52 Mind Your P's and Q's… or Else!

This chapter attempted to tell a story that we believed needed to be told … but cannot be as originally penned. It has undergone a number of changes and omissions on the advice of legal counsel. I've done my best, but the blank spaces represent the power of vested interests, which so often leaves those who need to know the whole story, with no other option but to read between the lines, or the gaps!

Ever wondered what happens when something you say seriously annoys a pharmaceutical company? I had done just that. Come August 2004, I was about to find out what the consequences would be. As part of the lead-up to the MeNZB campaign, I had distributed a lot of medical literature to various people. Amongst the recipients was the IAS.[1] As part of the preparatory groundwork, I had written a section on "risk factors" which apply to any meningococcal disease. They were these:

> ***"N Menigitidis … rarely colonizes the proximal airways of healthy young children."***[2]

So what might contribute to an environment which causes the child to be "unhealthy"?

1 Immunisation Awareness Society. www.ias.org.nz
2 Pollard, A.J. et al. 2001. "Development of natural immunity to Neisseria meningitidis." *Vaccine,* 19(11–12): 1327–46, January 8. Review. PMID: 11163654.

* Smokers.[3]
* Medical explanation: Tobacco[4] smoke changes mucus in the nose and throat, increasing risk of invasive disease.
* Lack of breastfeeding.[5]
* People with genetic polymorphisms affecting the immune system, such as: complement deficiency, factor D, properdin, mannose lectin binding, … and defects in interleukin 1 and 6 are three times more likely to die."[6]
* Iron anaemia.[7]

This statement was greeted with howls of derision from doctors on the radio and in print media, who, I presume, either didn't go on-line to read the medical paper before offering their opinion, or perhaps presumed that something written in 1982 could have no basis in fact.

My list continued:

* Chronic alcoholism, poverty, overcrowding, poor general health, poor living conditions.[8]

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3 Stuart, J.M. et al. 1989. "Effect of smoking on meningococcal carriage." *Lancet,* 2(8665): 723–5, September. PMID: 2570968. The people who carry the most bacteria and spread it around the most are smokers.

4 Pollard, A.J. et al. 2001. "Development of natural immunity to Neisseria meningitidis." *Vaccine,* 19(11–12): 1327–46, January 8. Review. PMID: 11163654. "The surface charge and hydrophobicity of the nasal mucosa has a bearing on bacterial adhesion and changes in charge and thus adhesion, may result from exposure to tobacco smoke, which is associated with an increased risk of invasive disease."

5 Moodley, J.R. et al. 1999. "Risk factors for meningococcal disease in Cape Town." *S Afr Med J,* 89(1): 56–9, January. PMID: 10070414. "Significant risk factors for meningococcal disease included being breast-fed for less than 3 months" … "provides further evidence for reduction of smoking, reduction of overcrowding and promotion of breast-feeding as important public health measures."

6 Vermont, C.L. et al. 2002. "Bench-to-bedside review: genetic influences on meningococcal disease." *Crit Care,* 6(1): 60–5, Feb. Epub 2001, November 26. Review. PMID: 11940267. http://ccforum.com/content/6/1/60. Accessed 6 December 2007. "It has been shown that some genetic polymorphisms influence the severity of the course of a disease and therefore can account for higher mortality rates. Individuals with complement deficiency for example, have a 7,000–10,000-fold higher risk of symptomatic meningococcal infections … Also associated with an increased susceptibility to meningococcal disease are deficiencies in properdin and factor D, both components of the alternative pathway.

[A] large study in children with meningococcal disease revealed that children who have defects in mannose binding lectin have greater risks of meningococcal diseas … People who have defects in interleukin 1 and 6 are three times more likely to die … It is clear that host genetic factors can be important in the various stages of meningococcal infections. Individuals with certain combinations of several polymorphisms within the above-described genes have the highest overall risk of dying from meningococcal disease."

7 DeVoe, I.W. 1982. "The meningococcus and mechanisms of pathogenicity." *Microbiol Rev,* 46(2): 162–90, June. Review. No abstract available. PMID: 6126800. http://mmbr.asm.org/cgi/reprint/46/2/162 "Iron anemia, with a low ph (6.6) increases the virulence factor of meningitis bacteria, 1,200 fold, from a 50% lethal dose of 3,600 organisms, to one of 4 organisms."

8 Peltola, H. 1983. "Meningococcal disease: still with us." *Rev Infect Dis,* 5(1): 71–91, January–February. Review. PMID: 6338571.

* For adolescents, being in bars or discotheques, binge drinking and smoking, have been shown to be high risk factors[9,10].

Then, I wrote this:

* Household crowding major risk factor (NZ study), and use of acetaminophen[11] (paracetamol).

Quote: Page 987: *"Analgesic use was defined as analgesics taken in the past 2 weeks, excluding, for cases, those taken for identified early symptoms of meningococcal disease. These analgesics were predominantly acetaminophen products ... because analgesics showed a stronger relationship with meningococcal disease, the use of analgesics may be a better measure of more severe illness than reported individual symptoms."*
Page 988. *"analgesic use and attending substantial social gatherings were also still strongly associated with the risk of contracting the disease.*
Page 989: *"Although we have interpreted analgesia use to be an indicator of recent illness, we cannot exclude the possibility that acetaminophen use itself is a risk factor for meningococcal disease."* (Underlining mine.)

The only terms I, or the IAS ever used, was that the use of acetaminophen products was a *risk factor* for meningitis. I had also used other older references to back that statement up. The IAS used some of the background information I had sent out, on their website, including the information on acetaminophen.

On 7 August, in an article in *the New Zealand Herald,* Sandra Paterson brought up issues with regard to meningitis, MenZB and acetaminophen which she said deserved some public discussion. She said[12]: *So does the widespread practice of giving paracetamol to children when they have a temperature – one of the key symptoms of meningocococcal disease: "Just give her some Pamol and bring her in tomorrow if she doesn't improve"*

On 30 August 2004, IAS received a letter from Pfizer[13] dated 26 August, and signed by Peter Baltus, the General Manager of Pfizer, demanding a list of actions be undertaken by 1 September 2004. Mr Baltus started the letter by stating that

9 Hauri, A.M. et al. 2000. "Serogroup C meningococcal disease outbreak associated with discotheque attendance during carnival." Epidemiol Infect, 124(1): 69–73, February. PMID: 10722132.
10 Oppermann, H. et al. 2006. [Meningococcal carriers in high school students and possible risk factors.] *Gesundheitswese,* 68(10): 633–7, October. (Article written in German.) PMID: 17099824.
11 Baker M. et al. 2000. "Household crowding a major risk factor for epidemic meningococcal disease in Auckland children." *Pediatr Infect Dis J,* 19(10): 983–90, October. PMID: 11055601.
12 Paterson S. 2004. "Vaccination: tell me more." *New Zealand Herald,* August 7, A23. http://www.nzherald.co.nz/section/1/story.cfm?c_id=1&objectid=3582728
13 Baltus, P. (Pfizer). 2004. "IAS Claims that Pamol is a risk factor to meningococcal meningitis", August 26. Read the letter at: http://www.ias.org.nz/pdf/p_pfizer_letter_040826.pdf

IAS had claimed that Pamol® is a ***risk factor*** for meningococcal meningitis.

Yes, IAS used a P word. Why is that? Because, like Sandra Paterson, (who did not get a letter from Pfizer about her use of the word Pamol® in her column, and neither did the ***New Zealand Herald***) every mother knows that if her child gets a fever the nurse/doctor/chemist will nearly always recommend Pamol®. It rolls off the tongue automatically. If you used the words acetaminophen or paracetamol when it came to babies, most mothers wouldn't know what it was. They might think it was an obscure drug. If you said paracetamol, most mothers would associate that with tablets they took with a brand name of say Panadol®, rather than the Pamol® which you might give to babies. IAS also put a picture of Pamol® on the website.

Mr Baltus went on to claim that statements made by IAS suggested that:

- Pamol® is one of the biggest risk factors for meningococcal meningitis;
- Pamol® should not be used for the treatment of babies or small children;
- the use of Pamol® in bacterial infections prolongs infection and worsens the therapeutic outcome;
- Pamol® is harmful;
- Pfizer New Zealand markets Pamol® inappropriately and harmfully.

Pfizer included with this letter an extraordinary "Press Release"[14] in which the lead author of the study mentioning acetaminophen said:

> ***Study authors refute false claims by anti-immunisation lobby***
>
> ***Meningococcal disease researchers are today debunking claims made by the anti-immunisation lobby that linked Pamol with the disease.***
>
> ***Speaking on behalf of the authors of the study into risk factors for meningococcal disease, Dr Michael Baker from the University of Otago's Wellington School of Medicine and Health Sciences said the study published in 2000 in The Pediatric Infectious Disease Journal is being "wrongly interpreted".***
>
> ***"In the study, analgesic use itself was not attributed as a cause of meningococcal disease and Pamol was not even mentioned," Dr Baker said.***

Neither IAS, nor anyone else giving information, would be ***stupid*** enough to state that paracetamol ***caused*** meningococcal disease.

The rest of Pfizer's letter to the IAS accused the society of deliberately,

14 Baker, M. 2004. "Study authors refute false claims by anti-immunisation lobby." *Media release*, July 19, Otago University letterhead, faxed by Dr Stewart Reid to Pfizer on 2 August 2004 at 08.55 p.m. Read Press Release at: http://www.ias.org.nz/pdf/p_pfizer_letter_040826.pdf. There is no ® after Pamol in the press release because Dr Baker didn't put one there.

deceptively, making false and misleading statements as to the relationship between Pamol® and meningococcal disease; of "detracting from Pamol's goodwill … and good name"; that IAS was misleading the public as to the nature, characteristics or suitability of Pamol®; that IAS was defaming Pfizer by suggesting it inappropriately and unethically promoted the use of Pamol®, and that all this was likely to cause Pfizer monetary loss as well as loss of reputation and goodwill. For good measure, Mr Baltus threw in the assertion that, because our information could "mislead" parents, IAS contravened the Advertising Standards Code for "advertising". Further, that putting up a picture of Pamol® contravened the Trade Marks Act, and was *"detrimental to the repute of Pfizer's registered trade mark."*

Then followed a list of what could only be called "consequences".

IAS was to *"immediately cease and forever desist from making or causing to be made the IAS representations or any representations which suggest that … paracetamol is associated with the development of meningococcal disease."* (Underlining mine.)

IAS was to *"immediately arrange the withdrawal of all current and planned advertising or other publications which make the IAS representations or which otherwise make misleading or deceptive references to Pamol®."*

IAS was to *"arrange, at its own expense, for corrective advertising to be placed in all publications in which the IAS Representations have appeared including the IAS Website."* It was to be the same size and prominence, and stating the reasons why IAS Representations were misleading and deceptive, and Pfizer was to approve the form and content of everything in advance.

IAS was to also provide a full schedule of all publications which contained either the assertions, and/or reference to Pamol®.

IAS responded[15] by saying that it had never said Pamol® *caused* meningitis, and conceded solely that the Trade-marks requirements had been breached, and removed everything which breached the Trade Mark Act. A lawyer advised a bit more bowing and scraping; advice which was grudgingly adhered to, and that's where IAS thought it would end.

But no. Pfizer decided that was not enough, and followed up with another letter[16] in which Mr Baltus demanded that IAS were not, in the future, to provide any information in the course of interviews, public statements or publications including information available from the IAS website, which would tend to suggest or imply:

15 IAS. 2004. "Immunisation Awareness Society – Pamol®." See response at: http://www.ias.org.nz/pdf/p_ias_letter_reply_040901.pdf

16 Baltus, M. (Pfizer). 2004. "Immunisation Awareness Society – Pamol®." September 15. http://www.ias.org.nz/pdf/p_pfizer_letter_040915.pdf

* that medication containing paracetamol is associated with the development of meningococcal disease;
* that the use of paracetamol in the treatment of children is detrimental, or
* that paracetamol is otherwise harmful.

The demand that IAS could never mention paracetamol was outrageous, since the word paracetamol is a generic term. No manufacturer has the legal right to attempt to control in what context the word paracetamol is used, or who uses it. Mr Baltus later claimed IAS had misconstrued his demand.

Independent information authored by me, stating my beliefs, was to be removed from the website and the statement on the website that ***"paracetamol containing medications may mask symptoms and may lead to a worsening of the illness"*** was detrimental to the goodwill and reputation of Pfizer, and was misleading to consumers, constituting direct advice to consumers not to use paracetamol in the treatment of their babies' and children's ailments.

Furthermore, if Pfizer did not receive the ***"undertakings demanded"*** by 5.00 p.m. Tuesday, 21 September, ***"Pfizer reserves all rights in relation to the IAS Representations as stated in the 26th August letter."***

Given that the preparation of the original material was mine, as was my personal statement referred to on the IAS website, the letter was handed over to me to prepare a preparatory answer for the IAS.

I was in no mood to concede an inch with regard to a drug about which I and the IAS had said absolutely nothing wrong. Neither was I interested in either the legal posturing, or the "consequences". The only thing I was interested in then, and now, is that parents be told what existed inside the medical literature. As far as I was concerned, the issue had gone too far, and I would present the information to prove it.

So I sat down and wrote a preparatory 23-page letter with 34 questions and all key issues, which was sent to IAS to add to, refine and use as they saw fit. They added more information and then sent a modified letter to Pfizer[17] giving them four days in which to reply.

The reply was[18] that the four days given them was unreasonable, and that they would respond by Friday, 8 October. IAS waited with bated breath as 8 October came and went. After all, you would think that Pfizer would at least have something interesting to say to them in reply. Instead, on 20 October, Pfizer's reply[19] dated 18

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17 IAS. 2004. "Attention, Mr Peter Baltus." September 21. http://www.ias.org.nz/pdf/p_ias_letter_reply_040921.pdf

18 Baltus P. (Pfizer). 2004. "Immunisation Awareness Society – Pamol®." September 30. Read at: http://www.ias.org.nz/pdf/p_pfizer_letter_041001.pdf

19 Baltus P. (Pfizer). 2004. "Immunisation Awareness Society – Pamol®." October 18. Read at: http://www.ias.org.nz/pdf/p_pfizer_letter_041018.pdf

October arrived. Note the time frames required when you have the upper hand!

What a yawn of self-promotion it turned out to be. Not one question was addressed, because as it said, ***"Pfizer does not deem it necessary to address any of these",*** and it primarily re-stated its peripheral baseless complaints of the previous letters, as well as informing IAS how wonderful the regulation process was, and how the New Zealand authorities were quite happy with Pfizer's information; that it met all regulatory requirements.

Pfizer continued to maintain that IAS's position was defamatory, detrimental to the goodwill and reputation of it's product and the company. Rehash, rehash.

There was one moment of hilarity for me. Pfizer took, as an example, question number 12, on page 10 in IAS's letter, and stated that in its view, IAS was "manifestly unqualified to make those statements".

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Any person or organization, when faced with absolutely clear medical literature, has a right to imply an opinion about perceived corporate hypocrisy, even when it is couched in a question.

The letter concluded with the final veiled "consequence" that ***"Pfizer reserves its rights in relation to the undertakings previously requested of IAS."***

IAS was not about to do anything it had not agreed to, which left the matter with the removal of the picture of the product bottle and information from IAS's website, and leaving the "apology" there.

However, something kept annoying me at the back of my mind. I went back and had another look at the press release referred to in footnote #14.

I contacted various media outlets, and no-one had seen the press release. I looked on the Otago Medical School website, and couldn't find it. Normally when a press release comes out, it is given a number and put on the press release page.

Curious as to the reason why the press release had been issued, I contracted someone to contact whichever parties were necessary in order to clarify whether the press release was on Otago Medical School's website. I provided them with a copy of the medical article in question as well. I wanted a neutral party to handle the issues.

The person contracted e-mailed a copy of the press release to Otago Medical School, which said that whilst it was on its letterhead, it didn't know anything about it. Otago Medical School also said that the press release never came from the medical school, or went through it, so advised the investigator to contact Wellington Medical School to get clarification from the party concerned.

A reply was received from a Professor Peter Crampton, who had no knowledge of the press release. Further clarification was sought, but no response was received.

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I decided for the first time in my life, to go down the road and buy some Pamol®!

I was keen to see just what Pfizer considered "information". The information on the outside of the bottle was not what I considered to be comprehensive information, even if it conformed to the legal requirements. But wait! The bottle said that if you wanted more information you could ring an 0800 number.

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Okay, the bottle said that if I wanted more information, I could go to a site called www.pamol.co.nz so there I went. And I have in my files a pdf of www.pamol.co.nz, which was a parked site containing absolutely zilch.

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A friend took a claim to the Advertising Standards Tribunal, on the basis that advertising a parked website on the outside of a bottle as a source of information, was false advertising. The claim was turned down on the basis that packaging information is not advertising.

In sitting back and thinking about it all, it was notable that there had been a great play in the media about how Pfizer had forced IAS to remove allegations, and misinterpretations, etc. In my opinion, the situation had been milked for all it was worth, as is done when the media is a willing participant in the game of one-upmanship. But the sentence that my eye rested on was his continual harping on about a product that was, "a 'heritage' brand, long relied on by New Zealand parents as safe and effective relief for mild pain and fever."[20]

Interesting, I thought. I wonder whether the parked site, www.pamol.co.nz is still there? I looked it up, only to find that it leads directly back to Johnson and Johnson in the USA.

In January 2008, my husband and I compared the outside of the "new" Pamol® bottle with the outside of the bottle I had bought in 2004. The information is much the same, except you are now referred to www.pfizer.co.nz for more information.

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20 2004. "Meningococcal jabs may need boost." *Sunday Star Times,* September 26, p. A13.