Insulin Dependent Diabetes Trust

January 2001 Newsletter

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2001 Another New Year

The Trustees of IDDT would like to wish all our readers a Happy New Year!

It is seven years after the formation of IDDT and I don't think any of us expected to be still here and still arguing the same case! But we are and we will continue to do so. We can do no other but continue because we are campaigning for the need for continued availability of natural animal insulins for all the people who need its production to continue and especially for those who suffer adverse effects from genetically produced 'human' insulin. Ultimately this is, and will continue to be, our primary goal but in the meantime there are interim goals that have to be met and these are determined by the changing circumstances.

IDDT Goals for 2001

- Putting the knowledge into practice

It is now an accepted fact that 'human' insulin is faster acting and more aggressive in its actions than animal insulin. There are enough 'official' statements from authoritative bodies saying that some people are not suited to 'human' insulin and may have more hypoglycaemia and reduced awareness of hypos, for this to be accepted. However, one of our goals has to be to ensure that this knowledge is known and actually used by diabetes teams so that people are readily given the opportunity to try beef or pork insulin and do not have to suffer unnecessary adverse reactions to 'human' insulin.

- Patients rights to information

We want to ensure that patients receive information about all species of insulin available to them – 'human', pork and beef. This is particularly

important if they suffer unaccountable hypoglycaemia, loss of hypo warning symptoms or other unexplained symptoms. All we are asking for is that the patients' basic Patient Charter Rights are followed. A letter to IDDT from the British Medical Association confirmed that failure to provide this right is a breach of the doctors' NHS contractual arrangements.

- Dispelling misinformation

People with diabetes are receiving incorrect information associated with animal insulin, especially about its future availability and therefore being refused prescriptions for animal insulins. It is noticeable that more and more people are telling us they have been informed that 'animal insulins are being discontinued'. For those of us that have been around since the mid-1980s, this is very reminiscent of this same damaging persistent rumour that forced over 80% of people to change to 'human' insulin. In the UK, **it was not true then and it is not true now.**

Novo Nordisk we know plan to discontinue their pork insulins, but this does **NOT** mean that animal insulins will cease to be available. CP Pharmaceuticals manufacture pork and beef insulins in vials and cartridges and they are committed to patient needs and so the continued availability of animal insulins.

Many healthcare professionals at all levels, appear to be unaware of this fact or perhaps they themselves are being misinformed. IDDT intends to have an aggressive approach to try to ensure that patients and healthcare professionals receive the correct information - that animal insulins are **NOT** being discontinued and this cannot and should not be used as reason to change people who are happy on animal insulins to 'human' insulin.

More Haunts Form The Past

'Human' insulin always did have the potential to cause hypo problems!

Modern technology has given us all the facility to search for information that previously was not accessible to us. Once again the following information exposes the truth and dates back to 1981, the year before 'human' insulin received it's fast track marketing authorisation:

- Science News, June 27,1981, Volume 119 page 119 and also in a report of a workshop held March13-15, 1981 entitled The Techniques of Recombinant DNA:

Two Eli Lilly scientists reported on several aspects of their processes for making human insulin using recombinant DNA…The two researchers agreed that the clinical trials were progressing rapidly with only one minor surprise: it appears that human insulin is absorbed slightly faster after under-the-skin injections than earlier beef and pork insulin.

- Link this with a report in the Sunday Times Supplement in 1992:

While working for Novo in 1982, Dr Gerlis wrote about it 'suppressing hepatic glucose output and causing decreased counter-regulatory hormonal response'. 'In lay terms', he says 'this means that patients could get hypos on human insulin which they might not get on pork insulin, and that the warning symptoms may be different.'

These statements mean that both Lilly and Novo knew that there could be problems with hypoglycaemia and hypo unawareness **before** either of them marketed their versions of 'human' insulin. We have to assume that this information was provided to both the Medicines Control Agency and the FDA prior to their marketing approvals – if not, then there are some very real questions to be answered.

1981 sounds along time ago but the recognition of the importance of hypoglycaemia has been understood since the early days of insulin treatment!

- So where were the ‘experts’ who advise these regulatory bodies? Why didn’t they recognise that this factor alone was sufficient to give rise to increased risks of hypoglycaemia? It is hard to believe they didn’t understand the increased risks of hypos and loss of warnings as a result of these facts but if they didn’t, then one has to question why they were ever classed as ‘experts’ in the first place!
- When people with diabetes started to report problems with hypos and loss of warnings, why were these denied by the experts, the regulatory bodies and the manufacturers when they already knew that the potential for this problem had shown itself before ‘human’ insulin introduced and licensed?

The UK class action in the early 1990s failed for lack of scientific evidence, yet we now know that before ‘human’ insulin was let loose on the diabetic community, it showed effects that clearly could give rise to the very problems of which people were complaining. There are some big questions that need answering:

- When the drug companies, the experts and the MCA and FDA already knew of the potential for these problems, why were the adverse reactions denied?
- Why were large-scale, long-term comparative trials never carried out, especially after the adverse reactions were reported by so many people?
- Would the science have exposed the truth and would the truth have meant that people with diabetes, and their doctors, would have returned to animal insulin? [It might have also meant that the class action would have succeeded!]
- Is this why ‘human’ insulin had to be defended by a PR Company and not on the basis of scientific evidence? [see Key Communications below]

Not simply a matter of history!
This is not history that we can put away and forget. The potential for more frequent hypos and loss of warnings has not been removed and people diagnosed since that time continue to be at risk of these adverse effects when treated with ‘human’ insulin. In 1995, a report from the US regulatory body, the FDA, listed the numbers adverse reactions [called adverse drug experiences or ADEs in the US] for all drugs during that year. Lilly’s ‘human’ insulin was 8th from the top [we do not yet have the figures for more recent years.] In the US consumers are allowed to report ADEs, unlike the UK, and of the total number of ADE reports, a third were made by consumers and therefore one assumes two thirds were made by health professionals or the drug companies themselves.

Our anger is justified. People were misled at the time ‘human’ insulin was introduced, they were misled when they complained of more frequent hypoglycaemia and loss of warnings and they are still being misled. Many of our doctors were misled too, as they believed what they were told by both the experts, leaders in the field of diabetes, and the manufacturers. This, however, does not mean that they should not have listened to and believed their patients!

Anger is an inadequate word for what many people will feel as they read this.
My daughter has always described the effects of her 8 years on ‘human’ insulin as “I lost my teenage years to ‘human’ insulin”. She can’t ever get those years back and the effect of losing those years changed the course of her whole life. Others have been damaged by repeated hypos, others by loss of warnings resulting in loss of job, loss of independence and in some cases loss of life [‘Human’ and animal insulin reviewed, Prof Rhys Williams et al July 1998]. Yes, anger is an inadequate word.

Bitterness is equally inadequate but we have the right to feel that as well! Not only for all the above reasons but because so many of us have been treated with disrespect by our doctors and healthcare professionals when complaining about ‘human’ insulin. We have not been believed, we have been classed as neurotic and as trouble makers.

An apology would be nice! But let us not labour under any illusions, an apology from the manufacturers is not what we will receive. An apology from all the people who have not, and still do not believe us, would be nice too, but this is not likely to happen either.

The way forward…
It is essential that we ensure that no one else with diabetes has to suffer the unnecessary adverse effects of 'human' insulin suffered by many of us or our families. It is not too late to take action but the will and determination to do so has to come from the medical and nursing professions, the researchers and the regulatory authorities in all countries, not least the UK and the US. It has to be understood that for people with diabetes, hypoglycaemia and the avoidance of it are acute daily problems and that loss of hypo warnings can have a devastating effect on their lives. It has also to be remembered that there is a whole range of other adverse reactions, which have an equally devastating effect on people's lives and we need an explanation for these.

Prevoius Haunts!

Key Comunications And Novo Nordisk
The front page of the IDDT's October 2000 Newsletter gave details from the website of Key Communications who had been employed by Novo Nordisk to "defend the safety profile of human insulin" during the early 1990s. At this time 'human' insulin was not only receiving a bad press, but the manufacturers faced the possibility of a class action against them by patients who suffered adverse reactions.

The information was removed from Key Communications' website within days of our Newsletter hitting your doormat! Not however, before it had been accessed by The Lancet as a result of a letter from IDDT's Joint chairmen – 'Academia and Industry' [Lancet Oct 13, 2000] in which we drew attention to the influence industry can have on consultants.

People who have first hand experience of the way the pharmaceutical industry works, have said that we should have expected nothing less than the involvement of a PR company. But nearly 10 years ago we, as patients, had higher hopes and greater trust!

- Is it naïve to believe that the drugs that we take should be defended on the basis of scientific evidence?
- Is it naïve to be surprised and disappointed that some of the doctors who treat our diabetes were 'media trained' by the PR company employed by the manufacturers of the drug that they were already prescribing
- Is it naïve to be surprised that these media trained doctors did not question the evidence of the drug's safety, efficacy and benefits and why there was a need for them to be 'media trained'?

Maybe we should have expected nothing less. I am sure that in future, we will all be a great deal more aware that all is not necessarily what it seems!

Born Again...

When talking to Jenny Hirst recently I mentioned that I had recently purchased a motorbike and we discussed the effects that riding it had produced on my blood sugar levels and she went on to ask me if I would pass on this experience to readers of IDDT. So here goes . . .

I have had an interest in motorbikes since the age of nine, I am now 55, and had my first motorbike on my 16th birthday. I had a number of accidents, most small, but went on to collide head-on with a car (who blindly pulled out of a junction straight into me - not my fault on this occasion!) and suffered a considerable amount of broken bones.

I recovered quickly being young and soon got another bike and went on to ride without loss of confidence but perhaps with a little more concern about what others on the road might do, although there was comparatively little traffic at that time.

My interest however was always racing. I grew up believing I would race motorbikes and, had my family bought me one, I would have gone on to do just that - but they refused! Which conveniently leads me on to say that I have always been a risk taker by instinct and my life has

followed that pattern up to the present.

With the dramatic development of motorbikes during the last decade I have spent the last four or more years wanting to get back in the saddle once again. The current terminology for sad cases like myself is ‘born again biker’. This age group, middle aged persons and older, currently make up over 60% of motorbike sales.

This year I bought my brand new dream machine - a thoroughbred racing bike with lights and number plates. I immediately found out that present day bikes bear no resemblance to those I had ridden some 30 years earlier.

Supersports bikes like mine are not just fast they are absolute missiles and it is far beyond words to describe the terrifyingly fast performance to a car driver. I drive a very, very fast car myself and I just could not imagine this sort of ferociousness. There is no comparison.

Being an insulin dependent diabetic for the last 24 years presents problems that the ‘normal’ born again biker would not have to consider. The riding experience is always an ‘adrenalin trip’ and I have to boost my sugar levels before going out and invariably when I return I test to find very much reduced blood levels despite these earlier boosts. The way that adrenalin affects my blood sugar levels was a complete surpise. Adrenalin at this level is like a starved sugar junky.

I lead a busy and very stressful life having run my own business for a number of years but even in the most hectic of times I have not experienced excitement, not to say a degree of fear, compared to riding a modern supersports motorbike. It is stupid but very addictive.

Insurance companies gave me quotations with hardly any ‘load’ for my diabetes. The general analysis for insurance is ‘how long have you had diabetes and how much (or little) insulin do you take?’ The reality should be to ask ‘what effects will this activity have and how can you be assured that you can control the condition under these conditions’.

Fortunately I have learned to adjust accordingly but it is a question of continual monitoring, learning and meeting a constantly changing physical requirement. Who gives insurance companies questions to ask that give no assurances in terms of risk and little in respect of positive value?

I once went scuba diving in the Red Sea (Yes! I did!!!) and when I told the instructor I was an insulin-dependent diabetic he replied ‘have you taken your insulin?’. ‘Yes’, I replied. ‘Well everything’s alright then’, he said and went on to take me to the sea-bed!

Now I’ve heard of risk takers but something is just not adding up . . .

For The Visually Impaired

Blood Monitoring And Taking Meters
IDDT has been campaigning for talking meters to be available for people who are blind or visually impaired. As a result of this Lifescan, US very kindly gave us two One-Touch meters and voice synthesisers for people to try and we asked for the help of any specialist nurses who had visually impaired patients who would be willing to try the synthesisers.

Patient View: Pam Bates on the Isle of Wight, wrote this piece for their Newsletter, Sweet Pea, October 2000.

“My machine was kindly donated by IDDT. As I have now got my independence back and able to do my own blood sugar testing, the island group have kindly purchased another 6 machines so that blind people on the island will be able to have the same independence as I have.

Now to hear about Bossy Boots as I have named my machine. Once you have switched the machine on his bossy voice tells you the last reading you did. It then tells you what code number strips you are using and to check them. Then it tells you to insert that code number strip

and it will tell you if you have not inserted it correctly. If it is inserted correctly, it will then tell you to place the blood sample. We then have countdown – then the fun starts!

If your blood sugar is less than 3.9 then it will tell you in its bossy voice "Call Doctor". If your blood sugar is higher than 8.7 it calls out "Control".

In all fairness I must say how grateful I am to have been donated this machine, but Mr Bossy Boots frightens the life out of me when he orders me around!"

Notes:

- The synthesisers can be attached to other meters and Pam is actually using a Lifescan Profile with her synthesiser.
- Joan Allwinkle, a specialist nurse in Edinburgh has done a lot of research into talking meters and progress has been made. The RNIB are going to advertise the availability of the Lifescan Profile Meters and Synthesisers, obtained from the US with full guarantees etc.
- The cost is another issue and we would strongly recommend that patients in need of these devices, with the help of their diabetes specialist nurse, approach their local health authority for funding

One step forward and two steps back

This is progress and undoubtedly has given Pam back her independence that she had lost. But it has also highlighted another problem – actually getting the blood on to the strip when you can't see. This is a messy, unsatisfactory and inaccurate process, but guess what? Nobody makes a device to enable the blind and visually impaired to physically be able to aim the blood on to the strip. Once more we have searched for such a device in the US and in Canada but without success. A little platform device could easily be designed to do this.

We Need Your Views Please

As members know, our quarterly Newsletters are produced in large print for people with visually impairment and we currently have about a dozen people receiving it in this form. We have received a request from a member to have the Newsletter put on tape and she has suggested that we ask if many other of our members would benefit from this facility.

We considered this possibility some years ago but frankly could not afford to do it then as it is a bit more complicated than it sounds. We have looked at the costs again and are now in a position to be able to afford to do this if there is a sufficient need amongst our members. We would be grateful if people who feel that they would like to receive the Newsletter on tape could have the slip below filled in and returned to me or telephone their view to IDDT. Filling in the slip is not a commitment on your part to having the Newsletter on tape, it will simply enable us to assess the need and review the costs more effectively.

Yes, I would welcome the IDDT Newsletter on tape

Name _____

Address _____

_____

Postcode_____

Return to IDDT [T],
PO Box 294,
Northampton
NN1 4XS or
Telephone 01604 622837

Driving Update

In the Autumn Newsletter we informed you that Lord Whitty, Minister of Roads, had announced that the government will review the scope for more individual assessment in the licensing for drivers with diabetes of light vans and lorries [category C1 vehicles]. So there is now an ongoing review of the existing arrangements. However at the same time, the DVLA has started research into the risk factors to help to draw up an individual assessment model but this will take up to three years to complete. Lord Whitty has said that any changes in advance of this research would have to be agreed by a wide range of interest groups during a public hearing.

This suggests that the original advice of the government's Medical Advisory Panel on Driving and Diabetes is not going to be changed easily or without evidence from research. Clearly this is going to take time and will be difficult for people affected by the restrictions. But it appears to be a sensible approach to what is now a difficult situation as we are all only too well aware of the dangers of driving with loss, or partial loss of warning symptoms of hypoglycaemia. However, many risk factors for driving light vans and lorries must also be risk factors for driving all vehicles - so we must hope that there is not a knock on effect for drivers with diabetes of any vehicles.

US - More Compassion For Cats!

The Food and Drugs Administration [FDA] in the US has now approved the importation of PZI beef insulin for cats with diabetes on the grounds of compassionate use. Great for the cats but no such arrangement has been made for human beings who need beef insulin!

Since the discontinuation of beef by Lilly, US citizens have to jump through tremendous hoops, and be able to afford to jump through these hoops, in order to obtain the beef insulin from the UK. One of the major problems is that not only do they have to have a doctor's prescription when insulin is an over the counter medicine in the US, but they also have to have a doctor's letter saying that they cannot use 'human' insulin. While many of us are animal lovers, it is understandable that there is some anger in the US when cats with diabetes are shown more compassion than people!

CP Pharmaceuticals Action In The US

For those who want and are able to import beef insulin for their personal use, arrangements have been made so that this can be done directly with CP. In addition, CP have been trying to obtain marketing approval for their beef insulins but this is proving very difficult. To clarify the position CP have given IDDT the following statement:

"CP applied for marketing authorisation for beef insulin in 1999, but the application was turned down. CP representatives were present at a meeting of the FDA that was designed to validate and make transparent how they make their decisions. The reasons for refusal even to consider the application were twofold:

1. Insufficient bio-availability data; CP knew that this would probably be the case when the application was submitted, but they needed to know the extent of the "deficiencies". It is arguable whether any new data is required – the Swiss, Finnish and now Swedish regulatory authorities needed none, but CP is prepared to conduct the additional testing.
2. The FDA stance regarding BSE; Even if CP had been able to comply with the requirements for the required dossier, their application would have been refused. The FDA insist on having proof of the absence of the BSE prion, even though one can never prove a negative. The British, Australian, Finnish and Swedish authorities have no similar concerns - or if they have them, have accepted the fully documented assurances of our suppliers and ourselves. There is no way, for the time being, round this obstacle. For the time being, until the FDA recognises that a validated analytical

test for the BSE prion exists, there is no way forward, despite CP's very considerable efforts. Having no way forward dissuades CP from generating any further bio-availability data at considerable expense, that the rest of the world does not require."

A Date For Your Diary

The Trustees are very aware that our Annual Meeting in Birmingham is too far for some people to travel for just a day. We were also very aware at the last meeting that we really were short of time for discussion, as well as having our main items of the day. So we have decided that we will start the meeting on Saturday morning and extend it to an overnight stay, finishing with lunch on Sunday. The weekend will be May 19th-20th, 2001 and will be at the Comfort Inn, Hagley Road, Birmingham [NOT the centre of Birmingham!] We will be seeking sponsorship so that the cost to you will be subsidised. The whole weekend including meals will cost delegates £20.00 each and if you just want to come for the day, the cost will be £10.00 each.

We hope that this means that many more of you will be able to join us at the meeting as it would be good to get to know many more of you and hear your views and you will also be able to meet the Trustees.

Further details will be sent to you in the coming weeks.

You Really Wanted To Know This!

Last year research was published that showed that body mass index [weight in relationship to height] was the primary fact that determined female attractiveness for men. It has been suggested that women's choice of what makes a man attractive is not so simple. A recent letter in the Lancet has attempted to clarify this problem. 30 female students were shown photos of 50 headless men with different waist/chest measurements, different waist/hip measurements and different weights. It seems that the waist/chest measurement is the key to whether the women found the men attractive and women prefer men shaped like an inverted triangle - broad shoulders and chest with a narrow waist. So for women, it is shape and not size that determines the attractiveness of men. Interestingly, though, women rate attractiveness in women the same way as men - weight being the important factor.

News From The Department Of Health

FUNDING THE INSULIN PUMP – DoH recommendation
Readers will recall that in previous Newsletters we have provided information about the use of insulin pumps. We did this on the basis that using an insulin pump is another option that people with diabetes should know about but at the same time we did point out that pump therapy is not suitable for everyone. We also pointed out that the purchase of the pump is expensive and that it has not been routinely available through the NHS.

In August 2000 the Dept of Health announced that hospital consultants can prescribe insulin pumps on the NHS if there are sufficient local funds to do so. They can also prescribe the equipment either permanently or on loan but the final decision rests with the local Health Authority. So pump therapy on the NHS still remains very much dependent on where you live. This announcement by the DoH does not seem to have moved this issue forward very much because if the pump was deemed clinically necessary for a patient, then the consultant has always been in a position to apply to the Health Authority for funding on the basis of need.

NB. Some people who have been persistent have received funding. A letter in the Formby Times, 23.3.00, from a student who wanted to go on to the pump but could not afford, explained that she contacted her local MP who took this issue up and the local health authority agreed

to fund her insulin pump. This is encouraging because it shows that persistence on the part of the patient and support from the local MP has resulted in the Health Authority paying for this patient's needs.

The Yellow Card Scheme Has Been Updated

The MCA and CSM have issued a new leaflet entitled ***'Information for Patients about the Yellow Card Scheme'.***

What is the Yellow Card Scheme? It is the system in the UK for monitoring information on adverse drug reactions [ADRs] and it was started in 1964 as a result of the thalidomide tragedy. It is run by the Medicines Control Agency [MCA] on behalf of the Committee on Safety of Medicines [CSM].

Who can report adverse drug reactions?
Doctors, dentists, coroners, pharmaceutical companies and more recently pharmacists are allowed to report adverse drug reactions. IDDT supports the decision to include pharmacists because many patients may feel easier talking to their pharmacist, who may have more time to listen and do the paperwork. The added advantage is that it may increase the numbers of reports – very necessary because the MCA has told IDDT in the past that ADRs are grossly under-reported by an estimated 90%! This new leaflet says that since 1964 the MCA has received 400,000 Yellow Cards so if my sums are correct, this means that about 3.5million suspected ADRs have not been reported during this time!

NB. Unfortunately patients are not allowed to report their ADRs directly to the MCA, but have to report them to their doctor or pharmacists who will then decide whether to make the report or not.

What is new about the Scheme?
The MCA has collected information that could identify the patient but now they have adopted a privacy policy so that the patient's name and date of birth are not requested. In future only patient's initials and a local identification number will be used so that there can be correspondence with the reporting doctor or pharmacist.

More Information
Yellow Card Scheme information can be obtained from The Pharmacovigilance Group, Post Licensing Division, Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ or by looking at the MCA web site at: www.open.gov.uk/mca/mcahome.htm

Information about the drugs you take
Apart from the obvious source of reading the Patient Information Leaflet before you take a drug, there are other sources of more detailed information that can be found in your local library or on the internet:

- The ABPI Compendium of Data Sheets and Summaries of Product Characteristics at www.abpi.org.uk
- The British National Formulary [BNF] at www.bnf.org

No Secrets

The National Institute for Clinical Excellence [NICE]
This is the body to whom government refers drugs for appraisal and its members advise ministers on which drugs should be made available on the NHS. Until now the Institute has tried to keep provisional decisions secret. When the Institute was established in 1998, drug companies argued that the appraisal process should be carried out in secret because announcing provisional rulings could adversely affect share prices and could cause unnecessary anxiety for patients.

But NICE has now voted to publicly disclose its provisional rulings following the 'leaking' of recent provisional decisions of controversial drugs to the press ahead of a final decision. Prof Sir Michael Rawlins, Chairman of NICE, told the BBC: "There are large numbers of people involved in the consultation process, and while NICE can guarantee

the integrity of its own processes, we can't control what others might do and therefore confidential documents have been regularly leaked."

How does NICE work?
The provisional decision is the initial view taken by the Institute's appraisal committee on whether a drug should be available on the NHS. After making that provisional ruling, it consults patients' groups and drugs companies who can make their case for or against that decision. An appeal panel can order the committee to reassess their guidance and after further consultation, a final decision is made.

Nurses To Prescribe

On October 26th the government launched a Consultation Paper suggesting that 10,000 nurses are trained to prescribe treatments ranging from minor injuries like burns and cuts, to chronic disease management including asthma and diabetes. At the launch Lord Hunt, Health Minister, said: "We have allocated £10 million from 2001 to 2004 to train more nurses to prescribe. This consultation is a key move to help provide patients with improved access to medicines and to help break down artificial barriers between professions. Our commitment to extend the formulary from which nurses can prescribe and widen the range of nurses who may prescribe, was reinforced in the NHS Plan, published in July this year. It will offer quicker and more efficient access to medicines and help us meet the demands for a modern NHS for the 21st century."

The Royal College of Physicians support this and their President, Prof Sir George Alberti, said: "We greatly welcome this new initiative. It is a logical extension of the role of many nurses, and will certainly improve the smooth management of the variety of conditions and diseases. Patients will certainly benefit."

An Alternative Place To Prick Your Finger

Many people find that the finger pricking is one of the worst day to day things about having diabetes and aiming for tight control means more daily tests. Not only can obtaining blood be painful but it can also make the finger tips sore – the very area of the finger that many people use the most. Below is part of an interesting article by Ron Raab. Ron has had diabetes since childhood and tests 3 times a day and is a Vice President of the International Diabetes Federation. Ron's method will not suit everyone but it is worth a thought!

The most commonly performed method involves using a spring-loaded device and penetrating the finger on the front tip. However, I have been using the **BACK** of my fingers and thumbs since the early 1980s and have found that this is an easier and preferable site. I do not use the spring-loaded device. I simply place the open lancet on the back of the finger at various positions around the U-shape where the nail meets the finger and penetrate the skin gently 1 or 2 mm from the nail.

The pain is less because one is in total control of the amount of pressure applied and because there are fewer nerve endings on the back of the finger than the finger tip. I have found the least painful position to be at the bottom area of the U-shape, not the sides. There is some variability and it is important for the individual to experiment to find out what is the most satisfactory.

The force applied by the spring-loaded device cannot be varied and may often be much more than is needed to draw the blood. By pricking the finger in the above way, various controllable forces can be applied.

Having done this for more than 13 years, I am obviously a strong advocate and suggest that others consider it and then make the choice. It could also be used in a rotating fashion to give the finger tips a rest. Keyboard operators, musicians and other people who use their fingers a lot may find this suggested site and technique of particular use, but certainly many other people who do not fall into these categories may also find them preferable.

We are all creatures of habit and often people are resistant to new ideas. Change can involve anxiety and apprehension until it becomes routine. Perfecting the new technique may take a few days. For example, slightly scraping the skin [which is virtually painless] may result in more blood than by pushing more deeply. Getting the blood on to the strip does require turning the finger over after the drop is obtained and again this technique comes with practice.

Reasons why this method is less painful

- I use the thinnest lancet, 30-gauge, so that the size of the puncture is smaller. One may think that it would be difficult to obtain enough blood with the thinnest lancet, but I have been able to obtain enough blood easily. [One can consider using an insulin syringe to puncture the skin if the thinner lancets are not available.]
- Using the manual system also makes it less painful. It may not be necessary to penetrate the needle to its maximum width, which is what normally happens when a spring-loaded device is used.

The ease and virtual painlessness of this technique has certainly contributed to my testing my blood more often.

Ron Raab B.Ec.

Medicines Control Agency Publicly Responds To IDDT

The Medicines Control Agency produce a bulletin every month to keep doctors and health professionals up to date with information about drugs called 'Current Problems in Pharmacovigilance.'

Volume 26, September 2000 contains the following statement:

"The Insulin Dependent Diabetes Trust, a patient representative group, has recently circulated a letter to some health professionals entitled 'Important Safety Information on Human Insulin' which suggests that there are concerns about the safety of human insulin.

A considerable number of scientific studies have been performed comparing animal and human insulin and the CSM [Committee on Safety of Medicines] has considered the available evidence on a number of occasions.

Although some patients have experienced problems on transferring from animal to human insulin, and some patients may be better suited to animal insulin, there is no evidence of a specific safety problem with human insulin, which is well tolerated by most patients.

We would like to reassure health professionals that there are no concerns regarding the safety of human insulin."

What a bold and brave statement for the Department of Health to make in the year 2000! It seems once more that the issue centres round the definition of 'safety'. IDDT has informed Lord Hunt that in previous correspondence with the MCA, they defined safety as 'an absence of harm'. Hypoglycaemia itself has the potential for harm and we have pointed this out to Lord Hunt too. The more aggressive action of 'human' insulin has the potential for more frequent hypos. It may cause loss of hypo warnings is admitted in the data sheets for 'human' insulin, in the British National Formulary, in MIMS, by diabetes associations round the world and by most diabetologists. Just how much proof of harm does he, the MCA/CSM and their experts require?

The British National Formulary states:

- Hypoglycaemia is a potential problem for all patients receiving insulin and careful instruction to the patient must be directed towards avoiding it.
- Loss of warnings of hypoglycaemia ….can be a serious hazard, especially for drivers and those in dangerous occupations.

Is this an absence of harm?
The Government's own Advisory Medical Panel for Driving and Diabetes has stated:

- The greater restrictions on driving of light vans and minibuses, is based on the risks and the dangers, [or 'potential for harm'], that hypoglycaemia and the loss of warnings can cause.
- The DVLA withdraw driving licences for drivers of any type of vehicle if there is loss of warnings and in many cases the newly diagnosed are advised to stop driving until it is clear that they have hypo warnings.

Is this an absence of harm?
It is not logical that one government department, the DoH, does not recognise the dangers of hypoglycaemia and 'the potential for harm' while another one, the Dept of Transport, takes the opposite view and brings in tighter driving regulations for that very reason.

The patient/carer perspective: "Hypoglycaemia screws up your life".
I didn't quote these words to Lord Hunt but this is a view held by many, though often expressed differently! Maybe only the people who suffer from frequent and/or severe hypos and/or loss of warnings can really know just how true these words are:

- Avoidance of hypos is an acute daily problem for people with diabetes.
- It means frequent blood testing – inconvenience and sore fingers.
- It can result in coma, seizure and even death.
- It can cause confusion, inability to concentrate, aggression and violence.
- Frequent hypos over time can cause a reduction in cognitive function.
- Hypoglycaemia itself can cause loss of warnings with a subsequent worsening in quality of life and loss of independence. Some people become afraid of going out unaccompanied because of blackouts without warnings. They can lose their jobs, their marriages and relationships. [Quote from Prof Amiel at an IDDT Annual Meeting]

I ask Lord Hunt, the MCA and their experts, is all this an absence of harm?

IDDT's position has always been, and will continue to be, that it is well documented that 'human' insulin may cause more frequent hypos and loss of warnings and this itself is not safe. It seems pedantic and pointless to argue that 'human' insulin per se is safe when the well-acknowledged problems that it causes in some people, patently are not safe and can cause harm.

And So The Discussions With Lord Hunt Continue...

I have been just waiting for him to cite the evidence from the review of 'human and animal insulin carried out by the then Cochrane Diabetes Group under Professor Rhys Williams funded by the then BDA! And he did, in his letter of October 16th 2000! Readers will remember that in the Autumn 2000 Newsletter there was an article pointing out that there are now 3 versions of this review:

- the original dated July 1998,
- the one on the BDA [Diabetes UK] web site dated July 2000 which for whatever reason, omits the section about deaths associated with 'human' insulin,
- the version published in Diabetic Medicine 2000;17 which is bears little ressemblance to the original review.

Needless to say, Lord Hunt quotes the latter! IDDT has, therefore sent Lord Hunt and the officials at the MCA, a copy of the original 1998 Review and highlighted the missing section on page 5 of the original review:

"The following observations can be made from this body of evidence:

- Increased frequency of hypoglycaemia and reduced awareness of impending hypoglycaemia do occur when people are transferred from animal to 'human' insulin.
- In some cases [probably a small number] these phenomena may lead to death.
- It is not possible to determine, from the evidence available, how commonly these phenomena occur.
- From mortality data it is likely that any association with sudden death is uncommon."

In this I feel a little sorry for Lord Hunt, clearly he is not in full possession of the facts and perhaps he is the victim of believing that everything that is published in a medical journal is bound to be true, correct and unbiased!

But what about his expert advisers from the field of diabetes? It is hard to believe that the expert advisers to the MCA knew nothing about the original Cochrane Review. It was presented in its entirety at the BDA Medical and Scientific Section Conference in May 1999 and it is equally hard to believe that none of these expert advisers were amongst the delegates! But that is one for our imaginations…

What about the frequent reassurances we receive that the CSM is constantly monitoring new information? Just how careful is this monitoring if all the experts knew nothing of the original Cochrane Review.

Rebuked Again!

Lord Hunt's letter again rebukes IDDT for circulating the Aventis safety information that "Human insulin therapy may be associated with hypoglycaemia, a worsening of retinopathy, lipodystrophy, skin reactions, allergic reactions, sodium retention and oedema".

He points out that this could cause unnecessary alarm to patients and healthcare professionals and this is why they have issued the statement. The fact that the statement is made in a DoH bulletin that is only for health professionals seems to be an ineffective and impractical way of reassuring patients!

I would suggest to Lord Hunt and his advisers that if they think this information causes alarm amongst patients, can they imagine the alarm felt by people who can no longer obtain their animal insulin? They face a future life that they know is one of a deterioration of their health and well being as a result of adverse reactions to 'human' insulin!

Rebuke or not, IDDT will continue to keep people with diabetes fully informed. The past experience of being kept in the dark about the problems with 'human' insulin has taught many of us valuable lessons – no one looked after our interests then and there is little evidence that this has changed since!

Avandia And Actos

In the Autumn 2000 Newsletter, we gave information about Avandia [rosiglitazone], the new drug for Type 2 diabetes treatment. In addition to listing the adverse effects of Avandia, we warned that NICE [National Institute for Clinical Excellence] advised the following:

- it should not be used in patients with heart failure, liver failure or severe renal insufficiency.
- it should only be used when control cannot be achieved with combinations of the traditional drugs, metformin and sulphonylurea.
- it should be added to other tablets rather than substituted for them and there is no evidence that adding Avandia to metformin or to sulphonylurea is any more or any less effective than the combination of metformin and sulphonylurea.

Avandia belongs to the same class of drugs as Troglitazone [Rezulin in the US], withdrawn in the UK only 6 weeks after it received its marketing

licence from the Medicines Control Agency and withdrawn in the US 29 months after marketing approval by the FDA following at least 90 directly related deaths. There are many unanswered questions and law suits pending from patients or their families.

We make no apology for repeating this. Patients need to be aware of the facts, especially when one sees the adverts for Avandia to the medical profession – it sounds like the answer to a prayer!

- Diabetic Medicine [Diabetes UK/BDA Journal]– "I think CONTROL of type 2 diabetes will reach new heights".
- Diabetes Care [American Diabetes Association Journal]– "REDEFINING type 2 therapy".

To find the warnings we have described, doctors have to read the very small print which in Diabetic Medicine for example, is on a heavy blue background making it extremely difficult to read!

It seems our concerns are justified. On October 31, 2000, Reuters reported that SmithKline Beecham, manufacturers of Avandia, have been warned by the FDA in a public letter, that they were 'seriously concerned' that some of their advertising materials for Avandia had 'minimised the precautions' regarding liver damage. The FDA also said that the some of the adverts 'failed to mention any liver-related precautions, which include routine testing to look for early signs of harm' and in terms of effectiveness the adverts 'suggest that Avandia is more effective than has been demonstrated by substantial evidence'.

Confusion reigns!
The US ads say it is for treatment on its own or in combination, but the UK ads say it is for combination therapy only. Who's right? Where's the evidence?

If this is not enough, we now have a situation where in some areas prescribing committees are insisting that Avandia should only be prescribed by consultants. Equally there are areas where GPs have been advised not to start Avandia treatment themselves nor to take responsibility for the drug if the hospital consultant starts the treatment.

Diabetes UK Nov 2000, in a mailing to health professionals stated that they are 'concerned that this confusion may restrict access to Avandia for many people with diabetes and feel that health professionals who are competent to prescribe it should be able to do so.'

Perhaps people with diabetes should be asked if they actually want access to this whole family of drugs! There is no evidence of benefit over combinations of existing drugs, some GPs being advised not to take responsibility for it, risks of liver damage and other side effects, surely this is a case for 'back to the drawing board' for this family of drugs. Let us have more research that demonstrates any clear benefits from them and benefits that significantly outweigh the risks before it is used on us, the patients! If this isn't enough, read about the other new one…

ACTOS [pioglitazone] is another drug in the same family made by Eli Lilly and Takeda, Japan's largest drug company, available in the US since August 1999 and approved and launched in the UK in November 2000. NICE is expected to issue guidance on its use in early 2001. A report in the Financial Times says that Takeda Industries has warned Japanese doctors of the 'potential dangerous side-effects of Actos'. The Health and Welfare Ministry urged the manufacturers to issue warnings after five of the 90,000 Actos users in Japan suffered non-fatal heart failure two of whom were also taking other drugs.

Latest News: Takeda has now joined the Health Ministry in warning that Actos may be linked to heart failure but the company and the ministry are leaving the decision whether to prescribe the drug up to individual doctors. A warning has been attached to its packaging cautioning that it not be used for patients with liver problems. Takeda said that in the US there have been about 40 reports of possible side effects among Actos users since sales began there.

Unbelievable Or What?

I know that many of us have difficulty understanding US politics and the Presidential election has proved it, but the following adds incredulity too! Clearly there are no holes barred when it comes trying to ensure that the best interests of industry are served!

The President of Eli Lilly [ref1] openly wrote to all their shareholders to say that they opposed Vice President Al Gore's proposal as "it would severely undermine the financial incentives for pharmaceutical R&D and delay cures for patients." He goes on to say that they support Governor George Bush.

During the campaigning healthcare was a major issue as US citizens, especially the elderly, have been taking organised bus trips to Mexico and Canada to obtain the drugs they need at a price they can afford. Maintenance of the high price of drugs in the US and opposition to price controls are very important issues to the pharmaceutical industry and they have been lobbying hard with high amounts of sponsorship money to support the candidate that would best look after their interests. ['Profits Obscene says US Senator' IDDT Autumn Newsletter 2000.]

Ref 1: Lilly's website accessed November 3, 2000

The Diabetes National Service Framework [NSF]

A disclaimer, if you like!

Many of you will have read that certain health conditions are being looked at to determine the best way forward to achieve good care and equal standards of care for everyone wherever they live – called a National Health Service Framework. Diabetes is one of these topics.

An Expert Reference group [ERG] was set up to advise the Minister of Health. The patient representation consists of only two people with diabetes and no carers. IDDT made representations to the Chairman of the ERG to say we felt that this was insufficient representation. However, we were told that this was not so and that other people would be involved through various focus groups. The Department of Health has worked closely with Diabetes UK on this matter and IDDT has had no involvement with the Diabetes NSF at all.

'Getting the Basics Right' – the title of a position statement put out by Diabetes UK in October 2000 lists their priorities for the Diabetes NSF that have been gathered from a series of workshops with healthcare professionals, committee members and people living with diabetes. Without going into all the details, there are a couple of glaring omissions from their list of priorities:

- Under 'Information and Education' it recommends initial and ongoing education for all, using appropriate and effective means – particularly with information on pregnancy and ketoacidosis. When the present treatment is for near normal blood glucose levels with a proven threefold increased risk of severe hypoglycaemia, it is amazing that there is no mention anywhere of hypoglycaemia and loss of warnings.
- Equally nowhere in the list of priorities is there a mention of family carers and the need for them to have information, education and access to diabetes services. Yet there is a whole list of people mentioned – those in institutional settings, older people, children, adolescents, pregnant women and those with visual impairment or limited mobility. Nearly all these people benefit from help from family or community carers, and yet there is no mention of the needs of carers!

The final document has yet to appear but at the moment it seems that our request for greater patient/carer representation was well justified. In the meantime we are letting you, our members, know that, on your behalf, IDDT did try to ensure that there was greater patient/carer representation.

Note: Looking at some of the quality of life research might also help establish the priorities of people with diabetes. One such study [ref1] has shown that quality of life was significantly reduced by the dependence on insulin, the presence of depression, the presence of retinopathy and the presence of other diabetic complications. It also showed that adults with diabetes would be prepared to trade off 12% of their remaining life in return for a diabetic-free health status.

Ref 1 Quality of life assocoated with diabetes mellitus in an adult population. J Diabetes Complications 2000 Jan-Feb; 14[1]:18-24

What Irritates Me...

Following up on our original request for your grumbles about diabetes related issues, IDDT received the following:

- Books and information leaflets about diabetes and its complications for patients appear to be very basic. Having had diabetes for many years, I am now facing some of the complications and I would like to know more than just the basics. I want to read more in depth information about my condition, to know about the likely progression of my complications and I also want to be able to have enough knowledge to be able to discuss these issues with my doctor. The books written for doctors are too complicated and there seems to be nothing in between.

Jenny's comments: I discussed this with our 'irritated' member and we thought it would be a good idea to ask readers if they could recommend any books they found useful and we could then publish the details in future Newsletters. Just let me have the title, the author and the publishers.

- What irritates me is the serious issue of the use of people with diabetes in films and TV dramas. I have seen at least two examples where a 'character' becomes weak and faint and is said to 'need his insulin'! The hero gets some and suddenly he is fine! Surely he is having a hypo and the last thing he needs is insulin! There is a serious lack of public awareness regarding the balancing act of diabetes and it is certainly not being helped by inaccurate portrayals like this, especially when all that is needed is a little research on the part of the writers.

IDDT Does Not Support Unlawful Methods Of Importing Beef Insulin Into The United States

It has come to our notice that some people are advocating and/or using methods of obtaining beef insulin from the UK that are not within the laid down regulations for people in the United States. The Insulin Dependent Diabetes Trust [IDDT] is not involved in disseminating information about these methods and in no way condones them.

We fully understand the desperation people in the US feel now they are being denied their beef insulin but there are legal methods of importing beef insulin into the United States for personal use. IDDT recommends that these are the only methods that are used.

Detailscanbefoundonourwebsitewww.iddtinternational.org by clicking the map of the US or on the web site of CP Pharmaceuticals Ltd, the UK manufacturer of beef and pork insulins www.cppharma.co.uk

Lilly Withdraws Some Of Their 'Human' Insulin Products In The UK

IDDT informed members last October that Lilly are to withdraw a number of products from their synthetic 'human' insulin range – these

are Humulin insulins. Lilly told the UK Pharmaceutical Journal that the products would be phased out over the next 6 months but this would be dictated by the speed with which the demand fell but they expected most products to remain available until March 2001. Lilly also said that the changes are being made so that they can focus on producing the insulins that are used by 'the vast majority' of patients. Nothing new there then!

Just to remind you, the products to be withdrawn are:

- All Humulin M1 products [10/90 premixed insulin]
- All Humulin M4 products [40/60 premix]
- Humulin I Humaject and 1.5ml cartridges [isophane]
- Humulin S 1.5ml cartridges [soluble]
- Humulin M2 Humaject, 1.5 ml cartridges and 10ml vials [20/80 premix]
- Humulin M3 1.5ml cartridges [30/70 premix]
- Humulin M5 1.5ml cartridges [50/50 premix]

All other products including Humulin Lente and Humalog and will remain available

How will this affect people using Humulin?

- People using M1 and M4 will have to change insulins. The options are to change to different premixes of Lilly insulin, to Novo Nordisk premixed insulin or to draw up in a syringe the same mix of Humulin I and Humulin S as the premix that has been removed – just like we used to do in 'the old days'! People who are visually impaired will not be able to do this and so they will be forced to change to one of the other options.
- People using Humulin I, Humulin S, Humulin M3 will not be able to obtain this in 1.5ml cartridges but all other forms are available, including cartridges for the 3ml pen. The drawback to the withdrawal of the 1.5ml pens is that children with little hands will have more difficulty handling the larger 3.0ml pen. Some of us have been around long enough to remember that one of the main selling points for the pen was that it was so much easier for children!

It does seem that the two most vulnerable groups, children and the visually impaired are the ones that will be most affected by these changes.

You should discuss all your options, including changing brands of insulin to Novo Nordisk, with your hospital diabetes clinic or your GP.

How is Lilly handling this changeover?

Lilly, through Diabetes UK, have informed health professionals that:

- they estimate that 54,000 people will be affected by the changes, in many cases by having to change from a 1.5ml pen to a 3.0ml pen and about 20,000 people will no longer be able to access the insulin they were using.
- they will supply new pens free of charge at specialist clinics.
- they are working closely with the diabetes community to ensure that everyone understands the changes and the potential implications
- they are funding a team of nurses for the NHS to help with the transition.

At least Lilly has learnt from past mistakes - the changeover from animal to 'human' insulin in the 1980s was done in many cases without even telling patients! Nevertheless there are similarities – in this case 54,000 people are going to have to change their present regime because of rationalisation by the manufacturers. Rationalisation in business all too often means more profit for the business and less convenience for the customer!

But some of this seems a bit strange

Pens are available on an NHS prescription now, so why do Lilly need to give them away? What happens in the areas that that do not have these special clinics? Is the team of nurses that Lilly will be funding for the NHS a new team of nurses or are existing nurses within the NHS going to be paid by Lilly? Are they going to remain a permanent feature within the NHS? Patients need to know which nurses are paid by Lilly – perhaps they will wear badges saying 'Lilly Nurse' in a similar way to

those who are supported by various charities.

Further information from Lilly on 0800 0850 777 or website www.lillydiabetes.co.uk

Humalog - Report From Lilly Research Centre, Surrey

Humalog is what is called an insulin analogue and there are two types of Humalog – the original short-acting one and a newer short/long mixture one. The other insulin manufacturers have their own versions of these analogues, NovoRapid from Novo Nordisk and LANTUS from Aventis.

An interesting report about analogues has been published by Lilly [ref1] saying:

- Fast-acting analogues as well as slow/fast-acting mixtures allow better control of post meal blood glucose levels in both Type1 and Type 2 diabetes than short-acting and mixtures of conventional insulins. [All studies compared analogues with 'human' and not animal insulin]
- When used alone short acting analogues do not improve basal glycaemia but twice-daily injections of analogue mixtures allow an average lowering of blood glucose levels of 1.8mmols/l when compared to conventional mixtures.
- Most studies did not find a reduction in HbA1c levels with analogues but when this was the case, it was observed more frequently in people with Type 2 diabetes.
- A reduced incidence of delayed hypoglycaemic attacks, said to be one of the most attractive features of analogues, was only reported in a minority of the studies. Again this was more frequently reported in people with Type 2 than Type 1 diabetes.

The report goes on to say that the reduction in complications relies on lower HbA1s levels and not on post-meal blood glucose levels but that most studies suggest that analogues are at least as efficient as conventional insulins on HbA1cs but possibly not more so.

What Conclusions can we draw from this? Remembering this report was published by one the manufactures of analogues there could be a temptation to paint analogues in their best possible light. So it is interesting that they are saying that Humalog has no advantages over treatment with 'human' insulin nor that it improves overall control. In addition, an increasingly quoted reason for prescribing Humalog is to reduce night hypos and yet the report says "the majority of studies do not support the belief that Humalog lowers the risk of nocturnal hypoglycaemia". So is its only advantage a practical one - that it can be injected immediately before eating?

It does appear to have some benefits in Type 2 diabetes which the report describes as surprising. If their results are confirmed then this opens a huge market for analogues!

Ref 1 Diabetes Metab 2000 June; 26 Suppl 3:52-6

From Our Own Correspondents

Diabetic Commonsense, by Beatrice Reid
Dear Jenny,

Thank you for your August mailing. I think Beatrice Reid's book is the best advice to people with insulin dependent diabetes I have ever read in my 40 years as a diabetic. Will you please send me two more copies.

Congratulations on the splendid work that you are doing.

Mrs B J
Wales

Jenny's comments: This is only one of many similar letters praising Beatrice for her book. IDDT has received many requests for more copies, even one request for 150 copies! On your behalf I would like to thank Beatrice for writing her book that has meant so much to so many people. I have tried to analyse why the book has struck such a cord with those of us that live with diabetes and it is just what the title says – a common sense approach to living with diabetes. At the same time it clearly demonstrates the balancing act that is life with diabetes and I would suggest that Beatrice became the first advocate for patient empowerment long before the expression was invented! Copies are still available from IDDT and you will find it on our website by visiting www.iddtinternational.org

What would they think now!
Dear Jenny,

Thank you for the last Newsletter. The more I read about 'human' insulin and the experiences of poor unfortunate people who are more or less forced to take it, the more astonished I am.

For those who seek excitement my advice is to not waste your money on hand gliding or bunjy jumping, just take yourself along to the nearest doctor and ask for daily injections of 'human' insulin. You will find that your days are filled with excitement – climbing on a knife edge in fact, never knowing what's going to happen next! I say to doctors and healthcare workers, for goodness sake stand up and be counted and admit that 'human' insulin is one of the worst things to happen to the treatment of diabetics since 1921. [I say diabetics and not diabetes so that we remember that we are talking about real people.] Can insulin that has adverse effects on so many people plus the propensity to give more injections, really be progress? I cannot help but think of two very compassionate men who must be turning in their graves – Banting and Best!

Mrs J.R.
North West

Aventis's admission

Dear Jenny,

The appalling responses to the IDDT Newsletter's discussion of Aventis's admission regarding 'human' insulin while sad, comes as no surprise. [Summer and Autumn 200 editions]

After being insulin dependent for over 40 years, and in good health for over half of these until I was prescribed 'human' insulin, I believe that many diabetic clinics have now reached a situation when the safety of 'human' insulin can no longer be asserted after years of prescribing the substance. The ensuing attempts to resolve its problems would be humorous if they were not so tragic.

Having constant and dramatic fluctuations in my, once excellent, control and experiencing hypos without any warning [together with hyperglycaemias that occur without any obvious cause], the doctor at the diabetic clinic advises me to 'run them high', i.e. have high blood sugars to avoid hypos.

I would like to add two comments here. Firstly, a diabetic having problems when using 'human' insulin may find these continue even after changing to animal insulin – 'human' insulin can have a permanent detrimental effect. This is my own situation and even the BDA has acknowledged that problems caused by 'human' insulin may continue after changing to animal insulin. [Balance, March/April 1999] Secondly, we should remember that animal insulin has its serious shortfalls too and we should be looking for an alternative to insulin. Unfortunately, in view of the extraordinary profits derived from insulin sales it is hardly surprising that no serious research has been conducted to find an alternative.

Something is clearly going amiss and sadly, it would seem that greed and a total disregard for health and well-being is the cause. Indeed, this is made abundantly clear by some of the responses received by IDDT concerning the dangers of 'human' insulin.

Dr DJN
South East

Parents Part

SCHOOL BOY BANNED FROM FOREIGN SCHOOL TRIPS – the conflicts, the ramifications

By Jenny Hirst, a parent

Last October the media [ref 1] reported that a 15year old school boy, Tom White, was being banned from going on foreign school trips because he had diabetes. The case hit the headlines because his parents are taking unprecedented legal action against his school by using the Disability Discrimination Act 1995. However, we need to read more than the headlines before getting angry at what appears to be a grossly unfair situation.

In fact Tom was not banned simply because he had diabetes, he was banned because on a school skiing holiday earlier in the year he had his first severe night hypo. The Chairman of the Disability Rights Commission is quoted as saying "It is blatantly unfair to ban Tom because he has had one severe hypo. There is no justification for this. A disabled pupil should have access to the same opportunities as everyone else."

Now doesn't this raise a whole load of issues, not least that to use the law, Tom is being classed as disabled – something many people with diabetes vigorously resist! This case raises many issues that perhaps we don't like to address.

- The most obvious issue here is that according to his doctor, Tom can lead a perfectly normal life. The reality is he actually does not lead a perfectly normal life – people without diabetes do not have, or risk having, severe hypos!
- The second glaring conflict is that to protect Tom's rights, the Disability Discrimination Act has to be used, classing Tom as 'disabled'. Not only does this conflict with the message from his doctor but it has ramifications for everyone with diabetes which may not be in their best interests. Is it possible to choose when to be classed as disabled? For example, can we deny being classed as disabled when it comes to employment issues but then choose to be disabled when it comes to using the law?

What about Tom? He is the person I feel sorry for in all this.

- Maybe for the first time, Tom has had to face the reality that diabetes does interfere with your life. He has also had to realise that there are times when he cannot manage alone – his severe hypo required the assistance of his teachers.
- His school has denied him the holidays he wanted. This is harsh and may not be right but by taking legal action, the whole school [and the whole country!] knows he has diabetes and that he is 'disabled'.

At 15years old the very last thing my daughter wanted was for people to know she had diabetes or to draw attention to herself in any way. So most of all I feel sorry for Tom – he is in a no win situation.

The Parents' Perspective – I feel sorry for them too!

Father is quoted as saying that it is totally unfair that Tom is banned because he has diabetes but in fact he is being banned because he had a severe night hypo which his father said was his first. This actually means that his parents have never had to deal with a severe night hypo!

Again, as a parent having dealt with severe night hypos frequently during my daughters years on 'human' insulin [never since being on animal insulin], they are unpleasant and frightening, even when you are used to them. You feel a great responsibility to handle them correctly. Tom was described as unconscious with his jaw locked – not easy! As this was Tom's first severe night hypo, his parents have never had to deal with this situation but they are expecting the teachers to do so, if necessary.

They have offered to pay for expert tuition for the staff. In my experience, you can have tuition till the cows come home but reality is very different - you are faced with an unconscious teenager who cannot eat, cannot open his mouth, is probably physically throwing himself/herself about

and maybe has a seizure.

The School's Perspective

The headmaster is quoted as saying that when Tom had his severe hypo his teachers took the necessary actions with great skill, great determination and great difficulty – clearly true because Tom came out of it all without problems. A statement from the school says "We have taken pupils with a range of disabilities on trips…. However, if a student behaves in a way which endangers his or her health or well-being or in a way that reduces the level of staff supervision available for other students, then we may decide not to take that particular student". The headmaster said "This has nothing to do with disability: it is rather that we make a risk assessment and take into account previous behaviour to ensure the safety of all our pupils."

Like it or not, the realities are that a severe night hypo could endanger Tom's health and he does require more attention from staff required to assist him.

The Doctors Perspective

The doctor has confirmed that Tom has had good control over his condition. What exactly does this mean? If he has 'good' blood sugars and 'good' HbA1cs then we all know that the down side of this is that he is at greater risk of severe hypos. Are Tom and his parents fully aware of this, I wonder?

If Tom had never had a severe hypo before, are they also aware that the risks of hypos are more likely:

- In cold weather [he was skiing]
- After physical exercise, hypos occur over the next 24 hours or longer
- With the excitement [of the holiday]
- A change in routine
- A change in the type of food available abroad may mean less carbohydrate intake
- Alcohol reduces blood sugars making hypos more likely [I am not suggesting that Tom drank alcohol but he is 15….]

Is there an answer?

Probably not! This is a complex issue. We can all understand that it is not fair, maybe not even right, that Tom is being denied the holidays. We can understand the reluctance of the teachers not wanting to have to take responsibility for this situation again. What would happen if anything did go drastically wrong and Tom suffered as a result of his severe hypo? Would the school or the teachers be criticised or even sued for their mishandling of the hypo?

As a parent, I am not sure that I would have wanted my daughter to go on holiday with teachers that lacked confidence in handling a severe hypo or who felt unable to take the responsibility for my 'child'. I am not sure that I would want to take responsibility for insisting that they did. How would I feel if things went drastically wrong?

My adult son manages a care home for people with learning disabilities and is naturally very aware of disability discrimination issues and the responsibilities of carers [the teachers in Tom's case] and he has also assisted with his sister's hypos! He looked at Tom's case in a very different way and suggested that it is a health and safety issue and not one of discrimination against Tom. Interesting thought and maybe worth consideration.

There are some hard realities of life with diabetes

It hurts when our children come face to face with these realities. Some children face them at a much earlier age than Tom – the first children's birthday party that your child is not invited to because he/she has diabetes. It happens, like it or not! We fight for them where we can but we do need to be sure that in that fight we do not damage the very people we are trying to protect - our children.

Ref 1 October 19, 2000 BBC News, The Guardian, The Independent.

All Too cosy, Again!

IDDT FOLLOW UP THEIR LETTER TO THE IDF AND THE WHO

In April last year IDDT-International wrote to the International Diabetes Federation [IDF] and to the World Health Organisation [WHO] to express our concerns about the systematic withdrawal of animal insulins from countries around the world. We also expressed concern about the subsequent exorbitant prices people in less developed countries have to pay for their only alternative of 'human' insulin. We asked for help and support for people denied access to the affordable animal insulins that they need, wherever they may live.

We have never received a reply from the WHO, not unusual! IDF did respond by saying this would be discussed at the IDF Insulin Task Force in June 2000 when representatives of the major insulin manufacturers would be present. By the end of August we had still received no response but our persistence resulted in the following response from the Co-Chair of the Insulin Task Force:

"The IDF Task Force believes that all patients on animal sourced insulin have the right to benefit from the continuous availability of this product in all countries of the world. This is the position we have made clear on several occasions to all our insulin producing Corporate Partners."

Reading this carefully there are some very obvious problems with this statement:

- IDF is only supporting the rights of people already using animal insulins to continue to receive them. They are not supporting the rights of newly diagnosed people to have the animal insulins, especially necessary in poor countries where they cannot afford the more expensive 'human' insulin. They are not supporting the rights of people who have only used 'human' insulin to change to animal insulin if they experience the adverse reactions and they are not supporting the rights of patients to have a choice of treatment.
- Even accepting this very limited support for those who need animal insulin, the IDF is only making this representation to their 'Corporate Partners'. They must know the strength of feeling that there is amongst patients about the withdrawal of animal insulins, yet they only make their views known to the very people who are denying access to animal insulin - the pharmaceutical companies! Should the IDF not be making their views, albeit limited views, known to the world to offer support to people who need animal insulin? Should they not be making very public recommendations to the governments of countries where people are dying for lack of affordable insulin?
- Finally that the IDF class the pharmaceutical companies as 'Corporate Partners' has to be of real concern. If the IDF is to have real credibility and independence in caring for the needs of all people with diabetes, then should it class industry as it's corporate partners? Should industry be such an integral part of the IDF where it can influence the decision making? The funding of the IDF must to a great extent come from industry so there must be some return on this investment, what is it?

We have to ask if this cosy relationship means that the IDF are not prepared to, or are prevented from, taking a stand against commercial decisions the pharmaceutical companies? It appears that the IDF is not going to offer any significant help and support to people who need animal insulin and so patients with diabetes are on their own.

But we are not entirely on our own!
There are others who recognise that organisations concerned with health issues should be independent from industry and that financial backing by industry risks compromising the organisations' integrity, advice and value. Read on….

WORLD HEALTH ORGANISATION [WHO] and hypertensive drugs – a letter in the BMJ [ref 1] points out that the WHO guidelines for the management of hypertension [high blood pressure] have been found to contain several flaws. One of these is that the target reduction in blood pressure is slightly lower than generally accepted. The authors make the point that this can lead to unnecessary drug treatment, overmedication and the increased potential for adverse drug reactions

and that the obvious beneficiaries from these recommendations are pharmaceutical companies that produce anti-hypertensive drugs. Is it by chance that Astra Pharmaceuticals sponsored the press release of the guidelines and they just happen to manufacture these drugs? The authors say that "accepting donations from companies compromises the WHO and could jeopardise the value of the advice and image of the organisation….It would be naïve not to recognise that the donor company will be expecting something in return, such as financial gain or being seen as one of the 'good guys'!". They recommend that the only way to ensure the credibility of any recommendations sponsored by WHO is to exclude all commercial enterprises from the developmental process.

WORLD HEALTH ORGANISATION [WHO] and breast feeding - WHO has had an international code for the feeding of infants since 1981 with the obvious objective of encouraging breast feeding. In 2000 a meeting of WHO and Unicef discussed a revision of this code and prior to the meeting several people were invited to write papers for discussion. Some of these authors criticised the marketing practices of baby food companies as major obstacles to the recommendations of encouraging breast feeding being adopted. When the papers were presented they had been revised by WHO to exclude all references to these criticisms. Several outspoken letters were published in the British Medical Journal [ref 2] suggesting that by suppressing details and explanations about marketing practices, WHO was stifling debate and that WHO did not want any discussion that suggested caution about their drive towards 'partnership' with industry. This is yet another example of an unhealthy cosy relationship between bodies such as WHO that decide on public health issues, and industries that stand to lose or gain financially as a result of their recommendations.

MESS – what an interesting name! It actually stands for Medical Education Service Suppliers and consists of medical education companies that are funded by the pharmaceutical industry. A report [ref 3] by a US consumer group, Public Citizen, says that MESS is threatening to undermine medical education in the US. Medical education companies are being paid more than one billion dollars, yes one billion dollars, a year to organise educational meetings and programmes and to prepare educational material for doctors and medical students.

Naturally MESS maintains that it is filling a gap left by lack of government funding for continuing education and is meeting the needs of institutions and physicians. However, Public Citizen argues that MESS exists to promote drug sales, not an unjustified claim as apparently MESS openly claim in their marketing material that such educational programmes are good for sales.

Ref 1 All commercial enterprises should be excluded from the development process. BMJ Vol 321; 14 October 2000

Ref 2 Changes to paper stifle debate. BMJ Vol 321; 14 October 2000

Ref 3 Lancet, 2000; 367: 494

Snippets

- A study, reported in Practical Diabetes International July 1999, compared the use of the shorter 8mm needles and the standard 12.7mm in obese and non-obese people using pens. They found a small number of people, most of whom were obese, had poorer blood glucose control after switching to the shorter needle. They found no differences in control when changing from B-D 8mm needles to NovoFine 8mm needles in either obese or non-obese people but B-D 8 mm needles were significantly less painful than either of the other needles used. [Just worth a note that 4 out of the 8 authors declared an interest in that they are employees of Becton Dickinson.]
- People with diabetes who also have neuropathy and loss of sensation are frequently reminded to be careful with hot water bottles because they could unknowingly burn their skin. The British Journal of Sports Medicine [1999; 33: 278-9] reports that ice packs may cause as much damage as hot water bottles if applied directly

to the skin. The damage can be avoided by placing something between the ice and the skin. This may sound obvious but it is worth a thought.

- A study in Nature [1999; 400: 418-9] compared, over a six month period, walking versus toning and stretching exercise in older adults. It showed that the walkers experienced positive improvements in memory, planning and scheduling.
- Worldwide sales of blood glucose self-monitoring products were about $2.7 billion in 1997 and that this market will reach$3 billion by the year 2000.

Anit Flu Drug - To Take, Or Not To Take?

Last year the anti-flu drug, Relenza, was turned down for use on the NHS by the National Institute for Clinical Excellence [NICE] on the grounds that "the data did not show that this product would significantly support the NHS's management of patients with flu." In plain English - there was insufficient evidence that it worked in at the risk groups from complications of flu. Glaxo, the manufacturers of Relenza, and the Association of British Pharmaceutical Industries argued strongly against this decision - but they would, wouldn't they?

Now NICE has changed its mind, apparently on the basis of new evidence from trials conducted by Glaxo and is recommending that it can be used for the elderly and other at risk groups but only when the national level of flu in the country exceeds 50 cases per population of 100,000. The Financial Times [Nov 23, 2000] reported that there is suspicion among some doctors that NICE has succumbed to industry and political pressure.

The effects of the decision to allow prescribing of Relenza:

- The cost to the NHS will be between 2.3 and 11.7 million pounds per year.
- This could involve each GP seeing an extra 3 to 17 patients.
- To ease this burden nurses and pharmacists will be allowed to prescribe it without the need for a doctor's consultation, nurses even after only a telephone conversation with a patient. This will be done under what is called a Patient Group Directive [PGD] even though the DoH's own guidance says that because of concerns about increasing resistance to antibiotics, particular caution should be exercised in allowing antibiotics to be used by a PGD.
- The Drugs and Therapeutics Bulletin*, the leading independent source of information on drugs, supported the decision by NICE not allow Relenza to be prescribed on the NHS and the Bulletin is standing by its original decision. Professor Joe Collier, editor of the Bulletin, says that the new evidence is weak and suggests very few benefits from using Ralenza.

To take or not to take, this is the question!

The evidence:

Relenza prevents complications of flu that require the use of antibiotics in only 6% of people but with a confidence limit that stretches from zero to 11%. In layman's language this means that researchers are 95% confident that Relenza reduces these complications somewhere between none of the time and in 11% of the cases. We have also to remember that if we take Relenza, we are taking yet another course of antibiotics!

Facts from the data sheets [ref 1]

- Relenza is inhaled and is recommended for use in adults and adolescents of 12 and over.
- Where it is effective it reduces the flu symptoms by 1.5 days providing it is administered as soon as possible or within 48 hours after the flu symptoms appear.
- It has not been assessed in children, pregnancy or nursing mothers.
- Due to the limited number of people treated in trials, it has not been possible to demonstrate Relenza's effectiveness in the elderly, patients with asthma or other chronic respiratory disease, unstable chronic illnesses or immunocompromised patients.

We hope that this helps you to make up your mind should flu hit you this winter!

Ref 1 Accessed from ABPI website Nov 30, 2000 at www.emc.vhn.net

- The Drugs and Therapeutics Bulletin maintained independence on ‘human’ insulin and in 1989 made the following statement- “Clinical advantages of human over existing animals’ insulins have not become apparent over the past six years.”

If you would like to join IDDT, or know of someone who would, please fill in the form (block letters) and return it to:

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From Your Editor – Jenny Hirst

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