young girl stated in the report [5]:

We report the case of a 16-year-old girl who suffered an acute and sustained onset of bilateral visual loss and transient left hemiparesis following an immunization against human papilloma virus, who was found to have both a tumefactive demyelinating lesion and chiasmal neuritis as part of a presentation of acute demyelinating encephalomyelitis.

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Vaccine Injury Compensation Program: Fatality after Gardasil

By Norma Erickson

Gardasil®-related fatal myocardial infarction in a teenage boy - case filed in United States Court of Federal Claims Office of Special Masters.

Gomez versus USDOH: Petition No. 15-0160V[1] filed by the Roberts Law Firm of Newport Beach, California for petitioners Adan Gomez and Raquel Ayon, on behalf of their deceased son Joel Gomez, states:

> *Joel Gomez received a Merck Gardasil vaccine on June 19, 2013 and again on August 19, 2013, and died in his sleep the following day on August 20, 2013. The death was caused in fact by receiving the Gardasil Vaccine.*

This statement is reinforced by a supportive Expert Report written by Sin Hang Lee, MD, stating:

> *Gardasil® did cause or contributed to a myocardial infarction in the decedent, and that the second dose of Gardasil® finally caused a fatal hypotension in this case on the day of vaccination. There was no other plausible cause for the death of Joel Gomez at the night of August 19, 2013.*

The record shows that Joel Gomez, the decedent, a 14-year old healthy boy who had regular visits to the pediatrician's office for periodic check-ups since birth showed no evidence of any pre-existing health issues, specifically no evidence of cardiac abnormalities, psychological disorders or substance abuse. The teenager had been training for the high school football team from four to five hours a day for the two months prior to his death without incident.

On June 19, 2013, the boy was given the first dose of Gardasil® in his left arm in the doctor's office. No adverse reactions were reported following this first vaccination by the boy to either his family or his physician. On August 19, 2013 the boy was given a second injection of Gardasil® as scheduled in the doctor's office. Then he went home and went to sleep. The boy was found to be unresponsive in bed the following morning on August 20, 2013 at 7:00 a.m. by his family.

Paramedics were called in and the boy was transported to the hospital where he was pronounced dead at 9:07 a.m. on August 20, 2013.

An autopsy was performed on August 23, 2013 by a medical examiner (ME) of Los Angeles, California.

The autopsy report stated significant abnormal findings to include:

> *...a long narrow band of dark reddish discoloration which is somewhat darker than the rest of the myocardium, extends over a length of 6 cm and has a width of 0.4 cm extending from the anterior base of the heart almost to the apex. ..this lesion is limited to the anterior free wall. Both lungs are extremely heavy. The lung parenchyma is dark-purple-red and completely soaked with edema fluid and blood. Microscopically, a localized lesion was found in the left ventricle of the heart.*

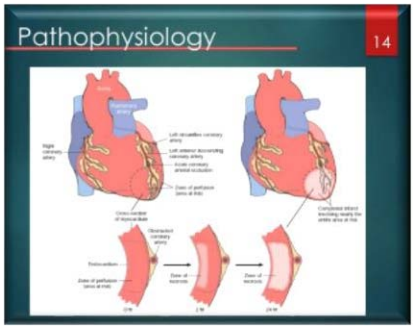
In the medical examiner's opinion:

> *The Decedent died of myocarditis, which apparently was completely asymptomatic. By histology, the disease had been present for at least several days or weeks. The cause is unknown.*

Dr. Lee reviewed the microscopic slides and concluded that the lesion of the heart was a healing myocardial infarct of a few weeks old after the first Gardasil® vaccination. In his opinion,

> *The HPV L1 gene DNA fragments bound to the aluminum adjuvant in Gardasil® can cause sudden and unexpected surge of tumor necrosis factor-α and other cytokines. Some of these cytokines released from macrophages are potent myocardial depressants, capable of causing hypotension with low cardiac perfusions in certain genetically or physically predisposed individuals.*

Why is this case significant?



This was an obviously healthy, athletic young boy under the care of a pediatrician since birth. The myocardial infarction occurred between two injections of Gardasil as described in the medical examiner's report. According to Dr. Lee, a healing infarct at the age of 14 is practically unheard of. In fact, Dr. Lee pointed out that the heart in this case presents a textbook description of myocardial infarction commonly observed in much older patients with a history of heart attack(s). The only factor in this boy's life that changed was his Gardasil vaccinations.

According to the petition filed:

> *Petitioners contend that Joel suffered from Myocarditis which was caused in fact by the Gardasil vaccine. Petitioners contend that the logical sequence of cause and effect show that the vaccination was the reason for the death. Further supportive of the causal relationship is established by looking to the proximate temporal relationship between the vaccination and the death. The fact that Joel was a healthy 14 year old boy with no health problems is strong circumstantial evidence that the death was caused in fact by the Gardasil vaccine.*

This means there is no way of knowing how many Gardasil-vaccinated girls (or boys) have developed permanent myocardial damage, whether one calls it myocarditis or infarct, either is a silent heart pathology. Is silent heart pathology no harm if the patient did not die?

In a telephone interview with Dr. Lee about the significance of this case for parents and medical professionals, Dr. Lee said:

> ***Teenagers vaccinated with Gardasil® should stay away from competitive sports such as football for at least two months, and should have an electrocardiogram to rule out silent myocardial infarction if there is any incidence of syncope, chest discomfort, tachycardia or hypotension within two months after Gardasil® vaccination.***

References:

1. Petition No. 15-0160V available upon request – please email admin@sanevax.org or sanevax@gmail.com

From: TGA Info
To: ADR Reports
Subject: FW: Research Guidance [SEC=UNCLASSIFIED]
Date: Monday, 9 May 2016 4:57:34 PM

Good afternoon

Please find attached an email for your follow up and response - if your area is not the appropriate area to respond to this email please let us know.

If you are responding directly to an external enquiry, you are responsible for ensuring that the TGA customer service standards are met.

Please ensure that any internal correspondence is deleted prior to sending the response.

If your area does not have access to a generic email address, the RAS can send approved responses on your behalf from info@tga.gov.au, provided there is sufficient time for the service standards to be met.

Yours sincerely

Regulatory Assistance Section
Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: s22 [mailto:s22@hotmail.com]
Sent: Monday, 9 May 2016 10:38 AM
To: TGA Info
Subject: FW: Research Guidance

Hello,

NHMRC recommended I send this request to your department.

I look forward to hearing from you,

Kind Regards,

s22

From: s22
To: nhmrc@nhmrc.gov.au
Subject: Research Guidance
Date: Tue, 3 May 2016 16:48:52 +1000

Hello,

My name is s22 and I act on behalf of s22 and s22 .

s22 and s22 had a daughter, s22 , who passed away at s22 s22

s22 had the Gardasil vaccination at school as do thousands of Australian girls. s22 s22

s22

They have done some research and there appear to be a few cases around the world where the drug Gardasil may have caused a negative reaction in some girls.

s22 parents did find a doctor in the USA , Dr Sin Hang Lee, who had established a test to prove whether Gardasil was present in post mortem tumours of possible victims.

According to s22 parents Dr Lee was suddenly restricted to light duties and possible taken to court. I have contacted him yesterday and he said he and I quote

"To detect HPV DNA in non -B conformation in human tissues is a big research project. Unfortunately I cannot do it anymore.
This is a global problem.
I am not aware of any scientist who is working on this subject"

I smell a rat. I believe Dr Lee has been silenced by the company that distributes Gardasil. Yes that's a big statement but this Dr had developed a test to prove the correlation between the vaccination and the growth of the tumour.

Dr Lee had agreed to perform his test on a sample of the post mortem tumour from s22 s22 and s22 tried to arrange for a sample of the tumour to be sent to him from the Australian Pathology group which housed the sample. After two years of trying to get the Australian pathology group (Healthscope) to liase with Dr Lee they were so frustrated they enlisted the help of the Health Services Commissioner of Victoria. Again there were numerous bureaucratic delays as the health Service Commissioner's office kept changing the staff in the role.

Eventually on s22 the Health Services Commissioner wrote with the good news.The laboratory which stores the tumour is now owned by Australian Clinical Labs

and they have agreed to provide a sample of the tumour for post mortem testing. **They stipulate they will require a request from the researcher or laboratory which is performing the test and that request must stipulate exactly how they are to prepare, preserve and transport the sample from them to the testing facility.**

s22 and s22 are still grieving the loss of s22. Obviously as loving parents they want answers. There is a doubt about the safety of the drug no matter what anyone tries to say. s22 s22 I challenge any of you who have children to put yourselves in their shoes and understand and have the empathy to help them.

I realise the company that distributes this drug is a muti milion dollar company. I believe they are the same company that produced stilnox and I'm sure you are aware of it's dangerous side effects. s22 passed out soon after taking stilnox and she ended up with a broken arm on her bathroom floor. The very doctors that helped develop this drug believe it is dangerous to some and is purely a financial windfall for the company. I quote an article form Health Impact News which I found on the internet.

"U.S. law prevents anyone from suing Merck or any other vaccine manufacturer as the U.S. Congress gave them total immunity from civil lawsuits in 1986, and that legal protection which gives them a free pass to put as many vaccines into the market as they want to, was upheld by the U.S. Supreme Court in 2011. In addition, the National Institute of Health receives royalties from the sales of Gardasil. So don't expect objective, true information from the U.S. mainstream media, or your U.S. doctor.
But Merck does not have the same legal protection outside the U.S., and it is here we must find information regarding lawsuits over injuries and deaths related to Gardasil.
- See more at: http://healthimpactnews.com/2014/mercks-former-doctor-predicts-that-gardasil-will-become-the-greatest-medical-scandal-of-all-time/#sthash.9dr4uKcx.dpuf

My s22 has had her Gardasil injection this week and I can't help but feel ill at the though of what happened to s22 happening to one of my own family. I'm sure you must feel the same.

I suppose I am invested in finding answers for s22 and s22 as a result of my own childhood experience. s22 s22

I can't develop or perform the test on s22 tumour or I would. I'm not some fanatic who is against all, vaccinations I know vaccinations have saved many thousands of lives across the world and without them we would be in a mess.I do however believe where there is enough evidence to create the doubt and where lives are being lost there has to be investigation . Lives have to come before financial gain. If litigation is impossible in the USA well just maybe it's fallen on the shoulders of Australia to protect the rest of the world's children. Again, this isn't about money it's about finding the truth behind this drug and if it has lead to the development of a rare and aggressive tumour in this one poor child it has to be stopped.

Australia is a young country and it is full of intelligent and talented people. Do we really want to stand by and allow any of our young girls to pass away so that a multi million dollar Us company can make profits? Or do we encourage the resarchers of our great nation to challenge what might be killing them? There are just too many cases of people in the USA who have worked on this drug speaking out against it and suddenly being silenced. What is Merck hiding? When do we take a stand?

I now appeal to your compassionate side and your sense of integrity and I ask for your assistance in"finding a laboratory which is willing to perform the test. I can send a link to the instructions for the test that Dr Lee developed in the USA before he was suddenly "silenced".

You might note his line in his answer to me which stated "this is a global problem".

Yours Sincerely,

s22 [redacted]

From: Minister Ley
To: Health Referrals
Subject: For info: New Lyme-disease-causing bacteria species discovered (New Request) [SEC=UNCLASSIFIED]
Date: Thursday, 17 March 2016 1:05:33 PM
Attachments: 15-00601s22 pdf
Your FOIA Request.doc
FOIA Request 4-4-2015.doc

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s22 | Junior Departmental Liaison Officer
Office of the Hon Sussan Ley MP
Minister for Health
Minister for Aged Care
Minister for Sport
Parliament House Suite M1- 41 Canberra ACT 2600
Phone s22 | Email: s22 @health.gov.au

From: s22 [mailto:s22 @comcast.net]
Sent: Thursday, 17 March 2016 12:10 AM
To: s22 @cdc.gov
Cc: NCID; s22 @cdc.gov; s22 @cdc.gov
Subject: Re: New Lyme-disease-causing bacteria species discovered (New Request) [SEC=No Protective Marking]

March 16, 2016

To our legislators on three continents (and 75 others) who were blind carbon copied on this email thread:

I would like to call attention to the recently published CDC autopsy study on five Lyme disease patients who dropped dead from their infection:

Cardiac Tropism of Borrelia burgdorferi: An Autopsy Study of Sudden Cardiac Death Associated with Lyme Carditis. (March 2016)
http://ajp.amjpathol.org/article/S0002-9440(16)00099-7/abstract

Excerpt:

"Fatal Lyme carditis caused by the spirochete *Borrelia burgdorferi* rarely is identified. Here, we describe the pathologic, immunohistochemical, and molecular findings of five case patients."

We can diagnose Borrelia infection using molecular diagnostics (DNA sequencing) post-mortem but not in the living? Pathology results from autopsy and biopsied tissue have proven antibiotic resistant/tolerant Borrelia infection time and time again. Why are we not collecting tissue samples from chronic Lyme patients' (liver, bladder, prostate etc.) and evaluating these samples using the same techniques that the CDC used for the five patients who died of sudden cardiac death? It is quite possible that tissue samples from horribly disabled Lyme patients are teeming with spirochetes.

Confirming an antibiotic resistance/tolerant superbug puts Lyme in an entirely different class of infection requiring immediate attention. As more and more of the world's population become's horribly disabled from Lyme (Patient examples) it has become crystal clear that the CDC has colluded to deny a life-altering/life-threatening infection

Question: There appears to be a deliberate avoidance for confirming persistent Borrelia infection in the living. **Why?**

DNA sequencing has the ability to detect early Borrelia infection (And multiple species) before antibodies are produced so why isn't this type of test readily available in Lyme endemic regions across the United States? Milford Molecular Diagnostics Laboratory

A positive DNA test is irrefutable evidence of active infection with 100% certainty while antibody tests (Serology) cannot be used to gauge treatment failure or success.

Please read the following petition update and Dr Lee's letter below:

Part 3: New species of Borrellia in the Hudson Valley, NY area?

https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/15826757
Please see Dr Lee's response below regarding "inconsistent results" claimed by the CDC for the novel Borrelia Dr Lee isolated in the serum sample of patient #9.
The CDC seems to have a track record of denouncing laboratory testing that could challenge the existing dogma as we have seen previously with Advanced Laboratory Services Lyme culture test.
New CDC/FDA Warning Against Unapproved Lyme Culture Test
http://www.medscape.com/viewarticle/823840
Current FDA approved Lyme disease tests (Antibody tests) cannot be used to gauge treatment failure or success which is ideal for concealing an antibiotic resistant/tolerant superbug allowing the thirty year old dogma to remain intact. Culture along with DNA sequencing has the potential to identify persistent infection which the CDC appears to be avoiding at all costs.
Instead of condemning these lab tests wouldn't it make sense for the CDC to collaborate with these manufacturers to provide proficiency testing and work out any discrepancies identified? **Why is this not happening?**
Dr Lee's letter to CDC Director, Dr Beth Bell:

From: "Sin Hang Lee" <shlee01@snet.net>
To: bzb8@cdc.gov
Cc: runagain@comcast.net
Sent: Sunday, March 13, 2016 9:48:02 AM
Subject: Please point out inconsistent results

Dr Beth P Bell
Director
The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention (CDC)
bzb8@cdc.gov

cc: Carl Tuttle runagain@comcast.net March 13, 2016

Dear Dr Bell:

In answering a question from Mr Tuttle concerning a publication in which I am the first author [1], you made an allegation "that the authors of this publication reported inconsistent results for this specimen….." as a reason for the CDC's inaction to investigate a novel borrelial infection in Hudson Valley. See Mr Tuttle's post regarding Patient #9 here:

Part 2: New species of Borrellia in the Hudson Valley, NY area?
https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/15796418
I hereby request that you point out the "inconsistent results" in the publication referenced above so that the authors can defend their data presented in a peer-reviewed article. An allegation of this nature and magnitude made by the Director of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) carries serious implications which will invariably damage the reputation and credibility of the authors of the publication. If you cannot point out the "inconsistent results" for an open debate, I will question your motives in making such remarks in the first place since your allegation is not based on facts and is now being circulated in the public domain.

The authors of the above referenced article [1] performed a series of tests with the support of Dr Marty Schriefer and Dr Claudia Molins of the NCEZID for the

purpose of evaluating the accuracy of a new diagnostic test for Lyme disease, utilizing the classic nested PCR and DNA sequencing technology. An official report on this case was submitted to the CDC on September 4, 2013 under a Material Transfer Agreement (NCEZID-R137154-00) authorized by you. Neither you nor any CDC staff members have raised any issue of "inconsistent results" regarding the finding of this novel borrelia. You have an obligation to point out these newly found "inconsistent results" in this article [1] which had undergone two rounds of peer review by 3 experts in the field before acceptance for publication.

Sincerely,

Sin Hang Lee, MD
Shlee01@snet.net

Reference
[1] Lee SH, Vigliotti JS, Vigliotti VS, Jones W, Shearer DM. Detection of Borreliae in Archived Sera from Patients with Clinically Suspect Lyme Disease. Inter J Mol Sci. 2014; 15:4284-4298.

From: "s22 [redacted] @comcast.net>
To: s22 [redacted] @cdc.gov
Cc: "NCID" <s22 [redacted] @cdc.gov>, s22 [redacted] @cdc.gov, s22 [redacted] @cdc.gov
Sent: Sunday, March 6, 2016 9:40:32 PM
Subject: Re: New Lyme-disease-causing bacteria species discovered (New Request)

Mar 6, 2016
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027
Attn: s22 [redacted], MD, MPH, s22 [redacted]
Dear Dr s22 [redacted]

I presented two questions to your attention on Feb 16, 2016 regarding serum samples used for developing diagnostic tests and received a response from: NCID/VBI BZB Public Inquiries (see below). Although my two questions were answered, the response has prompted further examination of the CDC's actions regarding the possibility of a novel neuro-invasive strain of Borrelia isolated in blind coded serum samples from your repository.

Original question: Has the CDC investigated this "novel *Borrelia*" similar to the collaboration with the Mayo Clinic's discovery of *Borrelia mayonii*?

CDC Answer: No. Please note that the authors of this publication reported inconsistent results for this specimen and that their attempts to further characterize failed. The Mayo Clinic's results were reproduced and culture-confirmed.

Additional questions:

a) Since these authors stated in the article, *"After the testing results were reported to the CDC, the blinded serum samples were decoded."*, did the CDC point out to the authors the inconsistent results for this specimen after receiving the authors' report or after the publication of their article?

b) Does the CDC now claim that the data presented in this publication are invalid and the article should be retracted for accuracy of science presented to the public?

c) Does the CDC claim that failure to further characterization of a borrelial 16S rRNA gene DNA segment invalidates the DNA sequencing data that the authors reported in a peer-reviewed article and have deposited in GenBank ID# KM052618 as evidence for a

novel borrelia?
d) Does the CDC claim that all microorganisms, including human pathogens, in particular pathogenic spirochetes, must be culture-confirmed in artificial media for a molecular diagnosis to be established?
e) Does the CDC claim all DNA sequencing-based diagnostic tests for borrelial infections must be reproduced on each human specimen to be valid, regardless of the density or the numbers of the microbes in the sample?
f) How does the CDC interpret the DNA sequencing data reported to the CDC and published as Patient #9 in these authors' article? Does the CDC consider these sequences are DNA contaminants from the air? Or the CDC considers these are representative of a strain of Borrelia burgdorferi sensu stricto causing neurologic Lyme in this case?

_____

I would like to point out that not only was a novel Borrelia discovered in this published study but there was a second pathogen (Borrelia miyamotoi) found in one serum sample which was 2-tier serology-negative and in two of the serum samples containing Borrelia burgdorferi, one sample was negative and one positive for 2-tier serology.
g) How can the CDC use these serum samples from their serum repository to gauge the accuracy of newly developed Lyme disease test kits when you don't know what they contain?
DNA sequencing from this study has identified serious flaws with current FDA approved testing (serology) for Lyme disease and there is talk on the street that this is the real reason why the CDC is avoiding not only this study and its authors but molecular diagnostics in general.
Please follow-up and answer the seven new questions in this message.
Sincerely,
s22 [redacted]
Hudson, NH

CDC Reply to the original two questions:

From: "NCID/VBI BZB Public Inquiries (CDC)" s22 [redacted] @cdc.gov>
To: s22 [redacted] @comcast.net
Sent: Friday, February 26, 2016 5:55:04 PM
Subject: New Lyme-disease-causing bacteria species discovered (Second Request)

Dear Mr. s22 [redacted]

Thank you for your inquiry. We have provided responses to your questions below.

Has the CDC investigated this "novel *Borrelia*" similar to the collaboration with the Mayo Clinic's discovery of *Borrelia mayonii*?

No. Please note that the authors of this publication reported inconsistent results for this specimen and that their attempts to further characterize failed. The Mayo Clinic's results were reproduced and culture-confirmed.

Patient #9 was previously treated for "neurologic Lyme disease" yet evidence of infection persists. Why hasn't that infection cleared after antibiotic treatment?

The serum sample that you refer to was received by CDC as part of an anonymized set of serum samples intended for widespread distribution for test development and evaluation. By both IRB review and patient consent, it is not possible to trace back to the patient. Patient #9 had received 4 days of antibiotic treatment at the time the sample was collected.

Thank you,

Centers for Disease Control and Prevention
Division of Vector-Borne Diseases | Bacterial Diseases Branch
Fort Collins, Colorado

email: s22 @cdc.gov

From: s22 @comcast.net]
Sent: Tuesday, February 23, 2016 9:10 AM
To: s22 (CDC/OID/NCEZID)
Cc: s22 (CDC/OID/NCEZID); s22 (CDC/OID/NCEZID)
Subject: Re: New Lyme-disease-causing bacteria species discovered (Second Request)
Second Request
Dr s22 .Please answer the two questions submitted below on Feb 16, 2016.
Thank you,
s22

From: 's22 @comcast.net>
To: s22 @cdc.gov
Cc: s22 @cdc.gov, s22 @cdc.gov
Sent: Tuesday, February 16, 2016 3:27:52 PM
Subject: New Lyme-disease-causing bacteria species discovered
Feb 16, 2016
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027
Attn: s22 , MD, MPH, s22
Dear Dr s22
I would like to call attention to the following CDC study:
New Lyme-disease-causing bacteria species discovered Borrelia mayonii closely related to B. burgdorferi
http://www.cdc.gov/media/releases/2016/p0208-lyme-disease.html
Excerpt:
"Centers for Disease Control and Prevention, in collaboration with Mayo Clinic and health officials from Minnesota, Wisconsin, and North Dakota, report the discovery of a new species of bacteria (Borrelia mayonii) that causes Lyme disease in people."
In August of 2013 the CDC provided 32 blind coded serum samples to Milford Laboratory Services for the purpose of evaluating the accuracy of a new diagnostic test for Lyme disease; "Nested PCR and Sequencing." (20 pre-treatment and 12 post-treatment sera from clinically suspect Lyme disease patients) **CDC Reference: NCEZID-R137154-00**
Per the following published study results of the serum samples you sent to Milford Laboratory Services, it appears that a novel Borrelia was isolated in one of these samples.
Detection of Borreliae in Archived Sera from Patients with Clinically Suspect Lyme Disease
http://www.mdpi.com/1422-0067/15/3/4284
Excerpts:
"Of the 12 post-treatment serum samples, we found DNA evidence of a novel borrelia of uncertain significance in one, which was also positive for the 2-tier serology test."
"The #9 patient **[Hudson Valley, NY]** *was diagnosed with "neurologic Lyme disease" and had been treated before the serum sample was drawn. Direct DNA sequencing of the nested PCR amplicon confirmed that the sequence of the amplicon is that of a novel borrelia in the relapsing fever group…."*
The novel partial 16S rRNA gene sequence was deposited in the GenBank labeled as CDC unnamed borrelia #KM052618 according to the document below presented at a meeting in

Boston November 8, 2014.

16S rDNA Sequencing Diagnosis of Spirochetemia in Lyme and related Borrelioses

http://www.dnalymetest.com/images/Nov._8_Handout.pdf

_____

Questions for the CDC

1. Has the CDC investigated this "novel Borrelia" similar to the collaboration with the Mayo Clinic's discovery of Borrelia mayonii?

2. Patient #9 was previously treated for "neurologic Lyme disease" yet evidence of infection persists. Why hasn't that infection cleared after antibiotic treatment?

Your prompt attention and response to these questions is greatly appreciated.

Sincerely,

s22 [redacted]

Hudson, NH

3 Attachments:

FOIA Request

CDC Acknowledgement letter

FOIA results: New York Medical College/s22 [redacted]

From: s22
To: s22
Bcc: s22 @bigpond.com
Subject: SaneVax Press Release: Vaccine Injury Compensation Program: Fatality after Gardasil
Date: Saturday, 14 November 2015 7:54:02 AM
Attachments: 11.2015-VICP-Gardasil-related-death-claim.pdf

Dear all - sharing this very important press release with you. s22

Please see our latest Press Release following the death of a young 14 year old boy from the USA following vaccination with Gardasil.

After examining the coroner's report on a 14 year old boy who died in his sleep less than 24 hours after his second Gardasil injection, Dr. Sin Hang Lee decided to make his findings public. He hopes by doing so will help parents and medical professionals avoid similar circumstances.

Dr. Lee wants all parents and medical professionals dealing with HPV vaccine survivors to know:

> **Teenagers vaccinated with Gardasil® should stay away from competitive sports such as football for at least two months, and should have an electrocardiogram to rule out silent myocardial infarction if there is any incidence of syncope, chest discomfort, tachycardia or hypotension within two months after Gardasil® vaccination.**

The link to the press release explaining the details is here - http://sanevax.org/vaccine-injury-compensation-program-fatality-after-gardasil/ (pdf attached)

With best wishes

s22
SaneVax Inc