

*Carbon
copy.*

As requested

1994

2nd letter

Mrs Hilary Butler,
25 Harrisville Road,
Tuakau 1892,
NEW ZEALAND.

4th April, 1994.

Dr. Kathleen Stratton, Ph.D.,
Institute of Medicine,
2101 Constitution Ave., N.W.,
WASHINGTON, D.C. 20418.

Dear Dr. Stratton:

Enclosed is a copy of a letter which I faxed to you on 7 January, 1994. Since I have not heard from you, I have assumed that either you have not received the letter, or you have not yet been able to find out how the misrepresentation occurred.

I also sent a copy of this letter to Dr Richard B. Johnson, Jr, M.D., at the March of Dimes, and have not heard from him either.

I realise that other matters may have otherwise occupied your time, but had hoped that notification of a potential error in a book destined to be THE universal definitive handbook on Adverse Events Associated with Childhood Vaccines, which you assured me in your covering letter was scientifically accurate, would have been considered to be an issue of importance.

~~As I have read through this book, I have to admit that I have repeatedly had to ask myself the question:~~

"If I know of one "misrepresentation", how can I be sure there are not many more?"

I note in your book that the vaccine DT is not associated with encephalopathy. In fact the book states categorically that this vaccine is not, and has not been associated with proven cases. I enclose for your information, a copy of one such case from this country. The child concerned has been paid the maximum allowable compensation from the New Zealand Compensation Commission. Matthew condition is progressively deteriorating, and he has, for the last year been on dual drug treatment for seizures, which are still poorly controlled. He has a cyclical pattern of grandmal seizure, and between these times has partial complex seizures occurring throughout the day. His assessors estimate that he misses around 3 hours out of every day at school, and is starting to exhibit violent tendencies towards the other children, of which he has no recollection afterwards.

I look forward to any comment you may have on any of the above.

Yours sincerely,

Hilary Butler.

Faced twice

Sent twice buths
apart.

No reply.

1 of 6

Letter to Dr Stratton
asking why on Page 229
in this book, a report that
Dr Morris I submitted to
Tom was incorrectly quoted.

Mrs. Hilary Butler
25 Harrisville Road
Tuakau 1892
NEW ZEALAND

7 January 1994

Dr. Kathleen Stratton, Ph.D.
INSTITUTE OF MEDICINE
2101 CONSTITUTION AVE., N.W.
WASHINGTON, D.C. 20418

Dear Dr. Stratton:

Your kindness in sending to me a copy of *Adverse Events Associated with Childhood Vaccines* is appreciated. It has made it possible for me to express promptly some concerns that arose after reading a single chapter. These concerns are expressed here as those of a mother who is interested in the welfare of infants and children, especially those in New Zealand, and as a member of The Immunization Awareness Society (New Zealand).

The single chapter that is the subject of this letter is chapter 8. This deals with adverse events that follow use of hepatitis B vaccine, a vaccine recommended for injection into newborns. In this chapter is found the following quoted information--information that has the same meaning when quoted here or when read in chapter context. Underscorings are mine.

- 1- *The final dose induces adequate high titer antibody in . . . 95 percent of children and infants . . . The immunogenicity and safety of hepatitis B vaccine in premature infants are less well defined . . . (p. 214).*
- 2- *. . . it is important to note that individual trials usually involve a few hundred subjects per study . . . When larger vaccination programs were monitored, observations of adverse events were necessarily less detailed and less accurately reported (p. 215).*
- 3- *Local reactions of soreness were found in approximately one-third of recipients; generalized reactions of fatigue, headache, or fever were found in 10-15 percent of recipients. The frequency was less in infants and children. The trials are notable for the absence of any serious adverse reactions. The studies were not designed to assess serious, rare adverse events . . . (pp. 215-216).*

Page Two

- 4- *Relative risks for GBS following hepatitis B vaccination were calculated under a variety of assumptions . . . Statistically significant increases in risk were found under all assumptions when the CDC data were used . . . but only with a 6-week at-risk after the first dose when the Olmsted County data were used. Adjustment for age in the CDC data and age and sex in the Olmsted data did not substantially change the results (p. 217).*
- 5- *There are reports of GBS following vaccination, but it is difficult to determine whether the frequency is greater than expected . . . The Evidence is inadequate to accept or reject a causal relation between hepatitis B vaccine and GBS (p. 219).*
- 6- *. . . the number of examples of adverse neurologic outcomes following receipt of hepatitis B vaccine are of concern, particularly those resulting in demyelinating neurologic disease. There is need to look for these outcomes in prospective postmarketing surveillance . . . (p. 222).*
- 7- *The possibility of a causal relation between hepatitis B vaccination and anaphylaxis is supported by biologic plausibility, by the temporal sequence of observed events following vaccination, and by the observation of a spectrum of host responses to the hepatitis B vaccine that follows a logical biologic gradient from true anaphylaxis to milder hypersensitivity reactions (p. 228).*
- 8- *Anaphylaxis was not observed in the 166,757 children vaccinated with a plasma-derived vaccine in New Zealand (Morris & Butler, 1992, p. 229).*

Eight passages from chapter 8 are quoted above. It is not difficult for me, as a mother with interests in the welfare of infants and children and as a member of The Immunization Awareness Society to understand alarm and apprehension in a mother who just gave birth to a healthy infant who was about to see her newborn injected with a vaccine to which the quoted information applies. However, I would have difficulty in understanding a mother under the same circumstances who was not alarmed and apprehensive.

The first seven of the eight quoted passages require no comment (underscoring of specific phrases is sufficient); the eighth one does.

In our (Morris & Butler) report submitted on 4 May 1992 to The Vaccine Safety Committee the following is found on page 2:

Page Three

In May 1988, the Hamilton Department of Health (Wellington) faxed to Hepatitis B co-ordinators in all area health boards a message from the principal medical officer: "We have received approximately 10 reports of anaphylactoid reactions occurring in children receiving hepatitis B vaccine. This is . . . a matter of considerable concern . . . Professor Ralph Edwards . . . reports 14 similar reactions . . . since 1985 in Australia and he feels sure that the potential for severe allergic response exists. Accordingly . . . the following policy should be adhered to . . . (1) For children who have developed vaccine-related urticaria alone it is recommended that subsequent vaccinations be given in a hospital setting . . . (2) If the allergic response includes ANAPHYLACTIC SHOCK, HYPOTENSION, BRONCHOSPASM or true ANGIONEUROTIC OEDEMA, then it is considered that any further vaccination is absolutely contraindicated. It is felt that for the above conditions to be classified as vaccine related, the onset of symptoms should be within 12 hours after an injection of hepatitis B vaccine"

Information in the eighth quotation from your book misrepresents information submitted to you in our 4 May 1992 report. This misrepresentation does a serious disservice to those who might believe that your book reports accurately data submitted to The Vaccine Safety Committee. If you disagree with this assessment, I will welcome your reasons for disagreement. However, if you agree that there is misrepresentation, I will welcome information on your planned corrective action.

Sincerely,

Hilary Butler.

Hilary Butler

cc: Dr. J. Anthony Morris
Dr. Richard B. Johnston

P.S. The seriousness of the misrepresentation called to your attention is emphasised by the fact that the 1988 report on the 166,757 children vaccinated with the plasma derived vaccine specifically mentioned in your book as having shown no anaphylaxis, was included in our report, and included 2 cases of anaphylaxis. These occurred in two boys (one 4 years old and one 4 months old) within minutes of hepatitis B vaccine injection. The cover sheet, summary sheets and case histories of the anaphylaxis cases detailed in this report follow for your reference.

From: **Self <Single-user mode>**
To: **kstratto@nas.edu**
Subject: **Adverse Events with Childhood Vaccines Book**
Date sent: **Mon, 30 Sep 1996 21:58:57**

Dr Katherine R Stratton
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave NW
Washington DC 20418

Dear Dr Stratton

As you may (or may not) remember, I wrote you a detailed six page letter on 7 January 1994 regarding a major error on pg 229 in your book on Adverse Events Associated with Childhood vaccines. The error stated that there were no episodes of anaphylaxis in 166,757 children in New Zealand.

You refused, or chose not to reply to my letter. I re-faxed it and mailed it several months later. You refused, or chose not to reply to it again.

Now I see that the FDA had put your error onto Internet.

As I said to you at the time.

"This misrepresentation does a serious disservice to those who might believe that your book reports accurate data submitted to the Vaccine Safety Committee. If you disagree with this assessment, I will welcome your reasons for disagreement. However, if you agree that there is misrepresentation, I will welcome information on your planned corrective action."

You did neither, and as a result of your inaction a lie has been perpetrated.

For the third time:

Dr Stratton: What do you intend to do to correct an error brought to your notice two and a half years ago???

It would be nice to think that this time you might have the courtesy to reply, since the fault is yours, not mine.

Yours faithfully

Hilary Butler
Email c/- peter@netlink.co.nz

Date sent: **Wed, 09 Oct 96 13:02:00 EST**
From: **"Kathleen Stratton" <kstratto@nas.edu>**
To: **peter@netlink.co.nz**
Subject: **Message for Hilary Butler**

Dear Ms. Butler:

I have received your recent emails. I'm sorry to say that I do not recall ever getting a lengthy fax and letter from you in 1994 about the issue you have raised. I received a lot of mail about our report in those days and I tried to keep track and respond to all of it. I like to think that I would recall such a detailed commentary, but I frankly do not. I apologize if I did in fact receive it and did not get back to you.

Our report does state that there were no cases of anaphylaxis in the 166,757 children from New Zealand who had received the plasma-derived vaccine. It is quite some time since that report was done and I can't pretend to be able to reconstruct in my mind the analytic details of every committee decision about how the data support causality. I have just now re-read the material you and Dr. Morris sent in 1992. I assume that the cases were not counted as positive indications of vaccine-caused anaphylaxis because the material presented was not specific enough to meet the criteria for anaphylaxis as laid out in the report. The report is final and there is no action that can be taken to address your recent fax.

I remind you that despite the fact that the committee did not find that your summary material represented data complete enough to support causality, the committee did indeed find for the strongest level (establishes) of causality between Hepatitis B vaccine and anaphylaxis based on other data. Any further consideration of your data could not change that. There is no stronger level of association to be assigned.

I am sorry if you do not believe that our report adequately represents your data. The committee did their best to review the material given to us and to use objective criteria to evaluate thousands of reports. I think they were very successful.

Again, I regret that for some reason I either did not receive or did not respond to your earlier comments.

Thank you,
Kathleen Stratton

Email: 20 October 1996

Kstratto @ NAS.edu via peter@netlink.co.nz

Dear Dr Stratton,

I note in your reply that you consider the FDA's use of an incorrect comment i.e. no anaphylaxis in New Zealand in 166,757 children (when there were 2) of no consequence, because in the book you gave it the highest rating by saying that it could.

FDA were NOT quoting your conclusions; there WERE quoting your incorrect comment (attributed to me in the book) as proof that Hepatitis B vaccine did not cause anaphylaxis here in New Zealand and thereby inferring that this proved it was unlikely to do so.

As co-author of the said report quoted in your book, I request that an erratum be printed and pasted into this page in every book currently at the printer and that in subsequent printings, changes be made in the text itself.

I still maintain that there was no excuse for this error in the first place, and your casual attitude to the FDA's use of your error, does nothing to reassure me of the standard of scientific accuracy of your committee in the future.

Yours Sincerely,

Hilary Butler

Copies for you

From: **Self <Single-user mode>**
To: **editor@medscape.com**
Subject: **MMWR "Update: Vaccine Side Effects etc"**
Copies to: **kstratto@nas.edu**
Date sent: **Mon, 30 Sep 1996 17:27:36**

Could you please forward this message to the Authors of your recent Medscape Article:-MMWR " Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions"
Jessica Tuttle, M.D. et al.

Hilary Butler
C/- Peter [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
New Zealand

Dear Dr Tuttle et al

On your MMWR Medscape on Pg 4 of 21 in the box on Hepatitis B you state:

"... and no adverse events were reported among 166,757 children who had been vaccinated with plasma-derived vaccine in New Zealand [5]."

As the co-author of the report on Hepatitis B in NZ which was sent to NIH, I strongly object to this statement. When Dr Katherine Stratton sent me my complimentary copy of the book I found on checking the Hepatitis B chapter a major error. I immediately faxed her and asked to know how this error could have happened. The error is this:-

In Section 6 of our report, on Pg 44 of the New Zealand Health Departments' summary is found the following:-

11.4.1 Anaphylaxis

"Anaphylaxis occurred in two boys five minutes after injection in a four year old and ten minutes after injection in an infant of four months. Both reactions occurred after the third vaccine dose, and neither child had experienced any reaction to former doses".

Also in our report was a memorandum dated 17/5/88 regarding Hepatitis B vaccines outside of the 166,757 children who were part of a "catch-up" campaign.

This Health Department memorandum documents 10 reports of serious anaphylactoid reactions: anaphylactic shock, hypotension, angioneurotic oedema, bronchospasm and urticaria. It also details 14 similar reactions in Australia in the previous 12 months.

The basis for good medicine is good science. The fault primarily lies with Katherine Stratton for refusing to correct this crucial error in the first place.

I only knew about this error because I wrote the report you quote. I have to wonder, on this basis, how much else that you quote is equally as fictitious.

Perhaps you could e-mail me at peter@netlink.co.nz and let me know how you intend to rectify this major error.

I also note that your Table 1 comparing Disease incidence in 1995 .Total provisional disease totals = 10,594
AND Reactions reported to VAERS in 1995 = 0

This more than stretches anyone's credibility because in New Zealand, a country of 3 million people, the Government data regularly logs more than 200 side-effects onto the computer database. For instance, last year we had more than 150 alone for adult dT which was an American formulation. Strange that you had none quite extraordinary... when your dT nearly killed 2 NZ adults who are left with permanent disabilities.

Yours faithfully

Hilary Butler

c/- peter@netlink.co.nz

copy to KSTRATTO@NAS.EDU



26th May, 1999.

John L. Mica, Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources,
B-373 Rayburn House Office Building,
WASHINGTON
U.S.A.

Dear Congressman Mica.

SUBJECT: Hepatitis B Vaccine: Helping or Hurting Public Health”
May 18, 1999.

It is perhaps unusual for someone from another country to petition to present evidence to you regarding the above hearing. However, I seek leave to do this, because on reading evidence presented to you by Alan P Brownstein, and the CDC Atlanta, the following comments were made:

Alan P Brownstein: Page 2: “Large scale hepatitis B immunization programs in Taiwan, Alaska, and New Zealand have observed no association between vaccination and the occurrence of serious adverse events”

CDC Questions and Answers about Hepatitis B and the Vaccine that Protects You, Pg 4 of 12. (same quote as above) Also:

A low rate of anaphylaxis (hives, difficulty breathing, shock) has been observed ... no cases were observed in 166,757 children vaccinated in New Zealand.

The Institute of Medicine, Bethesda Maryland called for public submissions about all vaccines in 1991. Dr [REDACTED] submitted a report which included the New Zealand Health Department's analysis of the 166,757 children vaccinated in New Zealand, and key Health Department memoranda. Our report was submitted on 4 May 1992.

In this report, I emphasis the many cases of Anaphylaxis/anaphylactoid reaction which fall within the definitions quoted to you by the CDC: the Table compiled by the New Zealand Health Department after vaccinating 166,757 children showed the following:

Hives (urticaria) 107 cases

Difficulty breathing (brochospasm) 70
Shock (requiring adrenalin intervention) 2

The Institute of Medicine sent me a complimentary copy of a book they published in 1994. You can imagine my surprise when I found on page 229 that there were no cases of Anaphylaxis/anaphylactoid reactions in these 166,757 children..

I wrote to Dr Katherine Stratton, the editor of this book, and upbraided her about this error. I got no reply. I happened to be looking on the CDC Website in 1996, when I found information identical to what was presented to you.

I challenged Dr Tuttle at the CDC about the inaccuracies in their report (and got no reply), and e-mailed Katherine Stratton to suggest to her that perhaps she might like to reply to my letters which had been sent to her a total of three times.

Her reply dated 9 October 1996 stated:

"I assume that the cases were not counted as positive indications of vaccine-caused anaphylaxis because the material presented was not specific enough to meet the criteria for anaphylaxis as laid out in the report. The (book) report is final and there is no action that can be taken to address your recent fax."

I am not sure what qualifies The Institute of Medicine to decide that a comprehensive 97 page Department of Health report detailing everything very carefully, does not conform to their idea of correct clinical medicine. It is an extraordinary action of their part.

Enclosed for your consideration are the relevant pages from the New Zealand Health Department report, and 2 Health Alert memoranda which were subsequently sent out to all Health Professionals in this country alerting them to the observed dangers.

It is my opinion that this report is self-explanatory, and **it does not say** what your experts allege.

Since that time, we have had several cases of Guillaine Barre Syndrome, and Takahashi's Polyarteritis following the use of the Hepatitis B vaccine.

The New Zealand Centre of Adverse Reaction Monitoring, which now posts its information onto internet, reports for the 18 month from 1st July 1996 to 31 March 1998, the following anaphylactic responses reported after the hepatitis B vaccine.

Hives (Urticaria) 36
Difficulty Breathing (bronchospasm) 5
Anaphylaxis 3

Anaphylactoid reaction 2

There are just under 4 million people in New Zealand, and that the majority of Hepatitis B vaccines are given to babies. We have a birth rate of 55,000 a year, and a compliance rate of 80% for the Hepatitis B vaccine. This equates to approximately 66,000 babies vaccinated three times each over the 18 month period, and an unknown number for adults. The relevant page is also enclosed for your detailed analysis.

I realise that you are extremely busy, but I would ask two further requests of your office:

- 1) Please could you send an acknowledgement that you have received this material.
- 2) Would it be possible to include with your acknowledgement a copy of the supplemental material provided to your committee by Burton A. Waisbren, Sr., M.D., F.A.C.P., F.I.D.S.A. I have his Testimony, but do not have his address or means to contact him. Or, if your privacy laws do not breach such a request, could you please include his address. Or, failing that, would it be possible for you to forward to Dr Waisbren a copy of this letter.

I trust that the enclosed information will assist the committee, since part of the Centre for Disease Control (Atlanta) and The American Liver Foundations presentations are a serious misrepresentation of a report, authored by myself and Dr. [REDACTED] in which we concluded that the Hepatitis B vaccine did cause, and had the potential to cause serious life-threatening reactions.

The experts who presented evidence to you told you what they wanted you to hear, not what the evidence shows. This leaves one question which I would like the committee to consider.

QUESTION: If these experts can lie about something as serious as anaphylaxis, what else have they lied to you about?

Sincerely,

[REDACTED]

[REDACTED]

cc. Kathleen B Stratton
Richard B Johnson

NATURE AND FREQUENCY OF ADVERSE REACTIONS

following

HEPATITIS B VACCINE INJECTION

in

CHILDREN IN NEW ZEALAND

1985-1988

J. Anthony Morris, Ph.D.*

and

Hilary Butler**

Submitted 4 May 1992 Vaccine Safety Committee
Institute of Medicine, National Academy of Sciences
Washington, D.C.

*The Bell of Atri, Inc., College Park, Maryland, USA

**Immunization Awareness Society, Tuakau, Auckland, NZ