Insulin Dependent Diabetes Trust

October 1999 Newsletter

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IDDT - International

By the time you receive this Newsletter 'IDDT – International' will have been launched as an organisation in its own right – October 9th 1999 being the target date. Who would have thought 5 years ago when IDDT was little more than a few angry people, we would be working on an international level? Certainly not I, nor I suspect did the other founder members expect that this would happen. We were, however, confident that the problems that some people were experiencing with 'human' insulin were very real and we felt sure that these problems could not be limited just to people in the UK and Switzerland, despite what we were being told. Therefore we did have the foresight to include 'international activities' in our Articles of Association.

Before going any further, I must make it absolutely clear for those who, for whatever reason, seem to want to misinterpret our views about 'human' insulin, that IDDT – International does **not** totally condemn genetically produced 'human' insulin and we have **no** wish to see it removed from the market.

IDDT – International and its future activities are based on the following principles and beliefs:

- Genetically produced 'human' insulin causes side effects for **some people** that largely disappear with a change to natural animal insulin. These problems do not just occur in people that have previously used animal insulin, however this is the group who are able to make comparisons.

- We believe that people with diabetes are all different and their insulin requirements vary – some people are best suited to

'human' insulin, some to pork and some to beef. For this reason all existing insulins must remain available to best answer the **needs** of everyone with insulin requiring diabetes.

- People with diabetes should be given information about all insulins – their duration and actions, their possible side effects and whether or not the insulin is a genetically modified product. The latter is especially important because the name 'human' is misleading to many people with diabetes. From this information the patient can then make an **informed choice** about which treatment they wish to receive and they are aware that if they do have problems with one species of insulin, there are others for them to try.

- That the evidence from people using any drug, including 'human' insulin, should be valued and not dismissed lightly as **'only anecdotal'**. Those who do this, fail to realise that all post marketing collection of adverse reactions to any new drug is always anecdotal because the adverse effects are reported to doctors by their patients. The difference in the case of 'human' insulin is that patients have continually reported the problems to their doctors but have largely **not been believed**.

- The link between 'human' insulin, hypoglycaemia, loss of warning symptoms and unexplained, sudden death or **'dead in bed syndrome'**, has not been satisfactorily explained. However small the number of deaths, **any avoidable death is unacceptable** and this issue needs further investigation. Equally any increase in frequency or severity of hypoglycaemia is unacceptable.

- The most commonly reported problems with 'human' insulin are **increased frequency of hypoglycaemia and loss or partial loss of warnings of an impending attack**. When either of these occur, every possible option to alleviate the problems must be attempted and this must include the use of pork and/or beef insulin. The effects of hypoglycaemia and loss of warnings on the lives of those in this situation and on their family life, can be enormous and appear to be grossly underestimated by many healthcare professionals.

- There are many other **unaccountable symptoms** that people experience when using 'human' insulin and these fit into clearly defined categories. These must not be discounted simply because they do not fall into a pattern that the medical profession can recognise.

- There is **no evidence** to show that 'human' insulin has any clinical benefits for patients over animal insulins and, perhaps most importantly, there never was any evidence to show any benefits. We question whether or not all the evidence from research is in the public domain.

- No large, long-term clinical trials were ever carried out to compare 'human' and animal insulins and so the treatment with 'human' insulin is not, and never was, based on evidence from **methodologically sound scientific research**.

- No formal post-marketing research was ever carried out despite the fact that 'human' insulin was the **first genetically produced drug to ever be used on people**. For this reason alone, we believe that the experiences of patients using it should have been, and still are, of vital importance in the development and use of other genetically produced drugs.

Partnerships in Healthcare

We read a great deal about 'partnerships' in health care – partnerships between doctors and their patients, between the pharmaceutical industry and the medical and research professions and between patients' organisations and the pharmaceutical industry. Added to this, all these bodies have a relationship with governments. But the very word 'partnership' implies equality and that the partners in a relationship are actually equal and that their ultimate goals are the same. But is this necessarily so when applied to health matters? To answer this we have to ask some questions.

- Do all the partners have the same agenda?
- Are the best interests of the patient always paramount for all the members of these partnerships?
- Partnerships are based on equality, do patients have the same equal power as all the other bodies involved in healthcare?
- Do patients or their representative bodies have equal access to information and independent funding?

These questions hardly require answers for us to realise that patients do not have the equal power they require to have an effective voice in decisions about health services generally or their own healthcare. What does need saying, however, is that all the other parties involved in these so-called partnerships have relationships with each other that virtually exclude the consumers or patients.

The medical profession works in partnership with industry – industry needs the doctors to 'sell' their products and doctors need industry to fund their research and other activities.

The medical profession often works in partnership with voluntary organisations in their particular specialty – often set up out of common beliefs and needs for funding of research. But all too often the medical wing of the voluntary organisation holds the power and the voice of the patients for whom the organisation was originally set up, is unheard or overruled.

Governments work with industry to obtain the best arrangements for health services

In return industry needs government to approve and enable them to market their drugs.

Government works with the medical profession – using them as experts or advisers on various issues but very often these experts are the very same people that are receiving funding from the drug companies for their research. A very good example of this is that the Committee on Safety of Medicines in the UK is very largely made up of professionals who have stated links with industry.

The pharmaceutical industry has been quick to develop relationships with patient organisations. Industry realises that there are benefits for them in building partnerships with voluntary patient organisations. They offer funding and apparent support to the organisations so having the immediate effect of reducing their independence and ability to freely represent their member's interests. Drug companies have realised that the temptation of funds effectively removes any possible opposition to policies that may not be in the best interests of the organisation's client group.

Negating the power of the patients' representative body in this way leaves individual patients isolated, unrepresented and virtually powerless.

It has to be concluded that patients, the consumers or users are not equal partners in any part of the health care systems and this can only disadvantage patients. Many of their representative bodies that do try to remain independent suffer from lack of funding and organisations that cover the broad consumer interests in health care cannot, by their nature, take up specific issues effectively.

IDDT- International forms the umbrella for patient equality

IDDT formed in the UK as a result of patients experiencing problems with 'human' insulin and believing that they were being ignored and not being represented against the might of the drug companies and the medical profession. Membership and independent financial support for IDDT has increased and with this the voice of the patients has become more powerful. However, the pharmaceutical companies function on an international level and so do the medical profession, giving them both greater power and control. For patients to even

attempt to have an equal partnership in health care, they must function and be represented internationally.

Without question the problems with 'human' insulin exist in many countries and the systematic withdrawals of animal insulin are planned internationally by industry. It is essential that patients and their families are in the best possible position to be equal partners in ensuring that their best interests are served at all times. This has to mean that we must function at an international level too. While the situations in various countries are different, the principles involved for us all are the same. We must work together to achieve the power to ensure that we succeed in achieving our ultimate goal - the right of people who require insulin treatment to have the species of insulin they need for their future health and wellbeing.

The Goals of IDDT – International are:

1. To resist the systematic withdrawals of all animal insulins.
2. To assist in establishing the most efficient systems for personal importation into countries where animal insulins have been withdrawn and to help to dissemniate this information directly to patients and their families.
3. To disseminate information from patients' experiences with 'human' insulin to all those requiring insulin treatment to enable them to have an informed choice of insulin treatment best suited to their individual needs.

- To try to ensure that independent, methodologically correct research is carried out into all the reported problems with 'human' insulin so that insulin treatment is evidence based.
- To ensure that regulatory bodies are made aware of these problems.
- To raise awareness and resist the situation that has developed, where prescribing and treatment is now being dictated by the pharmaceutical companies and their commercial interests and NOT by the clinical needs of the patient.

You Will Hear More About IDDT-International!

Membership of IDDT –International is open to individual people or to organisations.

If you would like more information or we can help you, wherever you live, please contact Jenny Hirst, IDDT, PO Box 294, Northampton NN1 4XS

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An Extract From A Medical Journal Published In August 2005

[You may not entirely understand the science, but the message is clear.]

In the early 1980's it was suspected that diabetes was a condition resulting from the immune system attacking insulin or other components in the biological chain of events in which insulin was produced and used. This theory was proven in early 1990's but as synthetic Human Insulin was already in production and in widespread use, research into bovine and porcine insulin was nearly non-existent.

During 2000 some researchers did make a significant break-through which not only enabled an objective decision about the most appropriate insulin for an individual but it also pointed the way to a new style of treatment to control rejection caused by the immune system.

The researchers asked the question "Why does the immune system attack the insulin?" They decided that it started during a period of heightened activity, that is during a previous illness or some stress

that the body underwent. They were puzzled by the varying levels of stress, varying ages of patients and why some people did NOT become diabetic even though they had similar medical histories. The researchers considered the structures of natural human insulin and cells involved in the formation of antibodies. Chemical and biological processes had been extensively researched but the physical attributes had been given almost no attention at all.

After quite complex experiments a procedure was developed to describe the shape of the insulin molecule which resulted in the detection of several isomers [the same chemical characteristics but different physical shape]. Further study revealed that it would be very difficult for some of these isomers to be bonded with the molecules involved in the production of antibodies. Even though they were chemically compatible their mismatching shapes made it unlikely that their combination would be able to form a stable compound.

The researchers concluded that these people would not develop diabetes because their immune system "did not like the mismatching shape of the insulin molecule", to put it in layman's terms.

Since their findings were published in 2000, many other researchers have confirmed them, while others turned their attention to finding why many people with diabetes preferred to use bovine and others porcine insulin.

From the patients point of view it was easy to answer – the bovine and porcine gave warnings of hypoglycaemia whereas the synthetic human did not, or else the warnings were not given soon enough. The mechanism is seen as quite complex with the presence of amino acids not found in 'human' insulin playing a significant role. It is clear, however, that because synthetic 'human' insulin has all the characteristics of normal human insulin [except its isomer variations]:

- the warning mechanisms are left to cells that become sensitised by low blood sugar counts;
- there are no early signs due to the foreign amino acids in the bovine and porcine insulins.

Another school of thought has suggested it is the lack of some amino acids, present in normal human insulin, which causes a different sequence of biological processes as blood levels drop, thus activating nerves well before it is left to activity at the blood and blood-vessel interface. Some patients who take 'human' insulin have reported that they appear to 'work through' some hypoglycaemic incidents without corrective action, thus indicating mechanisms that require further research.

In mid 2004 another significant breakthrough was achieved by a group who followed on from the research reported in March 2001. This group carried out antibody assays on a large group of patients who had used one, two or all types of insulin. The report published in September 2004, stated that there were statistically significant differences in the levels of antibodies where a patient had used two or three sources of insulin [bovine, porcine and 'human']. Thus, the report concluded it was possible to make an objective assessment of each patient so that the insulin used would produce the least number of antibodies. At this stage it was only possible to make such a judgement if the patient had used insulin from at least two sources. The group is now studying the relationship between the natural insulin isomers of the individuals in the study group and the isomers of insulin from natural sources. Their goal is to be able to relate the isomers to the antibody assays and, even if the patient had only used insulin from one source, to be able to recommend the appropriate source for any given patient. The leader of this group has been at pains to point out that although enabling a patient to control his condition is the driving force behind their research, they expect to increase the general well-being of diabetes sufferers because of the flow-on effects.

The principles involved in their research will be publicised in a paper to be presented at the 2005 World Health Congress to be held in November.

Footnote: ***I hope that this wishful thinking might stimulate some***

action into research which will lead to a way of objectively determining the most appropriate source of insulin.

David Williamson
Australia

28.9.99

News

- A two-year investigation has concluded that patients would be better served if more specialists could write prescriptions for some drugs. This would help to prevent inconvenient trips to the GP surgery. At present only doctors and dentists can write prescriptions but under the new proposals a range of healthcare specialists would be able to prescribe without referring back to the GP. This would include physiotherapists, chiropodists, family nurses and pharmacists.
- A NHS survey of patients' views has shown that more than 80% of people believe their GP knows what treatment is best. 90% consider that in their opinion, their GP made the right diagnosis most, if not all, of the time. The survey was carried out with 100,000 people but made no effort to consult consumer groups in the planning. It did not make special effort to involve the views of people with sight and hearing problems, those with learning disabilities and people whose first language is not English – the very people who could experience more difficulties than Joe Public who probably only visit the GP once a blue moon! Is this just paying lip service to consumer consultation?

News From Abroad

- We have read that the Glucowatch is now on the market in the USA. Readers will remember that we have discussed this in previous Newsletters while it was in the development stages. It is a sensor to be worn like watch that measures blood glucose levels and bleeps when the blood sugars go too high or too low. It takes the measurement every 20 minutes. It is rather expensive, costing 300 dollars for the actual 'Watch' and 4 dollars for the sensor – a new sensor has to be used daily. The trials for the Glucowatch took place on 39 people and showed that it did cause some skin irritation, so there have to be concerns about this for people with sensitive skin and especially children to whom this sort of device will be a godsend. Nevertheless this has to be a major step forward in the right direction and, no doubt, there will be further developments along these lines. Let us hope so and that the price will not be prohibitive.

White Gold

Did you know that sugar used to be called 'White Gold'?

Table sugar or sucrose was once a luxury that could only be afforded by the very rich because it was scarce and expensive – hence the name 'whit gold'.

A little bit of history.
Table sugar comes from sugar cane, a type of grass, or from sugar beet, a root vegetable. It is thought that sugar cane was first grown in the Pacific Islands 5,000 years ago and when the people migrated to India they took it with them. It was in India that it was first discovered how to extract the sugar. This was the only form of sugar until the mid-1700s when a German chemist discovered how to extract it from sugar beet but it wasn't until 1900 that the sugar beet industry was

truly developed. Sugar beet was first grown in the UK in Norfolk only 80 years ago

The different sugars.

There are different forms of sugars and they all provide same number of calories per gram but vary in sweetness:

- Fructose occurs naturally in fruit and is sweeter than sucrose.
- Glucose is the next sweetest after sucrose and is in fruit and vegetables.
- Maltose comes from grains.
- Lactose is the least sweet and this is found in milk.

What does sugar do?
All sugars are carbohydrates. Simple sugars consist of one or two sugar units and complex carbohydrates are made up of many sugar units – these are found in starchy foods such as bread and potatoes. As we know digestion breaks sugars down into glucose which is carried around the body to give us energy. Insulin controls the amount of glucose in the blood, but in people with IDDM there is no insulin produced naturally and so it has to be injected.

The simple sugars raise the blood glucose levels quickly and the more complex ones act more slowly – this accounts for why we take sugary drinks or food when hypo and follow this with slower starchy food to last longer.

Staggering statistics for the non-diabetic population!

1. We eat and drink 100gms of sugar a day on average.
2. 45% of us add sugar to coffee and 38% add it to tea.
3. 46% add it to cereals.
4. We buy less table sugar than we used to but we now eat more sugar in the processed foods we eat – between ½ to 2/3 of the sugar in our diet comes this way.
5. Nearly ¼ comes from snacks such as cakes, biscuits and drinks.

To be fair to food producers sugar is not added to food just to make it sweeter and taste nicer, there are other reasons. Sugar in ice cream adds to the texture and stops ice crystals forming; high concentrations of sugar stop bacteria forming in jam and sugar can add stability to mixtures – beaten eggs for meringues and it helps moisture retention in bread.

Another Little Gem!

Words of Advice From Baroness Jill Pitkeathley – we're doing it already but to how much effect!

This lady was the keynote speaker at the Annual Meeting of the LMCA [a charity looking after the needs of people with chronic conditions] and she talked about 'making the health service work for users and carers'. One of the key points she made was:

- Organisations must take any opportunity that comes their way to shout about the needs of users and carers.

So to those who criticise us for 'shouting' about the problems some people have with 'human' insulin and the need for animal insulins to remain available, I have to say that we are only following the advice of the Baroness! I do find it sad though that this advice has to be given.

Snippets

- Coffee and Gallstones – information collected from 46,000 men during the Health Professionals Follow-up Study has shown that drinking coffee may decrease the risk of gallstone disease. Men

who drank 2-3 cups of regular coffee per day had a lower risk of developing gallstones compared with men who drank no coffee. Drinking de-caff did not lower the risk. We really don't know what to eat and drink for the best, do we?

- The 1998 Annual report of the Charity Commission says that in1998 just over 6200 charities were added to the Register and just under 4300 were removed. At the end of the year there were186,248 charities on the Register with a combined income of £19.7billion. One has to wonder whether it is really possible to police such a vast number of charities.
- Rampant tooth decay –according to a report by the Health Education Authority almost one child in four suffers from rampant tooth decay. A dentists' survey has also found that the consumption of soft drinks by under fives has doubled over the last 15 years. Many of these drinks are labelled as 'no added sugar' but they may be acidic or contain high levels of natural sugars. IDDT comments that better education of the general public is needed to give a better understanding that sugars, albeit they are natural, are still sugars!

We Cannot Just Sit Back And Be Complacent

There are some issues that affect all of us, such as the Freedom of Information draft bill and there are some that affect only some of us – those related to various aspects of diabetes. But it is in all our interests to ensure that any unfairness or inadequacies that affect people who live with diabetes should be allowed to pass without recognition and without an attempt to put right these wrongs. Accepting that 'human' insulin and its problems are always our main concern, we raise just three issues that are uppermost in our minds at the moment. We believe that you can help with these issues by writing to your MP – not necessarily on all of them but on the ones that you feel strongly about. While they may not be relevant to you personally, they are matters that affect people with diabetes and their carers and the support of everyone living with diabetes is needed to ensure that these inadequacies are eradicated.

Talking blood meters

IDDT informed readers some time ago that talking blood meters for blind and visually impaired people are no longer available in this country. The manufacturers maintain this is because the market is too small to make it economical to continue to supply them. If this means that the number is people suffering from visual impairment is going down, then we are naturally pleased. But the manufacturers are completely ignoring the needs of those that are visually impaired and they clearly have no feeling for their needs.

The profit made on supplying meters and blood testing strips must be huge and must have risen tremendously over the last few years as more and more people are doing home blood testing, especially now both people with NIDDM and IDDM are blood testing. It seems that even this increase in sales cannot influence the sensitivities of industry. If looked at in isolation then no doubt supplying talking meters to a relatively small market is not profitable in itself. But surely even industry can see that talking meters could be supplied as an 'orphan' device – one that doesn't make money but helps those in need and the costs are more than covered by their profits on all their other products.

IDDT has written to the Secretary of State for Health to raise this matter and asked him to try to influence the situation. We have also suggested that as talking meters are available in the USA and can be imported from there, then the people that need them in the UK should be allowed to have them imported free on the NHS on a 'named patient basis'. This means that although they are not normally available on an NHS prescription special allowance is made because of the need. We also pointed out that this would be more cost effective than a nurse home visiting for every blood test or at worst the person having to be taken into care. We also pointed out the effects of the loss of independence and probable deterioration in health of the people concerned.

We will let you know what the outcome of our letter is. In the meantime, we would like to remind you that we do have a list of suppliers of talking meters in the USA. Please give us a call if this would be helpful to you, on 01604 622837 or write to IDDT at PO Box 294, Northampton NN1 4XS

- **The effects of viagra are far reaching ang unfair**

IDDT has received correspondence from people with diabetes about the effect the restrictions on the prescribing of Viagra have had for them. Just to remind you of the present situation:

- People with diabetes are a special category and are allowed Viagra on an NHS prescription but are restricted to only enough for use once a week.
- But the Government, in its wisdom, decided that all impotence treatments should fit into this category.
- So people who have been using other methods prior to the development of Viagra are now restricted to once a week use of their 'chosen' treatment, where their treatment previously was unrestricted. [A bad turn of phrase because nobody chooses to be impotent and perhaps Mr Dobson should remember this.]

While one can understand the need to restrict the use of Viagra on the NHS because of it being used as 'recreational' and because of its cost, this has meant that people with impotence already receiving treatment are being discriminated against. In reality they are being refused treatment if they want to be sexually active more than once week. The following points have been made to us in the letters we have received:

- In many cases treatment involves injecting the penis and nobody would choose to do this, so there is hardly likely to be an abuse of these drugs!
- Impotence can affect young people who naturally want to be more sexually active than once a week.
- It does not just affect the man, it affects his partner and their relationship together. It can lead to the woman feeling that her partner is no longer interested in her and because impotence is not an easy topic to discuss, it is understandable that some relationships will break down.
- If a couple want children then their chances of conceiving with a restriction of treatment for impotence being restricted to once a week, are considerably lowered.
- People with diabetes already have to contend with living with it and its various ramifications on their lives and those of their partners, with this restriction the government is adding pressures unnecessarily, so making life even more difficult for those affected.

Again we say that we understand the need to restrict the use of Viagra under the NHS and yet allow it to be available to those who need it. But it seems grossly unfair that people who already had a declared impotence problem, by the very nature of receiving treatment from their doctor, should have that treatment reduced. The introduction of Viagra has done them no favours! In fact, it is worth remembering, amongst all the hype about it, that it was actually only effective in 48% of the healthy people that took part in the trials – something not widely discussed.

It does not seem beyond the wit of man, or the Department of Health, to have a system where existing impotence suffers can continue with their existing treatment and to allow doctors to use their discretion for new impotence sufferers – or does the DoH not trust them to not abuse the system!

What can we do about this unfairness?
IDDT has already expressed all these points to the DoH but they seem to fall on stony ground. Impotence may not be your particular problem but as people that live with diabetes, we understand the needs of each other and we should stick together. We cannot just expect the people that are impotent to bring about changes in this restriction on their own, especially as it almost means declaring your impotence to the world. So if you can spare 10 minutes write to your MP and tell him how unfair this situation is for people who need impotence

treatment. It is the only way that the DoH will know that there is great unhappiness at this new regulation amongst consumers [and voters]. If we do nothing this unfairness will become accepted when it most certainly is not.

Freedom Of Information [FOI]

At our request, many of you wrote to your MPs about the proposed Freedom of Information Bill to try to ensure that information about health matters and drugs were included in the proposals. We made MPs aware that there had to be a repeal of the Medicines Act in order to enable this to happen. MPs responded well and we are grateful to you and to them for their interest and support.

Why is FOI especially important for us in relation to the 'human/animal insulin issue?

Without FOI we have:

- No information about the drugs we take, other than what the manufacturers choose to tell us.
- We have no information about the trials carried out before marketing approval.
- We have no information about adverse reactions reported before and after marketing.
- We have no information about costs and pricing.

In a situation like ours, where we are fighting a battle to show that there are problems with a particular drug, we are disadvantaged by the inability to argue effectively because we do not have the information that would add to our case. Yet the drug companies do have this information. What makes this situation worse is that

patients/consumers are not truly represented on any of the bodies that control the licensing of drugs.

So what does the new draft Bill say?

At face value it looks reasonable – it will give people the right to information including that held by government departments, public authorities and NHS bodies. Access would be subject to a series of exemptions but there would be a Commissioner who would have the power to overrule an authority's decision if it was thought to be wrong. The charges for information would be modest. However, in many important areas the draft bill not only does not provide true freedom of information but actually makes the situation worse than it is now.

- For example the present codes of practice for openness require that information is provided within 20 days – the new bill extends this time limit to 40 days. Why and in whose interest is this?
- The original White Paper allowed information to be withheld if the disclosure would do 'substantial harm'. The new proposal reduces this to allowing information to be withheld if disclosure would 'prejudice' commercial or other interests. This is much weaker than 'substantial harm' and can only be in the interests of commerce and not the consumer – this applies very much to information about drugs. It is another example of the powers of industry being greater than the best interests of consumers and patients!
- The new draft bill allows other widespread exemptions and never mentions the word 'harm' as the reason for these. If the bill becomes law then government departments would be able to withhold all information about new policies under consideration. This is worse than the present situation where the code of practice for openness only allows information to be withheld if disclosure can be shown to be 'harmful'. Examples of where disclosure could be withheld are a paper that looks at the closure of a hospital or investigations into professional negligence, such as the Bristol Case.
- The proposals relating to the Commissioner prohibits him/her from ruling that exempt information should be disclosed on the grounds that there is an overriding public interest. Instead authorities only have to 'consider' the discretionary release of such information and what makes this worse is that before 'considering' making this discretionary disclosure, the authorities would have the right to insist on knowing why you wanted the information. This means that they can refuse information to potential critics and prevent it

becoming public knowledge. You can imagine that IDDT would be one of the organisations that would have difficulty in obtaining information if this becomes law!

- The decision about whether the part of the Medicines Act that restricts disclosure about the safety of medicines and their testing, is to be repealed has not yet been announced. One has not to be too clever to realise that there will be considerable lobbying going on by the pharmaceutical industry to prevent disclosure – no doubt on the basis of their commercial confidentiality. But surely it is the job of government to put the interests and safety of the consumers before so-called commercial interests.

Where do we go from here?
The bill is only in draft form and is still undergoing the process of consultation. It has already received a great deal of criticism and we can still take action to try to persuade the Home Secretary to make alterations. I think alteration is a great underestimation of what needs to happen. I would recommend that he gets back to basics and considers the fundamental meaning of freedom of information. He should also remember that the proposal that the UK should have true FOI influenced some of us to vote for his Party at the last election.

So if you, like me, believe that we should all have a truly effective right to know, then please write once more to your MP and say so. If you dabble on the internet there is more information on www.cfoi.org.uk or you can telephone 020 7831 7477 – the Campaign for Freedom of Information.

Patient Information Leaflets Revisited

It has been brought to our attention that some tablets when required in small quantities are being supplied by pharmacies in their own boxes without a Patient Information Leaflet [PIL]. They are splitting the larger boxes supplied by the manufacturer and putting the pills in a new box and this is acceptable providing that they include a PIL. It is important that you read the PIL before taking any drug so that you are aware of any known side effects.

From Our Own Correspondents

Saga or Farce?
Dear Jenny,

I was certainly very grateful for the Summer Newsletter which detailed the continuing saga [or farce?] concerning animal insulin.

I was particularly intrigued by the letter from the 'Consultant Physician' who deigned to write saying that the Posner study was not a study due to its composition. While the good doctor may wish to descend to semantics, the reality is that a host of scientific discoveries originate from experimental and anecdotal data. Moreover, as he says that the BDA is under no obligation to publish these opinions 'that can well cause discomfort…to many people', one is tempted to ask: [1] Why was the study undertaken in the first place if it was so unreliable? [2] Can we take it that if it had arrived at another conclusion, its publication would have been acceptable? So is publication, therefore determined by the conclusions?

As Jenny comments, his remark that people who are 'perfectly happy on a particular treatment should not be caused distress is a nonsense as 'happiness' is purely relative. I would also suggest the good doctor spends a little time perusing the considerable amount of scientific data which adequately demonstrates the dangers of 'human' insulin.

The aspect which is becoming increasingly apparent to me is that members of the medical profession simply cannot admit the dangers of 'human' insulin even if they wanted to: having prescribed it now for

so long, they would place themselves in a legally vulnerable position if they acknowledged that people's health had been damaged/ruined by its use. Consequently, not only do we have a refusal to admit the situation, we have members of the medical profession resorting to sheer fantasy to defend what is now an untenable position – their position.

A further point which emerges is that physicians continually whinge about a supposed lack of resources in the NHS and yet the prescribing of 'human' insulin that is more costly than its animal counterpart and the costs of the problems caused by it, have places a considerable strain on the NHS, and has done for years. Therefore, a solution is easily available, but no, it is far easier to emulate the ostrich even though we all suffer for this.

DN
South East

Jenny's comment – I cannot add to Mr DN's letter, clearly written from the heart. But it is worth noting his point about publication bias. Reading some of the scientific journals there are concerns expressed that studies that show a negative result are less likely to be published than those with a positive result, so introducing bias. One has to go further with this thought and ask another question: ' when a study looking at a new drug, funded by the company developing that drug, produces a negative result [one that says the new drug does not do any good or has harmful adverse effects] does the drug company seek publication of that study?' I suspect not – if the company has funded it, it owns it and it is hard to believe that they will actively seek publication of a study that is not favourable to their product. But they will seek publication of studies with positive results and this is how bias occurs – we only see half the story!

Another view from a pump user.
Dear Jenny,

I have been using an insulin pump since 1981 and would agree with most of John's comments in the Summer Newsletter1999 and initially I received comments like 'I have never seen you looking so well'. But you state that using a pump obviously needs more blood glucose monitoring and this is not true in my experience. During the 20 years of diabetes that I had before 1981 my hypo warnings had effectively gone but after 4 years on the pump my warnings signs returned [even if in a slightly different form] and I could tell what was happening to my blood sugars. So I have never done more blood tests with a pump and if anything I do less. I do not think that the pump involves more care generally and probably involves less – it does not matter if I sleep in or miss a meal and it is very easy to cater for the unexpected use of energy. I would suggest that most 'care' type problems encountered by 'normal' diabetic regimes are reduced when a pump is used.

I very much agree that a pump is not suitable for everybody, but it could make a huge difference to some people's lives. The only restrictions that I would impose are that the person using the pump must be committed to controlling their diabetes, must fully understand diabetes and must be prepared to spend some time getting used to the pump. I do not think that the modern pumps in their present format are suitable for children because they make it too easy to get out of doing something that they do not want to do! And I say this as someone that has grown up with diabetes since infancy.

Mr HC
South East

Jenny's comment – I'd like to thank Mr H C for his views because he highlights an important point about blood monitoring and the differences in people with diabetes. He says that he has to do less blood testing with a pump than on a normal regime but this does not follow for everyone. He had lost his warnings before going on to the pump and therefore he was, no doubt, doing a lot of blood tests for his own safety before going on to the pump. Other people may not do very many and therefore the number they do with the pump may be greater. Some recent research has shown that only around 10% of people actually blood test as often as they are recommended to

by their doctor! So we must be very careful when we are making comparisons like this.

After 70 years of diabetes…
Dear Jenny,

I am in receipt of the Summer Newsletter 1999 and would like to add my comments to the arguments about 'human' versus animal insulin. I have had diabetes for 70 years and feel that people who have the experience of living with diabetes should have the right to voice their opinions on this issue, and others, without being talked down by the manufacturers and medical experts who, nine times out of ten have no practical experience of life with diabetes. Throughout the whole of my life none of these people have ever shown an interest in what it is like to live with this damned complaint – so who do they learn from, if they learn at all?

The hypos that I had while using 'human' insulin were suffered by my family who had to take the abuse and violence that I knew nothing of whilst in the hypo. I had to suffer the humiliation after the event when told what I had descended to while 'under'. I well remember being told by my then consultant that I did not hypo and this was all in my mind. The fact that my wife and family witnessed and suffered all this seemed to have escaped his notice. But this same consultant told me that he had experience of hypos because he had put himself into a hypo with an insulin injection! He did not say that he had people waiting to bring him round while he hypo'd.

I feel I could have continued to live a normal life if I had not been pushed into the changes of insulin to 'human' and who did this benefit anyway – it only put more money into the hands of the drug companies.

70 years ago I was told there was a cure around the corner. Since then millions of pounds have been spent on research into diabetes and what results have we seen for those millions of pounds?

Gerald Hards
Cambs

My name is Sydney
Hi,

My name is Sydney Elizabeth Gassen. I was diagnosed with Type 1 diabetes on February 10, 1998. I have a twin brother named Taylor and a big brother named Jonathan. I'm only 2 ½ so Mom is writing this letter for me. Although we are a family who lives with diabetes, I am the only one who actually has diabetes.

We would like to write to and hear from other kids, parents and families living with diabetes. We hope to share, discover and understand the things going on in all our lives.

Please write to me if you have time. Mom and Dad promise to read each and every letter to Taylor and me.

Thanks and good luck,

Sydney
sydneys_sugar@hotmail.com

Jenny's comment - clearly Mom and Dad, as well as Sydney, would like to talk to other families who live with diabetes. If you use email, why not drop them a line.

Did You Know?

- That 40% of dietitians throughout the country see less than half of all the newly diagnosed people with diabetes within the first 4 weeks after diagnosis. As part of the treatment for diabetes is DIET, especially in NIDDM, one has to wonder at the thinking behind this. Perhaps there is no 'thinking' but shortages of resources or dietitians. But to expect anyone to be able to attempt 'good' control without the assistance of a dietitian, seems like an impossible task

and can do nothing for their self-confidence at a traumatic time like diagnosis.
- That women who drink a lot of coffee tend to have shorter and more frequent periods. In a study of 403 women between the ages of 18 and 39 those who drank more than 300mg of coffee a day had significantly shorter periods and shorter menstrual cycles.

Are We Missing Something?

An article in Diabetes Interview [US March 1999] really made me think. We all read about miracle cures for various illnesses and I expect you, like me, treat them with some of scepticism. But this article really made me wonder if we should not treat some of these things with a more serious approach.

Apparently French people with diabetes and retinopathy are often treated with a patented pill called Pycnogenol – unheard of in the US and I don't know about over here. Pycnogenol apparently is made up of a particular group of bioflanonoids that have been shown to improve the elasticity of the very small blood vessels [capillaries]. It has also been shown to have antioxidant powers that get rid of the free radicals - these are harmful molecules that lead to vascular and other problems. Diabetes Interview talks to a man who was diagnosed with retinopathy requiring laser treatment in 1982. He searched for a possible solution himself and found Pycnogenol in France – his retinopathy regressed and he has had no laser treatment.

At this point I say to myself, well this could happen naturally but…

- A study published in Ophthalmic Research in 1996 proved Pycnogenol's beneficial effects on the retinas of pigs and cows.
- In the Journal of Cardiovascular Pharmacology, October 1998, it was shown to counteract the blood vessel restricting effects of adrenalin, to decrease the clogging of blood vessels by decreasing platelet clustering and adhesion.
- In the journal Free Radical Biology and Medicine, May 1998, it was shown to significantly decease nitrogen monoxide generation [this is important in many disease including diabetes].
- In Biotechnology Therapeutics, 1994-95, it was shown to protect the cells lining the lymphatic vessels and the heart from injury due to oxidation.

I feel I would like to know more about this and we should not dismiss too lightly the claims that are being made, especially if it is being used fairly widely across the Channel in France. To those that either have or are at risk of retinopathy, every avenue of possible prevention or stabilisation should be considered and explored. We now have laser treatment but this does not mean that we should be complacent and not look for other means of prevention and treatment. It surely must be worth some research funding or a review of published studies. I would be interested to know if anyone over here knows more about Pycnogenol, if so, please drop me a line at IDDT, PO Box 294, Northampton NN1 4XS or telephone 01604 622837.

Apology And Error

Complementary Medicine and Diabetes – Summer Newsletter 1999.

- I apologise to Dr Iain Chalmers for wrongly attributing a statement to him in this article. I said that 'He went on to point out that it is thought that more than 60% of orthodox treatments have not been scientifically proved….' He did not make this statement and I apologise for any embarrassment caused to him by suggesting that he would make such an unsubstantiated claim. The BMJ article in fact reads 'It is thought that more that 60% of orthodox treatments have not been scientifically proved.'
- The references in this article were also incorrect – Dr Chalmers' statement should have been 'ref 3'.

Diabetes And Disability Living Allowance

This is an article by John Kent and he explains the difficulties he encountered when trying to claim benefits as a result of being unable to work mainly due to frequent severe hypos without warnings. However, the article will be of assistance to anyone considering applying for this state benefit. We thank Steven for sharing his experiences with us and do understand that he feels somewhat cynical!

After being in excellent health after being diagnosed diabetic, I was changed to 'human' insulin in the early 1980s. Within less than a year of this change, my health began to deteriorate both rapidly and severely. From having only few and occasional health problems [none of which appeared to be caused by the diabetes] and being very active, I became very lethargic and this was followed by having very severe hypoglycaemias. Any hypos before this had not caused me any problems, being very rare and very mild: in all cases I had plenty of warning. Suddenly, I had no warning signs of a hypoglycaemia beginning and in many such instances these reached the stage when I was fitting or even unconscious. My blood sugar varied enormously for no apparent reason and other problems began, e.g. hearing loss, high blood pressure, poor memory and instances when concentration was impossible. On occasions when I was outdoors I would become confused and find it difficult to communicate. Complete memory lapses caused me considerable problems, for example, on being asked my address I could not remember it. By this I do not mean my house number or postcode, but the entire address as if my brain had 'switched off'. Much of this was very similar to a hypo, although I was not actually hypo at the time.

On trying to discuss the more serious problems with various doctors, I was invariably greeted with a vacant stare and it became apparent that no explanation was available [or if it was, it was not going to be offered]. In the case of poor memory and failure of concentration, I mentioned these to my GP who advised me to discuss these at the diabetic clinic. When I did so, the doctor made some inane remark and denied that diabetes/hypos could effect permanent damage. This is despite the fact that there is clear evidence that this is the case. * See references at the end. Moreover, few doctors will admit that 'human' insulin causes problems unless they are challenged with the relevant information. In simple terms, the 'best patients' as far as many doctors are concerned, are the silent or ignorant ones.

In the early 1990s I began to have hypos when shopping, walking or even relaxing. The most worrying occasions were those in the night that my [elderly and disabled] mother had to deal with. In most cases she was able to get me to take sugar, but on some occasions she was forced to call for paramedics. Each time I had a 'fitting hypo' I have sustained back injury to the point when I had to [and still] take morphine-based painkillers. Additionally, I have done a considerable amount of damage in my own home.

As an example of how the medical profession has so little grasp of the matter, when I recently had fitting hypos on two successive nights [losing consciousness in one of these], the paramedics insisted that I saw a doctor, despite my protests that this was a waste of time. I did this anyway and all that happened was an HbA1c and nothing further!

In 1994 I read a leaflet dealing with the DSS benefit of DLA [Disability Living Allowance]. It would be impossible to deal with the subject of DLA in any great detail in an article such as this, but essentially, DLA is made up of two components:

1. Mobility, this is either the higher or lower amount
2. Care, this is either the higher, middle or lower amount.

The amounts relate to the extent of the problem. I had no doubts whatsoever that my condition qualified me for DLA and I requested the relevant form to complete and submit in order to lodge a claim.

The form itself is in two parts and very lengthy asking a host of personal questions. Although I am used to completing forms I considered it sensible to ask for assistance at the local Citizens Advice Bureau. I asked for an appointment with someone who was familiar with DLA

Claims but on going to the CAB, I discovered that the person had never seen a DLA form before! I therefore ended up completing most of it myself: I found that most of the questions [which in some cases are repeated elsewhere] required detailed explanation and it was necessary to compose a letter to give accurate answers to these questions.

Having done this, I took the form to my GP who had to supply some information on the last page. I was naturally disappointed when I collected the form from the surgery, to see that he had not supplied anything resembling adequate and relevant information. I contacted the DSS who advised me that this was 'standard practice' by GPs because the DSS then has to write to them for the omitted information and this involves a payment being made to the GP. By this point it becomes obvious that there is very little support available and a considerable amount of determination is required if the matter is to be pursued.

After some while elapsed, I received a communication from the DSS refusing my claim although it advised me that I could ask for a 'Review' of that decision. I did so, but after 3 months, was advised that the Review had confirmed the original decision. **It also informed me that I could appeal to 'DAT' [Disability Appeal Tribunal] and I did this.**

By this stage it was obvious that the arguments being made to refuse my claim were patently absurd. For example, having explained that my mother has to wake me at 2am every morning to ensure that I have not gone hypo and to ensure that I do a blood test, the DSS replied that this could be resolved by having an alarm clock! The fact that an alarm clock is of little use if I have already become hypo seemed to be beyond them. I later discovered that the DSS have a GP advising them and this idea was presumably advanced by him. This to me explains a lot…….

I also contacted the local Social Services and was pleasantly surprised that a case worker existed who was experienced in this type of Benefit claim. Although I was able to compose an appeal showing flaws in the DSS response, the Social Worker was very supportive, providing guidance, and composed a lengthy appeal which made reference to the relevant legislation.

DAT, the Disability Appeals Tribunal, was held nearly 5 months later. The tribunal and its 3 members are independent of the DSS and includes a doctor and someone involved in disability issues either in a professional or voluntary capacity. They listened to the DSS's arguments together with my own and the Social Worker was able to show where the DSS's interpretation of the law was incorrect or inappropriate.

Apart from the zany arguments provided by the GP advising the DSS, I discovered that much of the problem had been caused by my own GP. The DSS said that I rarely mentioned having hypos to my doctor: I replied to this by saying that it was actually pointless mentioning the numerous hypos I was having because his answer was always the same: 'Keep doing the blood tests' [which did not stop them] and merely suggesting that I attend the diabetic clinic which was as much use to me as the Christian Science Reading Room.

We left the room while the tribunal decided upon my claim and after ten or so minutes we were called back and I was told that I had been awarded DLA, made up of both components. This was then backdated to when I had first made the claim.

The concluding comments I would make are:

- **Since this time there have been substantial changes in the rules**, eg the time in which an appeal can be lodged. Therefore anyone considering claiming DLA must obtain current information.
- **If making a claim for DLA you should be prepared for many obstacles**. Often it would seem that the fact that the claim is valid is irrelevant. The situation as it is now, reminds me of my school days – when one pupil did something wrong and refused to own up, then the whole class was punished. In the same way, because a few abuse the Benefit system, everyone suffers. Nonetheless

anyone who is entitled to such help should not be deterred by this.

- **It is essential to keep detailed records**. If, for example, the claim is based on frequent hypos, a log should be made detailing all such incidents, when help was required, why it was required and for how long. The DLA care component is determined by the amount of time that assistance is required. Secondly, although you may feel that your GP and clinic doctor are as much use to you as a chocolate teapot, you must ensure that they are kept fully aware of your situation.
- **Information about DLA is available from CABs, Post Offices, DSS offices and disability organisations. The Child Poverty Action Group [94 White Lion Street, London N1 9PF] publish excellent and very detailed handbooks and advice guides on all benefits at a reduced cost to claimants.**

I hope the above is of some assistance. Personally, I would prefer it if I was not claiming DLA, but in full time employment and in good health. However all that came to an end shortly after being changed to 'human' insulin and we all know the story from there. Sadly the pharmaceutical companies and the medical profession have painted themselves into a corner from which they cannot extricate themselves. A plague on both there houses as far as I am concerned.

*References

Diabetes and high blood pressure impair mental abilities [cognitive performance], Diab Care, Sept 1997

Hypoglycaemia may cause some loss of intelligence, Diab Care, June 1997

Memory loss and diabetes, Diab Care, 1997, 1:32-35

For information
The Weekly Rates for Disability Living Allowance are as follows:

Care Component

- Highest Rate £52.95
- Middle Rate £35.40
- Lowest Rate £14.05

Mobility Component

- Higher Rate £37.00
- Lower Rate £14.05

If you have needed help for 3 months and you are likely to need it for at least another 6 months, then you are entitled to claim DLA.

- If you need help looking after yourself
- If you become ill or disabled and needed help before your 65th birthday
- If you are aged 5 or over and under 65, and have difficulty walking or need help getting around
- Paid at different rates

DLA can be claimed for children aged 3 months and over and generally need extra help and looking after – more than other children of the same age.

Attendance Allowance
This is very similar to DLA but applies to people who became ill or disabled and needed help after your 65th birthday.

For full details of these benefits see Leaflet SD1 they are easily available in your local Post Office.

Christmas Cards - A Gentle reminder!

We would like to thank everyone who has already ordered their IDDT Christmas cards and remind those who haven't that Christmas is not that far away! Please help IDDT by ordering some of your cards from us.

'Smiling Snowman' comes in packs of 10 for £2.70 per pack plus 50p per pack for p&p. Send your orders to Sue Morris, IDDT, PO Box 294, Northampton NN1 4XS and make your cheques payable to IDDT.

Monitoring Insulin Pork Insulin Supplies From Novo Nordisk

I would remind you that at a meeting with Novo Nordisk UK last year we were promised that their supplies of pork insulin would be available in the UK for as long as they were made for anywhere else in the world. They admitted that they had no idea how long this would be. They also said that because their pork insulins were being withdrawn from countries in Europe this year we were not to assume that this would automatically happen in the UK. We are happy to believe this statement but we are still left not knowing how long supplies will continue – it could be 20 years but it could equally be 2 years or less. We have no means of knowing and no guarantees. One thing that we do know, however, is that when pork Velosulin was withdrawn last year there was very little publicity about it and only a short time for people to decide what to do. Once more the decision almost had to be taken at the pharmacy when trying to fill a prescription.

In the past we have kept track of possible changes with your help by recording expiry dates. We feel that we should do this on a regular basis so that we can be aware of any possible changes that may be afoot. So 6 monthly we are going to include a form in the Newsletter for you to fill in and return to us. Please help us to monitor the situation so that we can all be prepared.

ONLY if you use any of the following **PORK** insulins made by **NOVO NORDISK** should you fill in the following form:

PORK ACTRAPID

PORK INSULATARD

PORK MIXTARD 30/70

Name of insulin [eg pork Actrapid]

Expiry date

Your name

Town

If you use Novo Nordisk pork insulins, please help us to help to keep you informed by filling this in and returning it to IDDT – X, PO Box 294, Northampton NN1 4XS.

NOTE – unlike many other countries, we in the UK do have a choice of animal insulins. CP Pharmaceuticals also supply pork and beef insulins and in cartridges for use with pens. So while no one likes change, a withdrawal of Novo Nordisk pork insulins does not mean that you will have to use 'human' insulin.

Eating Disorders

We are not including a specific 'Parents Part' in this Newsletter but I feel the following story by Michelle Tichy will be of interest to many

parents of children and young people with diabetes and to those affected by one of the eating disorders that we hear so much about. We are grateful to Michelle for sharing her story with us to not only help others in similar positions but to help give all of us a better understanding of these problems. The views are those of Michelle and are not necessarily those of IDDT, but we welcome this first-hand experience.

Eating disorders are bad news for anyone but an eating disorder with diabetes is particularly serious. Before reading Michelle's story we need to know what an eating disorder actually is:

Basically eating disorders are serious preoccupations with food, weight and/or body image. Clinically there are 3 types:

- Anorexia – self starvation triggered by an extreme fear of gaining weight
- Bulimia - a binge/purge cycle stemming from a fear of gaining weight.
- Compulsive eating – bingeing thought to be caused by a need to numb negative emotions and negative self-image.

My Story

by Michelle Tichy

I was diagnosed with Type 1 diabetes in February 1982 - I was 7 years old. The first couple of years were OK aside from adjustments to the new routine and my parents increased fighting. I guess I blamed myself for their fights, I was always putting myself in the midst of these fights and often I tried to deflect their anger at each other on to myself. By the time I was 11 it was clear that they were headed to separation and divorce.

My response to the pain that this caused me was self-inflicted pain and a warped perfectionism. I developed an eating disorder that can best be classified as 'borderline anorexia' in that my symptoms were: rigid food rituals, strict rules about the amount of food eaten, purging, excessive exercising and extreme fear of gaining any weight. At the same time I developed a fanatical fear of ever getting high blood sugar, so I ran normal to low. My eating disorder continued for the next 7or 8 years, made worse by puberty and I actually delayed menses until 6 months after I turned 15 and this can be considered a symptom of anorexia. Since my weight never went below normal the only clinical diagnosis I ever received was 'borderline anorexia' and this was inaccurate because of the purging bulimia. This is one reason that I choose not to use clinical definitions for eating disorders that do not take into account the realities of all sorts of eating and body image problems.

My eating disorder was never caught by any of my doctors, in fact I was their star diabetic patient because I kept my blood sugars so close to normal! Even the dietitians missed the fact that I was barely eating enough to continue functioning. I never lied to any of them but I never offered any information to them about my Eating Disorder.

I cannot pin point the cause of my eating disorder to one thing specifically, the following are the main causes I see:

- Indoctrination by doctors on the importance of diabetics being thin.
- Society's standards of beauty.
- Stress/ perfectionism.
- My family falling apart.

I have been in recovery now for 3 years – it is rough at times.

My view of the connections between diabetes and eating disorders.
People with Type 1 diabetes have eating restrictions placed upon them by doctors generally from diagnosis. They are told to follow a specific diet and to reduce their sugar intake to next to nothing. From my experience as a 7year old, it felt like I had been locked into a cage and was only allowed to eat certain things, none of which

was ‘fun stuff’. Some of my diabetic friends that were diagnosed in adolescence felt direct pressure to be fanatical about food and their weight. It seems to me that direct pressure from doctors to be thin and constantly concerned about food is a clear way to create the groundwork for eating disorders. My assertion is validated by research on diabetics and other young people with chronic conditions which has shown that young diabetics have a higher probability of developing eating disorders than those in the same age group who have no chronic illness.

More common eating disorders related to diabetes:

- Running high blood sugars [hyperglycaemia] so that your body produces ketones and in doing so there is weight loss.
- Reduction of insulin dosage so that you run high blood sugars and so that you don’t have to eat very much.

My views on being healthy with diabetes and avoiding or overcoming body image problems and eating disorders

- Know yourself and what it feels like to be high or low.
- Respect yourself, neither an eating disorder nor ignoring diabetes is healthy.
- Doctors are resources to keep you healthy. If you don’t trust yours enough to be able to talk to them, maybe you need a different one.
- Try to be the best you can – not some societal ideal.
- Remember to try to get something from each food group at each meal.
- Do everything in moderation from food to exercise. Find activities you enjoy to both ‘de-stress’ and be active [walking tennis etc]. Try meditation or yoga for stress relief and getting to know your body.
- Find people to talk with about your insecurities. Join a support group.

Michelle can be contacted by email at myhsthe@aol.com

Driving Information

‘Some patients with diabetes drive when they know they are hypoglycaemic.’

This is the title of a news item in The Lancet [August 28,1999] and it is reporting on research published in JAMA 1999: 282: 750-54. It is a worrying title and the results of the research are equally worrying.

Previous research has shown that there is a sharp drop in driving competence when blood glucose values are 2.6-3.6mmol/l but there is little information about how blood glucose values affect decisions about driving. So the researchers examined 65 patients with IDDM in an initial study and repeated it 2 years later using 93 patients. Driving simulators were used to test driving ability and participants recorded on a hand held computer whether they felt able to drive. The results were somewhat frightening because in both studies participants said that they would still drive 43-44% of the time when they estimated their blood glucose levels were 3.3-3.9mmol/l and 38-47% of the time when actual values were less than 2.2mmol/l.

These results in themselves are worrying but both the title and a statement in the article are causes for concern because they are not only misleading but they show a lack of understanding of hypoglycaemia. Statements like ‘when they KNOW that they are hypoglycaemic’ and ‘the researchers did not analyse the REASONING behind the drivers’ decisions’ make assumptions that the ability to make rational, reasoned decisions is actually present. To me as a family carer, the reality is very different from this. Most carers know that even with mild hypos, the usual ‘mental clarity’ is often not present even though the person with diabetes may well be totally unaware of this and, as we know, they often get extremely angry if we suggest that they are hypo.

“I’ll have something to eat when I get there”

“I’ll stop at the next café”

As carers we have heard phrases like this all too often and suffered the resulting anger when we dare to suggest that this is perhaps not a wise move. But what we also know, is that our partners would not make such statements if their 'mental clarity' was not impaired by the hypo and they would not drive.

When an article in a professional journal uses words like 'know they are hypo' and 'reasoning' in relation to hypoglycaemia, it is clear that there is a lack of comprehension about the realities of hypos, how they actually affect people and the difficult position in which carers are often placed.

The saving grace is that Bruce Zimmerman, president of the American Diabetes Association is quoted as saying ' We may have failed to educate our patients about the dangers of driving with low blood glucose levels.' This is indeed a significant statement and it is a quote that I am sure will be used in the defence of people with diabetes that have motor accidents while hypoglycaemic. But people with diabetes can only receive proper information about the effects of hypos if the health professionals themselves, truly understand those effects. If people are not told that their judgements may be impaired, they can hardly be expected to take the necessary precautions especially when their judgement is actually impaired! There appears to have always been a reluctance or inability on the part of the medical and healthcare professionals to discuss any form of cognitive impairment with patients and their families. But it is vital, especially in these days of tight control and subsequent loss of warnings, that people are told and reminded regularly that even with blood sugars just below normal there judgements may be impaired. Knowing this is obviously very important in a driving situation but it is also important for very many other aspects of life – making decisions at work for example.

People with diabetes cannot be blamed for putting themselves or others in unsafe situations if they have not been informed that impairment occurs even with mild hypoglycaemia. Let us hope that future education programmes for people with diabetes and their families will include warnings of impaired cognitive function so that those of us that live with diabetes do not have to learn the hard and possibly dangerous way.

- It is worth remembering that in 1924 Joslin said "Diabetes is a disease for which education is not an additional treatment, but ***the*** treatment." I like to think that he would also have considered education had to be relevant to people's everyday lives to ensure not only good diabetic management but also their safety.

Photocard Driving Licences

The introduction of the new style driving licences that requires a photograph has now started and has to be completed by 2001 to meet the EC directive on driving licences but the paper licences will remain valid for the foreseeable future. This process started for certain categories of people in July 1998 but from April 1999 the photocard licence has to be obtained if you needed a new licence for the following reasons:

- To apply for your first provisional licence
- To renew your licence without a reminder, with a reminder was introduced in November 1998
- If you have lost or spoiled your licence
- If you want to add or remove provisional entitlement or remove out of date endorsements.

Clearly this arrangement is going to affect people with diabetes sooner than many other people because of the requirement to renew your licence within three years.

What do you need to do?

1. You need application form D750 – this will come with your renewal or is available from post offices

2. Return your current licence with the application
3. Send either your valid passport or birth certificate with the application – not a photocopy
4. Provide a passport style photograph that is signed on the back by someone that has known you for at least 2 years and this person must belong to a list of 'suitable' people eg MP, magistrate, councillor, professionally qualified person etc.

How often will you have to renew your photocard licence?

Normally this will be renewed every 10 years to the age of 70 to keep the photograph up to date. If you are on a medically restricted licence and or your licence has to be renewed more frequently for other reasons, then your photograph will not need to be renewed on each renewal. The DVLA will send you notification when you need to

renew your photograph.

Hello To Kirsty

I'm sure that you will all recognise that IDDT has grown over the 5 years since we formed and we welcome this – increased support, increased membership, increased funds and increasing numbers of phone calls all mean that we must be doing something right! But as you all know we are all volunteers and this growth means that IDDT's activities are being limited by our time. We have to continue to grow in order to achieve our goals. After some long hard discussions the Trustees came to the conclusion that we needed some administrative assistance so that our time could be spent on the real issues of importance to you and not wasted on admin jobs such as stuffing envelopes or even keeping our database up to date. But at the same time, we recognised that the value of IDDT is that it is made up of people that have first hand experience of living with diabetes and this must never be lost otherwise we go down the route taken by many organisations before us. We also recognise that what limited resources we have must be spent wisely and as far as possible directly on IDDT's aims.

Thanks to the generosity of Trustee, Peter Griffiths, we have been able to solve this problem and our new system is now in operation. Peter has an office for his own work and a secretary, Kirsty, whose time is not fully committed. Kirsty is therefore working from Peter's office for IDDT on a fee basis and IDDT is not having to pay any office costs. Kirtsy is taking many of the daytime calls and sending out the information packs. While Kirsty does not have diabetes, she has worked with Peter for some time and so does have some experience and understanding of diabetes. The callers details are then faxed to Jenny or one of the other trustees who then rings the caller back, usually in the evenings. If there is an emergency call Peter or one of us is always available.

Many of you have already spoken to Kirsty and we have received letters praising our speed at sending out information, so the system does work. It relieves the pressure on the trustees and gives us more time to spend listening and talking to the people who call us – one of the main functions of IDDT.

I am sure that this system will benefit IDDT and lead to further growth not only in membership and enquiries but also in our abilities to represent you and your needs. However, we all recognise that 'big is not necessarily beautiful' and there is great value in remaining a small organisation – we can keep in touch with the needs of our client group, the people who live with diabetes.

Note from Jenny – I apologise if I have not responded to your calls or letters as quickly as usual but after a difficult pregnancy my daughter has recently had a premature little baby girl and I would be a funny Mum if their needs did not come first!

News From CP Pharmaceuticals

The UK

Hypurin Porcine 30/70 Mix Cartridges.

You will remember that we were all delighted when CP introduced porcine insulins into their range, so removing our fears of there being no alternative but synthetic 'human' insulin if Novo Nordisk remove their porcine insulins from the market, as they have done in other countries. At the same time, they also introduced their porcine and bovine insulins in cartridges for use with pen injection devices – the first time this option has been available for people in the UK to have both the convenience of the pen and being able to use the natural animal insulin that suits them best.

You will probably also remember that their pre-mix insulin, Hypurin Porcine 30/70 Mix in cartridges, had to be withdrawn because of abnormalities in the crystals in the product. CP have been carrying out a re-formulation of this insulin and announced in July that this work has now been completed. On the basis of laboratory and manufacturing scale stability tests they are confident that they have overcome the problems. They also say that they have to allow 6 months stability testing to be completed before they are able to release the product to the market but they are very optimistic and expect to be releasing the stock by the end of October 1999. Your health professionals will receive a letter from CP to let them know when Hypurin Porcine 30/70 Mix Cartridges will be available for your use. However, if you want to use this insulin, do check its availability because it may be that CP's letter becomes buried in paper.

The United States but good news for everyone!

There is good news for people in the US who need to use bovine insulin and this has important implications for everyone, in whichever country they may live. Lilly the only suppliers of beef/pork insulin in the US withdrew this insulin from the market with very little notice, so leaving people requiring it in difficulties. Some of these people tried to use the personal importation system to obtain the beef insulin they need from CP Pharmaceuticals in the UK but this is a slow process and sometimes the insulin importation was stopped by the American Department of Agriculture [USDA].

The good news is that thanks to the persistent combined efforts of Congressman Nethercutt and Amy Flachbart, the JDF and Jane Adams and Charles Savage and his team from CP, meetings have been held with the FDA [the US drug regulatory body] and USDA and the following key points have been established:

- The FDA and USDA are now fully aware of the implications of the impending shortage of bovine insulin and have indicated their support in finding ways to speed up the legal entry into the US of products such as CP's range of insulins.
- CP have been strongly encouraged by the FDA to discuss and agree a facilitated and expedited means of obtaining licences for these insulins. This may take a year to achieve.
- The USDA has agreed to simplify, and facilitate the turn-round, of its importation application form.
- The JDF will increase its programme of informing people with diabetes, their doctors, Institutions and the general public about the availability of CP natural animal insulins, through the personal importation programme.

This is a major step forward and not only because it will help the people who need bovine insulin to obtain it. If we look a little deeper, it actually means that the FDA now recognises that there is a need for natural animal insulins and that not everyone with diabetes can use synthetic 'human' insulin without having adverse reactions. This has major implications for everywhere in the world – if the FDA in the United States recognises this as fact, then regulatory authorities in other countries must surely follow their lead.

There are further implications for the medical profession as the majority of them have not believed their patients when they have reported these adverse reactions and they use 'human' insulin as first

line treatment. Where does this acknowledgement by the FDA leave them? I should think in somewhat of a quandary and if I was in their shoes, I would be asking myself a few pertinent questions such as:

- If the FDA is acknowledging that there are problems with ‘human’ insulin in some people, should I have listened to my patients in the first place?
- If I carry on prescribing ‘human’ insulin, how am I going to know that my patients are getting the insulin that suits them best?
- Have I believed the insulin manufacturers’ sales patter, when I should have looked more closely at the research in conjunction with the information that patients have been giving me for the last 15 years?
- Where do I go from here in terms of what I prescribe, especially as I know the dangers of hypoglycaemia, the dangers of loss of warnings and that some people do report that their health and wellbeing has deteriorated since using ‘human’ insulin.

Surely our doctors do have consciences and they must, in the middle of the night, ask themselves a few searching questions. Surely their loyalties and duties are to their patients and not to the pharmaceutical industry or their funding.

Naturally we would like to have seen that natural animal insulins remained available through the usual licensing route and let us hope that this is reintroduced, but in the meantime an improved personal importation programme is a realistic and practical step to enable people to obtain the insulin they need. Thanks to the help of those who understand these needs, people with diabetes by their determination and united efforts, have used their power to take control of their health needs against the might of the large pharmaceutical companies. Progress and encouragement for us all!

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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