



# Insulin Dependent Diabetes Trust

April 2000 Newsletter



## The Good News

Pens and pen needles to be available free through the NHS from March 1st 2000. This long awaited decision means that people will now have the choice of injection devices totally uninfluenced by cost. So everyone requiring insulin, whether natural animal or synthetic 'human' insulin will be able to chose both the type of insulin and the injection method that suits them best.

Further details are available inside this Newsletter.

## The Bad News

Following a statement on February 7th 2000 from Novo Nordisk that pork insulin was is being withdrawn from the US, Novo Nordisk's Director of Corporate Communications, Susan Jackson, said that the

company is planning to remove pork insulin from the world market by the second half of this decade.

“Since the introduction of ‘human’ insulin, the role of animal derived insulin has diminished significantly world wide. Novo Nordisk does plan to discontinue manufacturing these products world wide...The exact timing of this discontinuation will be determined by the individual country”, says Jackson.

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## IDDT - Calls For Support

IDDT-International wrote to the Presidents of the American Diabetes Association [ADA] and to the Canadian Diabetes Association [CDA]

in January this year calling for their support. I am pleased to say that ADA and CDA are both going to help to get information to their members about personal importation of the natural animal insulins they need.

Jenny Hirst attended a meeting at the British Diabetic Association in November 1999 the outcome of which appeared to be that the BDA could not change its policy because there was no new evidence on which to do so. I would suggest they and others read the article inside this Newsletter entitled 'Evidence'.

“All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience, and should act towards one another in a spirit of brotherhood.”

This is the universal declaration of human rights adopted by the United Nations General Assembly in 1948. It may be a statement adopted over 50 years ago but it still holds true today. It applies to healthcare as much as any other aspect of life. It is with this statement in mind that IDDT calls for the support of all diabetes organisations that state that they look after the needs of people with diabetes. If this is true, then they look after the needs of all people with diabetes, including those who need natural animal insulin because they have adverse reactions to synthetic so-called 'human' insulin. It may be hard to understand or explain why these adverse reactions occur but the people to whom this happens deserve to be treated with equal importance, with respect for their dignity and rights, and as people endowed with reason and conscience.

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## The Fight For Survival

This is probably the most outspoken Newsletter that I have ever written but why not? We have nothing to lose any more.

There is nothing more certain that if all animal insulins disappear over the next few years, we will have a repeat of the problems of the 1980s. I make this statement because I have faith and trust in people with diabetes and perhaps above all I believe them – they do know their own condition. I can also make this statement because I do have some faith in the science – in this case if only because there isn't any to support this decision! There is no evidence to suggest that synthetic 'human' insulin has any advantages over natural animal insulin and no evidence to disprove the experiences of people that have adverse reactions to synthetic insulin.

It will give no satisfaction to IDDT to be able to say – we told you so. However, we will have done all that we can to try to help people who are suffering at the hands of big business under the guise of patient care and we will be able to sleep in our beds at night. There are some that will not.

When we hoped that logic, common sense, reasoned arguments and even appeals might be effective in ensuring that the needs of so many people would not go unanswered, we were wrong. When we hoped that patient care in its real meaning, would count above all else, we were wrong. When we still had some faith and trust in the health systems and those that work within them, we were wrong. When we believed that research was carried out in our best interests, we were wrong. When we have tried to fight this battle without upsetting people with diabetes happy on 'human' insulin, perhaps we were wrong.

Now we have been left with no choice – it is a fight for our survival and we will not lose the animal insulin that is literally a lifeline to some people without taking the gloves off and using everything at our disposal. If people are upset by this and if there is panic, I am sorry. But I will never forget the state my daughter was in after 9 years of 'human' insulin and the incredible difference in her when she changed to pork and beef insulin. I will never forget the look of fear in her eyes last year when in hospital and emergency, she had to have 'human' insulin. She is typical of thousands of people that will suffer as a result of this heartless business decision. But my daughter is lucky – she

lives in the UK where we have CP Pharmaceuticals committed to the production of animal insulins and she is lucky because she knows this – many in the UK do not and may be forced on to ‘human’ insulin. We have to get the message to them.

But we cannot and will not ignore people like us in other countries who are being left with no sources of animal insulin or no sources that are affordable. We will be more vocal, we will use everything that is at our disposal to expose this disgraceful catalogue of events and we will stop at nothing to try to ensure that the health needs of ALL people requiring insulin treatment are met.

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## IDDT’s Response To Tony Blair

“The key to GM is its potential, both for harm and good” was the title of an article in The Independent on Sunday, 27 February 2000, and we received very angry phone calls from members.

They were not on their own, the Trustees were angered too! He made the statement that was subsequently repeated by Mo Mowlam on various BBC radio programmes. Clearly the on line message for Ministers was to cite the production of synthetic ‘human’ insulin by biotechnology as a wonderful example of the potential for good. As this happened just before our print deadline I cannot cover IDDT’s full response to Mr Blair but will do so in the next Newsletter. For the moment, I want to reassure members that IDDT responded with vigour and frankness. We wrote to Tony Blair, Mo Mowlam and The Independent on Sunday. We also sent statements to all the national daily and Sunday papers and letters to the editors of local papers. This statement is on IDDT-International web site which can be found at [www.iddtinternational.org](http://www.iddtinternational.org). Needless to say, we have pointed out that insulin produced by GM technology not only has no proven benefits and is not cheaper, as predicted, but it produces unexpected and unacceptable adverse reactions in a sub group of people that cannot

be identified until they actually have the problems. We have suggested that with the full information, perhaps he would be suggesting that the ‘human’ insulin saga should be used as an example of the potential for harm and the need for more research and great caution. We have, however, given Mr Blair a let out by pointing out to him that it is hardly surprising that he has been ill informed because the problems people have encountered have largely been ignored and swept under the carpet. Here is the offending extract from Tony Blair:

“There is no doubt that there is potential for harm, both in terms of human safety and in the diversity of our environment, from GM foods and crops. It’s why the protection of the public and the environment is, and will remain, the Government’s over-riding priority. But there is no doubt, either, that this new technology could bring benefits for mankind. Some of the benefits from biotechnology are already being seen in related areas such as the production of life-saving medicines. GM technology has, for instance, helped diabetics by the production of insulin. GM crops, too, have the potential for good – helping feed the hungry by increasing yields, enabling new strains of crops to be grown in hostile conditions, or which are resistant to pests and disease.

The key word here is potential, both in terms of harm and benefit. The potential for good highlights why we are right not to slam the door on GM food or crops without further research. The potential for harm shows why we are right to proceed very cautiously indeed. And that is exactly what we are doing.”

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## More Withdrawals Of Animal Insulins - In The United States

**By Jenny Hirst**

In early February this year Novo Nordisk announced the withdrawal of their pork insulin from the US despite IDDT-US being told in only

November last year that they had no plans to discontinue it. They have already withdrawn their beef insulins and so Novo Nordisk are no longer supplying any animal insulins for people in the US. This follows closely on the heels of Lilly's withdrawal of beef/ pork insulin in the US. But perhaps of even greater concern to all of us, wherever we live, is the further statement that the company is planning to remove pork insulin from the world market by the second half of this decade – the reducing sales of pork insulin, being the apparent reason for this.

I am not going to go through all the old arguments about the role of animal insulin diminishing – consumers are no longer fooled by this. We know that techniques have been used to artificially diminish the market. We know that this statement itself, will further diminish the markets - even doctors that favour animal insulins, are not likely to put the newly diagnosed on an insulin that is likely to be withdrawn shortly. We have long memories and the experience of the whole disgraceful animal/'human' insulin saga where patients' needs and experiences have been totally ignored and where patients were changed to 'human' insulin for no good clinical reason with no evidence of any benefits from the change. Protracted arguments will not work because business decisions have been made and those do not involve the health and wellbeing of the significant minority of people who need to use the apparently redundant animal insulin that has kept them alive and well.

Novo Nordisk place the blame with the physicians. Their representative, Susan Jackson goes on to say:

“World wide we are seeing the demand [for animal insulins] diminish significantly. I guess you could say that this was a business decision to react to the fact that 'human' insulin is the treatment choice by most physicians.”

- What has happened to the talk of patient choice, of equal patient/ doctor partnerships? To the benefits of patient involvement in the decisions about their treatment and the legal requirement in countries such as the UK, for patients to have information about

alternatives, risks and benefits before they, the patient makes the choice of treatment? All these seem to have passed by Novo Nordisk and the physicians to whom they refer – it appears that it is only doctors and not patients that have the choice.

- Why is diabetes care so far behind other fields of medicine where patients are involved in the decision making process about their treatment?
- Do physicians in diabetes care have so little respect for their patients that they think we are not capable of making decisions if we are given all the evidence and information?
- Or is this the rub? What evidence? We all know and so do they, that there isn't any evidence that 'human' insulin has any clinical advantages for patients.

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## So What Would The Physicians Tell Us If They Decided We Deserved The Choice?

1. 'Human' insulin is more aggressive in its action, has a shorter duration and greater peak of action than both beef and pork insulins, so you or your child will probably need more daily injections with 'human' insulin than with animal, but this doesn't really matter.
2. According to the UK Department of Health, some people are not suited to 'human' insulin but we don't know which people – could be you or not.
3. Some people have reduced or loss of warning signs of hypos using 'human' insulin. But this is OK you will just have to learn how to recognise the less obvious signs that you may have with 'human' insulin and if you fail to recognise the signs, then you will have a severe hypo leading to seizure and/or coma.
4. 'Human' insulin produces less antibodies than animal insulin, but we don't know the significance of this, if any. Perhaps the antibodies produced to animal insulins slow its action down making it easier to control your diabetes.
5. A significant number of patients and their carers have been

reporting problems with 'human' insulin for the last 17 years, but we don't take any notice of them. They are only people with diabetes – the drug companies have told us that 'human' is better, although they have not produced any evidence of this.

6. 'Human' insulin is not human insulin. It is synthesised from bacteria but they could not really call it bacteriological insulin otherwise no one would want to use it.

Yes, this is an angry [and sarcastic] response but not an unjustified one or one for which I apologise. Novo Nordisk and Lilly cannot be prevented from making their business decisions but the medical and nursing professions could have given more support to patients that need animal insulin.

- They could have brought their considerable influence to bear on the drug companies so that animal insulins do remain freely available for everyone. They are the prescribers and the people that the drug companies sell to – not us.
- They could have looked for independent evidence that 'human' insulin was, and is, safe for everyone with diabetes requiring insulin treatment. They could even have taken notice of the research that does show that there are and always were problems with 'human' insulin.
- They could have carried out comparative trials that would have provided insulin treatment based on evidence not assumption or the word of the drug companies.
- They could have asked themselves why people like us keep fighting to retain animal insulin and why some of their colleagues are prepared to stand up against the tide within the medical profession and criticise 'human' insulin. There is no gain in this for any of us.

Our anger is not misplaced, it is justified and so is our lack of faith and trust in the healthcare system and some of the people in it. We have been let down by every possible system and organisation you can name and here are just a few of them:

- The regulatory authorities for approving the first genetically produced drug, 'human' insulin so quickly and without any formal post marketing research. For doing little with the large number of adverse drug reports that they have received. For taking so long, 16 years in the UK, to admit that 'human' insulin does not suit everyone.
- The medical and nursing professions for not believing their patients and for not truly understanding the effects of hypoglycaemia, especially when accompanied by unawareness of symptoms.
- National and international diabetes associations for not listening and supporting their members and speaking with a much louder voice on their behalf when the adverse reactions first appeared so many years ago.
- The drug companies that profess to have patient care as part of their agenda but happily make business decisions that ignore the needs of so many people.



## **“We Have No Plans To Withdraw Pork Insulin”**

Using this well worn, meaningless statement, when announcing the withdrawal of beef/pork insulin, Lilly said that they would be continuing to produce Iletin2, their pork insulin. But this statement offers no guarantees or reassurances to people who need animal insulins. It also appears meaningless because there is considerable difficulty in actually obtaining Lilly's pork insulin from pharmacies in many States throughout the US.

Supposedly as reassurance, this statement is trotted out by the FDA, the US drug regulatory body when people have complained about the withdrawal of beef/pork insulin. The fact that the FDA and their medical advisers don't appear to know that pork and beef insulins are different is decidedly worrying! While pork is not what people who are stable and well on beef/pork want, it may well be a better alternative for them than 'human' insulin that they know causes adverse reactions.

However the reassurance ceases if you actually try to purchase pork insulin! It appears impossible to do so and by sheer coincidence, if you believe in it, all traces of information about animal insulins, both beef/pork and pork, have disappeared from Lilly's web site. Not only does this make it difficult for both patients and doctors to obtain information about the availability of pork insulin, but it also implies that it is no longer available.

### **What do our investigations show?**

IDDT US and IDDT Canada, along with others have been investigating availability of pork insulin. Closer to home, one of our UK members who is working in the US also did some investigating for us and what do you think he found on visiting three large pharmacies?

- None of the pharmacies had any pork insulin in stock, whether from Lilly or Novo Nordisk.
- None of the pharmacies offered to obtain any from their suppliers for him.
- None of them would say whether or not it was available, although one did give him Lilly's phone number.
- They all offered him 'human' insulin.
- One of them offered him Lilly's discontinued beef/pork insulin.

Being a determined kind of guy, he then contacted both Lilly and Novo Nordisk in the US. Both were very helpful and very pleasant and both talked about each other's products and I quote "as if they were hand in glove with each other" – strange for so-called business competitors!

From Novo Nordisk:

- He was told that from February 7th, 2000 pork insulin production will cease for the US and that they expect stocks to run out by the end of July this year. But pork lente supplies will disappear quickly because most US users are on lente.
- They told him that Lilly is continuing to supply pork insulin!

From Lilly:

- He got the same answer 'we have no plans to discontinue pork insulin'.
- When pressed, they told him that there was definitely no shortage.
- When asked about the lack of stocks within pharmacies, they told him that any pharmacy could order pork insulin from their suppliers and that Lilly has no influence on the delivery to pharmacies – that's the wholesalers responsibility.
- Surprisingly the spokesperson did tell him that he could obtain CP's insulin through the personal importation process, actually not true yet for pork because you can only import if there are no supplies within that country and Lilly say there are!

### **Been there, worn the T-shirt!**

I don't know if we are supposed to have short memories and just maybe I have got it wrong but I feel as if I have been here before. A couple of years ago IDDT was contacted by friends in the US who were having difficulty obtaining Novo Nordisk beef insulin. I made enquiries from Novo in the UK and was told there was a 'slight production problem' but this would be rectified. Was it? No! The next we all heard was that Novo Nordisk had withdrawn beef insulin from the States!

Now we have Lilly's statement 'no plans to discontinue pork insulin' but it is actually difficult to find! Even worse there appears to be a ring of silence from pharmacies at the sharp end of dealing with people trying to purchase it. My imagination and past experience leaves me deeply suspicious and these suspicions will only be removed by seeing easy access to Lilly pork insulin again.

### **Where does this leave the FDA?**

Frankly in a very difficult position. They believe what they are told by Lilly that pork is available and they pass this on to the consumer, but the consumer can't actually get it. If Lilly have a 'production problem' with pork insulin, why don't they say so and tell the FDA? Failure to do so is involving the FDA in providing information that, at best, is inaccurate and misleading. The worst interpretation I leave to your imagination.

## Where does this leave the consumer?

Simple answer – in an impossible and desperate position!

The consumer goes back to the FDA again and they get told the same story. They go back to Lilly and once more they get the same story – ‘no plans to discontinue pork insulin.’ Meantime unsuspecting people are being forced on to the only apparently available insulin – ‘human’! Works well, if you are not the patient!

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## Thanks Yous And Congratulations!

### Many Thanks

We very much appreciate a magnificent donation from Great Yarmouth. A group of people involved in amateur dramatics held a performance in memory of Kevin Boulton who had diabetes and died of cancer last year and the proceeds were shared between IDDT and a cancer charity. We received over £1000 and we are very grateful to all the people who must have worked so hard and to the late Mr Boulton’s sister for contacting IDDT.

We would also like to thank IDDT member Bill Holden from Norwich, who attended the presentation and accepted the donation on behalf of IDDT. His willingness to help in this way was appreciated by all the Trustees and demonstrates the spirit of IDDT.

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## Thanks To John

John Hill has been our treasurer for some years and has done an excellent job for IDDT. He has done much more than simply count the money and carefully manage our expenditure - many of you will

have spoken to him on the telephone. “The nice man in Wales”. John decided to give up the job of treasurer at the end of 1999 and take life a bit easier. We are all pleased that he is remaining a Trustee of IDDT and thank him for all his hard work.

Sue Morris is taking on the job and we welcome her to the position. Sue ‘manages money’ as part of her working life and so we know that she will manage IDDT affairs carefully. You can be assured that IDDT funds will continue to be in good hands.

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## Congratulations!

Congratulations to Bruce Beale who runs IDDT’s web site in the UK – the IDDT site has been awarded the best diabetes site by Schoolzone which is used by as an information resource by teachers. The award is granted by a judging panel of 250 teachers and we received their 5 star award, higher than all other sites in the UK! Well done, Bruce and many thanks for all your hard work.

I must add that we are delighted that teachers are looking for information about diabetes in order to help and understand our children with diabetes while at school.

For those interested the web site for Schoolzone is [www.schoolzone.co.uk](http://www.schoolzone.co.uk)

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## Industry Agrees With Patients, But Perhaps Only When It Suits Them!

After nearly twenty years of use, it is widely accepted that ‘human’ insulin does produce adverse reactions in some people. All drugs

have adverse reactions for some people, so why should insulin be any different? Even the pharmaceutical industry accepts this, but perhaps only when it suits them!

A submission of PhRMA, the US pharmaceutical trade and lobbying union, dated December 3rd 1999, referring to the recent changes in drug pricing policy in Australia says **“The introduction of Therapeutic Group Premiums....does not recognise that some products are not interchangeable, and that individuals do not necessarily respond in an average or predictable way...”**This is in entire agreement with the views of IDDT - not all insulin species are interchangeable and some people do not respond in an average or predictable way to ‘human’ insulin. If, indeed, the pharmaceutical industry really does believe this statement because it is not too happy about the changes in drug pricing in Australia, then one has to wonder why they have such difficulty in applying these beliefs to insulin!

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## Good News For Pen Users

Most of the papers have covered this good news so I am sure that readers will know by now that from March 1st 2000 pen needles became available free through the NHS on a GP prescription, although at the time of writing this only applies to England and Scotland. It is hoped that Wales and Northern Ireland will follow suit. This is good news indeed for those that prefer pens but disposable syringes will remain available for those who prefer syringes. Above all, it means that people with diabetes will now have the choice of injection methods uninfluenced by cost. This may now influence animal insulin users to try the pen as a more convenient method of injection, especially when going out or on holiday.

Here is clarification of what is now available:

- Needles to fit any brand of pen.

- Re-usable pens of the following types:

1. Novo Nordisk’s Novopen only available for 3ml cartridges and only their own brand of cartridge,
2. Owen Mumford’s Autopen available for 1.5 and 3.0ml cartridges,
3. Becton Dickinson’s BD pen again available in 1.5 and 3.0ml sizes.

The Autopen and the BD pen can be used with cartridges of both Lilly and CP Pharmaceuticals cartridges but Novo Nordisk have changed their cartridges so that they are not interchangeable with any other pens but their own make.

- Disposable pens will continue to be available.

Note – IDDT understands that there is a considerable difference in the prices to the NHS of the various pens, Novo Nordisk’s being in the region of £22.00, BD pen being around £18.00 and the Autopen being around £13.00.

The estimated number of people using pens is 225,000. In addition to free pen needles, the pens themselves will also be available on the NHS free of charge. But then they have always been free – the difference now is that the NHS is picking up the bill instead of the drug companies. If every one of the 225,000 people have only one new pen at a cost of £20.00 this will add around 5 million pounds to the NHS diabetes budget.

Jenny’s comments - Lord Hunt, Minister of Health is quoted as saying that people with diabetes ‘people with diabetes deserve access to top quality standards of care and treatment’. Sorry to put a damper on this but I hope Lord Hunt remembers this when he considers the plight of the blind and visually impaired people with diabetes who do not have access to blood glucose meters that are suitable for their needs. It would not cost anything remotely resembling 5 million pounds to help this group of people with a medical device that not only gives them independence but also helps them control their diabetes. There is no evidence that pens improve diabetic control, basically they are

injection devices, albeit convenient and more socially acceptable than syringes. I feel out on a limb with this one. I am pleased that needles are to be free but providing pens on the NHS when the only benefit is to the drug companies, must surely make us question our priorities when this comes before the needs of blind and visually impaired people.

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## Novo Nordisk Withdraw Pens For 1.5ml Cartridges

I must apologise to readers for not providing this information sooner but we only found out by accident and we immediately contacted Novo Nordisk Customer Care. They confirmed that they have stopped producing the 1.5ml pen. I was assured that the 1.5ml cartridges will continue to be available. However, the cartridges that fit the 3.0ml pen are different from cartridges made by Lilly, so that if you want to use Novo insulin you have to use the pen made by Novo Nordisk. Bearing in mind that the Novopen costs the NHS more than all other NHS approved pens, it seems like a very shrewd move!

Forgive my cynicism but it strikes me as a remarkable coincidence that this happens during the 12 months that the DoH is deciding whether or not to allow pens to be free on the NHS. At some point, and we know not when, 1.5ml cartridges of Novo Nordisk insulins will cease to be available on the grounds of reduced demand no doubt, and everyone will have to change to the 3.0ml pen. Not only will there be the saving on no longer supplying pens free but there will be an increased number sold because eventually people will have to change to the bigger pen. The tab for all this will be picked up by our strapped for cash NHS

If we look at the costs involved it gets better!

- You would expect the cost of the 3.0ml packs at worst to be twice

- that of the 1.5ml packs because they contain twice as much insulin.
- You could even expect the 3.0ml packs to be cheaper because the production costs are less for the manufacturers – they are selling twice as much insulin by producing half as many cartridges. [Buying a big pack of washing powder is always cheaper than two small ones!]
- So if the 1.5ml packs cost £9.87, then you would expect the 3.0ml packs to cost no less than £19.74. But do they?
- No! The 3.0ml packs cost £22.87. This means that insulin in 3.0ml cartridges is costing nearly 14% more than the same insulin in 1.5ml cartridges.

This is great news for the manufacturers – increasing profits and lowering production costs. A double whammy! In reality their job is to make profits for their shareholders, something they are clearly achieving. How do Novo Nordisk manage to justify increasing the price of insulin and while at the same time lowering their production costs? But the real question is who on earth makes the pricing decisions on behalf of the NHS? Do they know what they are doing? Do they forget that it is public money that they are spending/wasting?

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## Remember The Following Information About Pens

- All the insulin manufacturers say that insulin in cartridges is stable for up to 4 weeks once opened if stored at 25 degrees C in a refrigerator. It should then be discarded.
- In use cartridges should not be stored in the refrigerator.
- Novo Nordisk's table for exposure to temperature says that insulin should not be exposed to temperatures of between 8 and 25 degrees C for longer than 96 hours [four days.] This is particularly important if you use a 3.0ml cartridge and only need small doses – you may not use empty your cartridge within the required 4 days.
- Remember that the efficacy of insulin is affected by heat and

vibration and insulin in pens carried around with you, often in pockets close to the body, is more exposed to both heat and vibration. The larger 3.0ml cartridges mean that your insulin is being rattled around for longer and exposed to body heat for longer than with a 1.5ml cartridge.

- If you find that towards the end of a cartridge your blood sugars are rising then consider the possibility that your insulin has become less effective. If you have increased your dose to counteract these highs, then be careful of hypos when you start a new cartridge with fully effective insulin.

Golden Rule: If in doubt discard your insulin and start a new cartridge or vial.

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## Reminder About Tipping Your Pen

Many of us that have been around diabetes for a long time remember the original instructions that the vials containing longer acting insulins have to be rolled or tipped several times because these insulins contain several components that need mixing. Pens containing the longer acting insulins also need tipping and rolling for the same reasons.

Research published in November 1999 in The Lancet and carried out in Germany has shown that Isophane [NPH] needs tipping or rolling at least 20 times to ensure a good mix. 109 pens were collected from patients but only 35% of them had the correct Isophane[NPH] mix. Questioning patients showed that only 9% of them had tipped or rolled their pens more than 10 times. The researcher showed that after education about tipping and rolling the errors reduced in 35 out of 44 patients and perhaps very importantly, the rates of hypoglycaemia dropped significantly.

## Evidence

I have started to hate this word because it has been used so many times against the people with diabetes who have complained that they have had adverse reactions to synthetic 'human' insulin – reactions that disappear with a change to natural animal insulins. These personal testimonies are in fact 'evidence' and they are evidence in the same way that personal testimonies are given and accepted in court – the only difference is that we have not pledged to tell 'the whole truth and nothing but the truth' with a hand on the bible. But I am sure that we all would!

### So why does the word irritate me so much?

It doesn't, but when accompanied by 'scientific' then it does. Does the attaching the word 'scientific' give the evidence any more credibility? Is the word used to impress those of us that are not scientists, the gullible general public and even the decision makers? I am sure that there is an element of this. Is the evidence from people who are not scientists less valid than that from people defined as scientists? If this is so, then it displays an arrogance beyond belief!

If decisions are made on the basis of scientific evidence without taking into account all the other forms of evidence, this displays complacency. It assumes that the research methods used are perfect and irrefutable – not so, there can be no such thing as perfect research if only because research is limited to the known methods at the time. Methods move forward and much of the research carried out 10-15 years ago would be unacceptable by today's standards. It also assumes that there has been a determination to look for evidence, this is not always so - especially if there are vested interests and conflicts of interest about a particular issue.

Scientific evidence is just one part of solving a problem. To achieve a sensible, rational conclusion to any problem, all the evidence must be judged and scientific evidence is just one part of the evidence, whether in a court case about a crime or in relation to the effects of a drug. Failure to recognise this displays tunnel vision and a closed

mind as well as arrogance!

Applying this to 'human' insulin...

'There is no scientific evidence of problems with 'human' insulin' - the quote I hate.

- Firstly, this is not true because there are studies that show the problems but secondly, most of the research is old now. What would it show now if we used large randomised controlled trials? What would it show if we used methods now available for 'scientifically' analysing patient and carer experiences of 'human' insulin?
- In view of the ongoing controversy, has there really been a determined effort to carry out enough research to draw any scientific conclusions that actually stand up? The answer lies in the point above – no.
- Patients, some of whom have never used animal insulin, are still reporting problems with 'human' insulin, yet those making this statement are relying on scientific evidence, some of which is 20 years old!
- Not believing, or equally awful, ignoring the people that have reported problems with 'human' insulin, but relying entirely on the rather suspect scientific evidence and dismissing or discounting all other forms of evidence appears to display the arrogance, the complacency and the tunnel vision to which I refer.

Harsh words may be but I would find this attitude a little bit more credible if the scientists could offer a "scientific" explanation for why so many people have the problems with 'human' insulin. The accusations that we are old fashioned, don't know how to control our diabetes or we need to see a psychiatrist, in itself demonstrates the point that there has not been a real determination to do the necessary research!

## Bath Alert

This is an interesting device that will be particularly useful for people with diabetic neuropathy where the feet have lost the sensations of pain and heat. There is always a danger of scalds if the bath water is too hot and you can't feel it because of the loss of feelings in the feet.

Bath Alert flashes and sounds a buzzer if the temperature of the water goes above 40 degrees Fahrenheit. It also detects the water level and warns if the water has gone above this and the bath is in danger of flooding. It is suitable for use in bathrooms and kitchens for children and the elderly. It costs £12.95.

For further information contact:

MBO Sales UK, PO Box 43, 1 Elstree Way, Borehamwood, Herts WD6 1NH or telephone 0181 938 2368.

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## Kidneys

I think we all know that one of the long-term effects of diabetes can be kidney disease. I think we all equally know that prevention of the development of kidney disease is one of the reasons that we need to keep good blood glucose control. We may well have also picked up information along that way that aggressive treatment of blood pressure and stopping smoking, are also methods by which kidney disease can be either prevented or treated. But when my daughter was diagnosed as having 'kidney problems' during pregnancy that unfortunately have not gone away, I realised that this was an area of diabetes that I knew little about and certainly had not discussed in IDDT's Newsletter. So I started at the beginning.....

Definition of kidney disease or nephropathy [its medical name]

Diabetes at Your Fingertips, the very useful book, defines it as:

“In the first instance nephropathy makes the kidney more leaky so that protein [albumin] appears in the urine. At a later stage it may affect the function of the kidney and in severe cases leads to kidney failure.”

### **What are the ways in which diabetes can affect the kidneys?**

- If there is a lot of sugar in the urine, because you are running high for whatever reason, then this can lead to infection that can spread from the bladder to the kidneys. Chronic kidney infections do not always produce symptoms and may only show up on routine clinic tests.
- In both longstanding and poorly controlled diabetes the kidneys have to work hard to get rid of the excess sugar and the small blood vessels in the kidneys can be damaged, in the same way as those supplying the eyes and causing retinopathy. It is logical therefore that if both diabetes and high blood pressure are present the risk to the kidneys is greater.

### **Does kidney damage produce symptoms?**

- In the early stages there are no symptoms and any kidney damage should be picked up in the urine tests carried out at your normal clinic visit when albumin levels are measured.
- If large amounts of urine are lost then this leads to frothing of the urine and a build up of fluid in the body with swelling of the ankles [oedema] but this should be spotted in the routine clinic urine tests.
- When there is longstanding kidney disease, kidney failure may occur.

### **What is microalbuminuria?**

Apart from being a long word that I can never spell let alone say, it is the name for the condition that I have just described where abnormal amounts of protein [albumin] leak from the kidneys. The presence of microalbuminuria is detected by testing all the urine collected during

a 24 hour period. The test carried out in the laboratory checks the ratio of albumin to creatine, another substance that if higher than normal, is a good predictor of kidney damage. This ratio is measured in micrograms per milligram, m g/mg. Someone without diabetes normally excretes less than 25 m g/mg per day although this ‘normal’ figure is less in men [18] than in women [25].

Don’t panic at one high result! Results of urine tests for protein can be high for various reasons - for example it could be due to an infection or if you had been exercising vigorously around the time of the test. If subsequent tests are consistently higher than expected then your doctor should carry out further tests and, if necessary, treatment.

### **What do the results mean?**

From personal experience, when my daughter was given the results of her first 24 hour urine collection, we knew they were high but did not know how high. The actual figures were meaningless to us because we didn’t know the normal range and how high they can go. For example a figure of 29 sounds dreadful but not if you look at the worst possible figures! So that other people are able to understand their results and maybe not worry quite so much, with the permission of Diabetes Interview I am printing their table of ranges of albumin/ creatine ratios:

|                       | <b>Male</b>         | <b>Female</b>       |
|-----------------------|---------------------|---------------------|
| Normal albuminuria    | 17m g/mg or less    | 25 m g/mg or less   |
| Low microalbuminuria  | 18-65m g/mg         | 26-29m g/mg         |
| High microalbuminuria | 66-250m g/mg        | 93-355m g/mg        |
| Proteinuria           | More than 250m g/mg | More than 355m g/mg |

Obviously your doctor will decide when and if you should receive treatment for microalbuminuria. It is obvious that the key to preventing kidney damage is early detection of the excretion of protein in the urine and early intervention with treatment to slow down the progression of microalbuminuria to prevent further kidney damage.

## ACE inhibitors

The current trends in treatment are to use ACE inhibitors – the full name being angio-converting enzyme inhibitors. ACE is an enzyme found in our bodies which activates a hormone called angiotensin causing the blood vessels to constrict and so raising blood pressure and putting pressure on the heart. ACE inhibitors prevent the action of angiotensin resulting in a lowering of blood pressure. ACE inhibitors have been shown to protect the kidneys from damage by lowering blood pressure. However, not everyone with microalbuminuria has high or raised blood pressure so what happens to these people? It appears that there has been some debate amongst the medical profession:

- In Diabetes Interview Dr Alan Marcus, California says “Some physicians feel that having diabetes is reason enough to use ACE inhibitors, while others wait until certain levels of proteinuria are reached.” While Dr Daniel Einhorn says “It is well established that even in the absence of high blood pressure or abnormal creatine, ACE inhibitors prevent progression of microalbuminuria to proteinuria [excessive protein in the urine] and ultimately diabetic renal failure.”
- The American Diabetes Association [ADA] recommends the use of ACE inhibitors in people with kidney disease only if they have high blood pressure but the National Kidney Foundation in the US recommends their use in people with diabetes at risk of kidney disease who have normal blood pressure.
- Dr Loenard Feld, a renal specialist in Atlanta says in Diabetes Interview “Waiting for these patients with kidney disease to have high blood pressure and then loading them with ACE inhibitors would be a bad idea, as most of them would be in the advanced stage of kidney disease by then. The key to treatment with ACE inhibitors is early detection and prompt intervention at this correctable phase.”
- In a 1995 issue of The Lancet researchers issued a consensus

statement recommending the use of ACE inhibitors irrespective of blood pressure, once microalbuminuria has been diagnosed.

- A study presented at the European Association for the Study of Diabetes Annual Meeting last year indicated that the treatment with ACE inhibitors in people Type 1 diabetes and with microalbuminuria reduced the progression to kidney disease and even enhanced the progression to normal albuminuria levels.

NOTE – ACE inhibitors can have fairly mild side effects, the common one being an irritating cough. They are also not suitable for everyone including pregnant women.

Jenny’s comments – it is interesting that in the quotes above the people who specialise in kidneys are quite clear that early detection and early intervention is the way to prevent, treat and even regress problems with protein in the urine but those who specialise in diabetes are debating the issue. It seems logical to me that kidney specialists know about kidneys, heart specialists know about hearts etc. It should not be forgotten that even though these conditions may be caused by diabetes itself, the treatment of these complications should be strongly influenced by the specialists in them. This also adds to my personal view that the blood vessel system is responsible for many of the complications and I have never understood why it has taken so long to come to the conclusion that perhaps a more aggressive approach to normalising blood pressure could well reduce the complications. It seems common sense to me - a mere ordinary mortal.

I am pleased that my daughter’s microalbuminuria was detected and is being treated with ACE inhibitors and she has not got high blood pressure. Her eye specialist has said that this could also have a beneficial effect on her retinopathy.

### **Low Protein Diets Are Not Needed in Chronic Renal Failure.**

For many years the part of the treatment for chronic renal [kidney] failure has been low protein diets. But recent research has shown that these have little beneficial effect. The authors of this study [ref 1]

also say that there is little evidence in the journals to show the role of low protein diets in people with diabetes. They also maintain that the nutritional safety of these diets is suspect because patients with chronic renal failure have low energy intakes, which is further reduced by these diets. In the Modification of Diet in Renal Disease Study even nutritionally sound, non-diabetic patients developed sub-clinical signs of malnutrition and the malnutrition could have been worse with a longer follow-up time. The final point that they make is that these diets are difficult to follow, and the people need a lot of support from the dietician. They conclude that low protein diets are not necessary in chronic renal failure.

Ref 1 Miner Electrolyte Metab 1999 Dec;25(4-6):311-316

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## From Our Own Correspondents

### Encouraging News

Dear Jenny,

I have been a member of your Trust for a few years now, and I much appreciate the work you are doing in trying to make people aware of the problems caused by human insulin.

Recently I went for a check up at the diabetic clinic, which often means being seen by a different doctor each time I go. It was no different this time. After all the usual questions about my health, I was surprised when, on telling the doctor I was partially sighted and have other problems since I had used human insulin, the doctor actually said that yes, there had been many diabetics who had problems after using human insulin. It is the first time in the seven years since I used human insulin, and become ill because of it, that I have heard a doctor say that yes, there had been problems for many diabetics using human insulin and that they were aware of the problem.

So it seems your work is bearing fruit and the message is getting across to the medical profession about the problems caused by human insulin. The doctor did admit that it was not known why the problems occur but at least he admits that they do occur.

I would like to thank you for all you have done on this matter and send my good wishes to all those working for the Trust.

Mr B.R  
Sussex

### Shouting it from the hill tops!

For once I am printing the real name of this gentleman. He asked me to because he wants everyone to know the difference that animal insulin has made to him. Robert Cassalls from Northern Ireland, has had diabetes for 40 years and his sister first contacted IDDT because she was so worried about him - his general health, his erratic blood sugars and his rather strange behaviour sometimes. I had a chat to him on the telephone and he learnt that animal insulins are still available. He changed to animal insulin and this is what he now says:

I want you to print this because I cannot thank you enough for the change you have brought about in my life. I find this even more surprising as I am a member of the local BDA Committee and yet I did not know that a change to animal insulin could make such a difference to me. I am now in control of my diabetes and in control of my life. I could not believe that almost within hours of taking my first dose of Hypurin pork insulin, I started to feel better. What is more when my sister visited me she noticed a difference. I had got to the state where my blood sugars were going so high on occasions that they were off the meter, it was almost as if the 'human' insulin was not working at all. But then I would also have hypos for no apparent reason and without warnings. With pork insulin I have dropped my daily intake of insulin by large amounts, my blood sugars are within the normal range and if I want to eat a bit more I know that I can do so with an extra bit of insulin. I haven't been able to do this with 'human' insulin, but above all I feel so much better. We must spread the word,

how many other people are suffering as I did and don't know that a change from 'human' insulin could make life great again!

Robert Cassells  
Larne, N Ireland

### **Pork still worked better than 'human' insulin plus metformin**

Dear Jenny,

My husband had an awful time on 'human' insulin and even had to be referred to a psychiatrist as well as suffering all the other side effects. We took an article about IDDT's Dr Kiln to the consultant and he just smiled pityingly and said 'you don't want to believe everything you read in the papers. Realising that 'human' was not working the consultant did not try a different insulin, she put my husband on metformin in addition to 'human' insulin. He then had to suffer the side effects of metformin as well as those of 'human' insulin.

We looked into the insulin situation and he changed to pork. He is so much better! All that happens now is that we have to face the hospital clinic every 6 months. I wish they could be more understanding and caring and naturally they will not admit that they were wrong. Fortunately we do have an understanding GP who recognises that my husband is a lot better on pork insulin.

Mrs N.H.  
South West

### **Bowel Neuropathy**

Dear Jenny,

I read in one of your Newsletters about someone with problems with bowel neuropathy and I thought I would like to pass on my experiences that may be useful to others. I started with bowel problems last May and I was having to get up at 3.00 am every morning. I was picking up bowel infections and didn't know when I wanted 'to go'.

I looked up the research references that you sent and showed them to my doctor. He asked if I would like to try a fairly new drug called Ciproxin which cannot be taken for long periods. It helped but I also take a product called Lepicol – it is available from health food shops, is suitable for people with diabetes and can be taken regularly. It is supposed to get rid of the bad bacteria and promote the good bacteria. I feel this has helped too.

Mr L.L.  
Lincs.

Jenny's comment: I think the message here is that you should not suffer in silence or be embarrassed but go to your GP and discuss the problems, as Mr L.L. did. There may be help for you.

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## **More About Pycnogenol**

In the last two Newsletters we had articles about Pycnogenol – the natural bark product that has a number of properties that could help people with diabetes as it is the strongest natural anti-oxidant available. Its properties also include binding with certain proteins, collagen and elastin, and this could help in having a sealing effect on leaky blood vessels. This could explain why Pycnogenol appears to have assisted some people in preventing or arresting their retinopathy, where the small blood vessels leak [haemorrhage].

I am very aware that I must not make claims or imply that this product does something that it doesn't or is a miracle cure. But I am also of the view that as it appears to have no side effects and its properties sound valuable to people with diabetes, we should know more about it. It is a natural product and as such people have a choice as to whether they want to try it. I am also very aware that many of the complications of diabetes are due to blood vessel damage and if the blood vessels can be protected in some way then this would help to prevent or at

least slow down the progression to some of the complications. On a personal note, I cannot help but wonder if the emphasis on tight control of blood sugars has meant that other possible preventative methods have been overlooked. It still seems logical to me that protecting the blood vessels and ensuring that blood pressure is tightly controlled in everyone with diabetes has got to be beneficial in preventing complications – but then this is only an opinion and not proven by the science yet!

I have been in touch with the manufacturers and received some interesting papers. They also tell me that there is a publication in the process of preparation dealing with Pycnogenol and vascular disorders of the retina and they will let me have the information as soon as it is available. I will obviously pass it on to you. However they did send me details of a case study carried out in France in 1970 which probably explains why Pycnogenol is widely used in France.

- The study was conducted by D Magnard, J P Franck and P A Dorne, published in Lyon Medical 4[1970]. They looked at the possible benefits of Pycnogenol in ophthalmology with particular emphasis on diabetic retinopathy. There were 40 patients with different forms of retinopathy, 19 with diabetic retinopathy and they were treated with 80-120mg/day of Pycnogenol for 5-6 months. The outcome was scored by physicians as excellent [9 cases], good [27 cases] and moderate [3 cases].

Interesting results and hence worth more than a passing interest!

I know that some of our readers have already looked into Pycnogenol and some are already taking it. If you are trying it, I would like to hear from you to know how you get on. I have also had several enquiries about where it can be obtained – the answer is health shops and pharmacies that sell complementary natural products or one source of supply is by mail order from Larkhall Natural Health, FREEPOST, SN 1422, Bradford-on-Avon BA15 2SZ.

## Interesting...

A study [ref 1] listed the historical decline in mineral contents of the fruit and vegetables we eat, between the years 1930 and 1987 and came up with some interesting findings:

- Modern potatoes were shown to have 40% less potassium in them than those grown in 1930
- Carrots grown today contain nearly 50% less calcium and 75% less magnesium than they used to.
- Tomatoes contain 90% less copper.
- Apples, oranges and apricots contain 66% less iron than they once did.

This suggests that we need to eat an awful lot more fruit and vegetables to obtain the same nutrients that we once did. It also makes you realise that perhaps when we older people say that things don't taste the same as they used to do when we were young, they actually don't and it isn't our rose coloured specs after all!

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## Editor's Dilemma

In the Winter 2000 edition of the Newsletter I published an article entitled 'Unbending Determination' from Alison Gordon about the death of her Dad, Ken. I did this for Alison and her family who had great admiration for Ken who had diabetes from his early twenties. However, I was aware when I published it that there were some statements in the article that may well cause some concern and even anger amongst some of our readers and indeed some that I found difficult to accept. And I was right, although the criticisms have been made with some trepidation in view of Alison's bereavement.

The parts that caused the most upset, these statements:

- “Because of Dad’s approach to his diabetes, it has always been difficult for me to understand people bemoaning the fact that they or a loved one have diabetes.”
- “Diabetes was perfectly ‘normal to him and thus to us, his family.”

Despite the delicacy of the situation, I feel that both Alison’s article and the concerns that followed have to be expressed in the Newsletter because of IDDT recognises that we all are different, we all have different experiences and we all have different ways of handling living with diabetes. The reality is that the complications of diabetes do occur leaving people with a lower standard of health and quality of life. To this group, the above statements, quite unintentionally, do seem unrealistic, perhaps unfeeling and appear critical of those whose experience is that life with diabetes actually is not a bed of roses! For those of us that do have problems, this approach can make us feel inadequate and something of a failure. It is clear, though, that Alison’s experience of diabetes is not first hand and is very limited to that of one person – her Dad whom she obviously loved and admired greatly.

My feelings are that this is the daughter of someone who did have good health for many years and who clearly shielded his children from any concerns he had for the possible future complications of diabetes. For this he is to be admired even though it left Alison with a rosier and inappropriate view of diabetes than is probably true. Nevertheless, I think it is right that the other view is published here and this is just part of one letter I received in response:

*“Apart from being unclear how multiple injections of insulin for years and years can be considered perfectly normal, the article is so typical of those that appear in BDA material portraying the view that having diabetes has not affected me at all, so why do people complain.*

In actual fact, diabetes is something to ‘moan about’ and it is something that affects people in a very major way. From being diagnosed at the age of four in 1958 to the early 1980s [when I suffered a complete health breakdown following the change to ‘human’ insulin] it hardly affected me and was barely a minor inconvenience. But at this time I

was certainly not so short sighted or insensitive enough as to believe that all other people with diabetes enjoyed the same situation. If one is unfortunate enough to have poor health then it is possible to have a stoical attitude to the matter, although this of course depends on personal temperament and individual circumstances.

In my own case, I find it difficult to maintain such an attitude when I realise that the loss of good health in 1983 was avoidable – by this I refer to the ‘human’ insulin pushed upon the trusting diabetic community. I wonder if Alison would have the same attitude if her Dad had felt unwell virtually all the time; had frequent severe fitting hypos without warnings causing serious back injury. All this resulting in a fear of going outdoors with a loss of good health, home, employment and the independence that comes with these because of it.

If people with diabetes enjoy excellent health, then it is to be positively welcomed but they should not presume that everyone shares this good fortune. If people with diabetes have poor health but are able to have some semblance of normality in their lives, then they should bear in mind that many others are not able to.

I consider the principle danger in Alison’s view that diabetes is quite normal is that there is a greater possibility that the dreadful damage wrought by ‘human’ insulin on some of us will not receive the long-overdue attention it so obviously merits. Furthermore, the long awaited cure will be delayed even further.”

As a Mum of someone who has had diabetes 25 years, I confess that my sympathies are with the writer of this letter and not simply because it was ‘human’ insulin that caused the health problems for him. But because having brought up a child with diabetes, I don’t feel her life was, or indeed is, ‘normal’ nor for that matter has my life or that of the rest of the family, been ‘normal’. Yes, I have bemoaned the fact that she has diabetes, especially when things are difficult. Yes, I have felt inadequate and a failure, especially when I used to read [I don’t any more!] about parents who felt and believed that diabetes didn’t affect their children. Great if it doesn’t seem to, but the important words here

are 'seem to'.

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## Which Doctor?

A new web site was launched on January 8th 2000 and it will provide a much-needed source of information to doctors, patients and the general public. Do read on even if you are not in this world of computers and the internet because it could be useful to you!

The site has been set up by Will Anderson, a surgeon in London, and it allows anyone to find information about doctors who have specialist interests or research interests. For instance, if you were moving house to a new area and wanted to find a GP who had a special interest in diabetes or any other condition, then the information listed on this web site will assist you to find one. It will also allow family doctors to make more appropriate referrals for their patients.

In the past all that has been available is the Medical Directory – a huge book that lists every doctor in the UK but this is merely an alphabetical list of doctors and cannot be used as a search tool to find out 'which doctor is doing what and where'. This new web site will also have the advantage of making doctors more accountable because they have to declare their qualifications, speciality, specialist / research interests and contact details when they register.

The web site is [www.which-doctor.co.uk](http://www.which-doctor.co.uk)

Access is free. Remember, even if you don't have access to the internet, you probably know someone that does or there are usually convenient access points within the local community.

## Non- Invasive Blood Monitoring Update

### GlucoWatch

This is a device we are all impatiently waiting for – it is worn like a watch and intended to continuously monitor blood sugars non-invasively and beep when they are too high or, more importantly, when they are too low. The existing position is that GlucoWatch was recommended for approval by the FDA advisory panel in December 1999. Recommendations by the FDA Advisory Panel do not necessarily mean that the FDA will grant approval but it is the normal pattern. Cygnus, the manufacturers, say that the Glucowatch could be on the market in the US later this year.

The FDA Panel laid down conditions.

1. An education programme
2. Label revisions
3. A post marketing study of the detection of hypo and hyperglycaemia.
4. It will be available on prescription only and is intended for use in adults of 18 and over.

The FDA Panel issued warnings.

1. The Glucowatch is less effective in detecting life-threatening low blood sugars than at detecting high blood sugars.
2. That its readings can differ from blood tests by around 30% - meaning that if it reads 8.3mmols/l [150mg/dl] the actual result maybe anywhere between 7.5 and 9.2mmols/l [135 and 165mg/dl]. The FDA warn that this could be a problem in detecting and signalling the alarm of hypos or blood sugars that drop below 3.8mmol/l [70mg/dl]. They are right, of course, although the manufacturers say that the device can be programmed to set off the alarm at a higher blood glucose level and before the blood sugars drop that low.

GlucoWatch is NOT intended to replace finger prick blood tests.

The FDA and Cygnus agreed that patients should never decide to use insulin on the basis of GlucoWatch results without doing a normal finger prick blood test. Cygnus sort approval from the FDA on the basis of the device picking up trends in blood sugar levels rather than a replacement of invasive blood tests. This has to concern us because we are all too well aware that the temptation to rely on it with no finger prick will be too great for some people. We also know that recommendations are not always followed – we only have to look at 'Humalog' and pump therapy – neither are recommended for under 14 year olds but both are used in this age group!

### **Results of the trials**

A study published in Diabetes Care 1999 gave the results of comparing GlucoWatch with other 'normal' meters in 28 people with Type 1 diabetes in the home environment. The GlucoWatch performed well between measurements of 3.8 and 13 mmols/l [70mg/dl and 240mg/dg in the US] but there was a lag of 20 minutes between the GlucoWatch and the blood glucose meters. The study also showed that rapid temperature changes, excessive sweat, electrical noise, high background currents and open and shut circuits can cause the GlucoWatch to skip tests. In the home tests 26% of all tests were skipped. The side effects were mild skin irritation, oedema and redness of the skin, all of which went away when the GlucoWatch was removed.

### **MiniMed Continuous Glucose Monitoring System**

This device is a minimally invasive glucose sensor using an enzyme electrode implanted in the subcutaneous tissue [tissue just below the skin surface] that is connected to an external monitor. It measures the interstitial glucose levels [the glucose in the cell fluids] and is worn for 3 days. Readings are made every 10 seconds and averaged over 5 minutes. The device was approved by the FDA in June 1999.

According to an article in The Lancet by John Pickup, Feb 5th 2000, the main difficulties are variations between the blood glucose values and those in the interstitial fluid – peak glucose concentrations may be 2-45 minutes later in the interstitial fluid than in the blood. He

adds that because interstitial glucose levels often fall before blood glucose levels, this form of sensor does offer opportunities to give early warnings of impending hypoglycaemia.

Jenny's comments - So it appears that we have not got there yet! Both these devices are going along the lines we need for successful management of diabetes but both are not yet reliable. Finger prick blood tests are not yet a thing of the past and, arguably more importantly, we are not yet in the position of having continuous monitoring that will detect impending hypoglycaemia, especially important at night.

These devices are a vital development for people especially those who have reduced or loss of warning symptoms of hypos. They are, therefore, very important for people who cannot use 'human' insulin because of the adverse reaction of loss of warnings admitted by all the producers of 'human' insulin. Indeed, one could even go so far as to say that our objections to the removal of animal insulins would be considerably reduced if the manufacturers had waited until these devices were reliable, approved, on the market and accessible to everyone in terms of cost.



## **Nearer To Home - Volunteers Needed In West Wales**

Hi, my name is Dr. Stephen Hastings.

I am a researcher in a company named Whitland Research in Whitland , Carmarthenshire, West Wales. Our Company is involved in the development of a non-invasive glucose monitor, which involves shining light through the finger-tip of the subject - a painless and harmless procedure!!

We are looking for volunteers with diabetes to take part in an initial trial of the instrument. As part of this trial, we would require a few

finger prick blood samples (in addition to scanning with our monitor) in order to compare the existing invasive techniques to our own. We would appreciate it if word got around in the diabetic community about our exciting new experiments, as the sooner a painless technique is on the market the better!

If you are interested in taking part in these experiments we are able to offer transport to local volunteers, please contact us by phone on:

01994 240 686 or by e-mail: S.Hastings@newscientist.net

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## A Legal Precedent - Hypoglycaemia Automatism

I know from the reactions we received that many of you read about the case of Mr Padmore, the man with diabetes who stabbed his friend while in a state of hypoglycaemia and was found not guilty of murder. This case is reason for great concern, or at least, it should be. All sympathy must be extended to the victim's family, but we must also recognise that Mr Padmore is a victim too.

Apparently he had taken his injection while preparing dinner and the last he remembers was having a knife in his hand. He had a hypo with no warnings and went into a state of 'hypoglycaemic automatism', according to Mr Dennis, prosecuting. He was described by Mr Dennis as having no awareness of his actions and that his actions were truly involuntary. A police officer that attended the scene said his facial expression twisted with rage and he fought like a man possessed.

Those of us that live with diabetes know that Mr Padmore was not responsible for his actions because we see these events in our own lives. The carers amongst us that have to witness violent or abusive hypos experience the fears of episodes like this in their daily lives, although thankfully not usually with such dire consequences.

- This case further highlights the dangers of hypoglycaemia and of the loss of warning symptoms of the impending attack that allow blood glucose levels to drop to this dangerous level.
- Mr Coffey, defending Mr Padmore, said that Mr Padmore was now taking animal insulin to reduce the chance of him having another attack.

Mr Padmore's case was described in many of the papers as 'unique because of the lack of symptoms'. We know that this situation is not unique but what is unique is that the court accepted that Mr Padmore was responsible for his friend's death but accepted that the issue they were looking at was whether he had the necessary mental responsibility for his actions. The decision reached in clearing him of the murder charge acknowledges that severe hypoglycaemia without warnings resulted in him not being responsible for his actions.

- It has set a precedent.

I do not think any of us would doubt that the decision reached was the correct one but it is the issues that it raises that have to concern us, as people that live with diabetes.

- What will be the effects of this precedent?

It has now been accepted in law that hypoglycaemia with no warnings leaves someone without the necessary responsibility to be responsible for their own actions. It has also highlighted to the general public that people with diabetes in this situation can be a danger to others as well as to themselves. But is the general public going to be able to differentiate and understand the difference between people with warnings and those without warnings or that not everyone with diabetes has violent or aggressive hypos?

I fear not. Even people with diabetes that do not suffer the same awful effects as Mr Padmore are guilty of assuming that this only occurs because they do not look after themselves properly! And how many times do we read and hear health professionals saying that we

should do more blood tests to avoid hypoglycaemia? Even they do not recognise that a blood test at any given time only shows what the blood sugar level is at that moment – it does not show whether it is going up or down! [An argument used frequently by my daughter in her teens when I, equally frequently, tried to encourage more blood testing!]

The decision in this case will help others in similar situations because it has acknowledged the effects that hypoglycaemia and loss of warnings can have. But there are ramifications that could be to the detriment of everyone with diabetes.

It has highlighted the fears that many patients treated with 'human' insulin have had:

- That hypoglycaemia and loss of warnings will result in harm or even death to others or to themselves.
- Events like this put everyone with diabetes at greater risk of discrimination, of being feared by others, of employment problems and thus preventing them from living life freely and healthily.

#### Loss of Warnings/hypo unawareness

The reasons for loss of warnings are well documented, long duration of diabetes being the most commonly cited reason. It is also caused by frequent episodes of hypoglycaemia itself and we know that intensive therapy and aiming for near normal blood glucose levels, trebles the risks of severe hypoglycaemia.

There is much evidence from patients that some people using 'human' insulin lose their warning symptoms, which return with a change to animal insulins. This evidence has frequently been ignored and undervalued because of its anecdotal or 'unscientific' nature, surprising, as the basis for systems of reporting adverse drug reactions is anecdotal evidence.

The Department of Health has stated that some people are not suited

to 'human' insulin. Since 1991 the Patient Information Leaflets inside every pack of 'human' insulin have warned that 'human' can cause loss of warnings and last year Novo Nordisk, one of the manufacturers of 'human' insulin admitted in a press release that soluble 'human' insulin has been associated with an increased risk of hypoglycaemia.

From all this information, it is not difficult to see that it is possible that there is a sub-group of people who, if treated with human insulin and also with intensive therapy, are at risk of severe hypoglycaemia and loss of warnings. But at the moment there is no way of identifying this sub-group of people, especially if those people that do complain of problems are ignored.

Safety and absence of harm.

The Committee on Safety of Medicines [CSM], has declared to IDDT that human insulin is safe and when subsequently asked to provide a definition of 'safe' they said it meant 'the absence of harm'. I would suggest to the CSM that Mr Padmore's case has shown that hypoglycaemia when accompanied by loss of warnings, is not safe by their own definition. It has to be noted again that Mr Padmore has since changed his insulin to natural animal insulin "to reduce the chance of him having another attack".

Could this case be a turning point for our medical advisers?

- Unless or until this sub-group can be identified, will they now join with their patients and question whether treatment with intensive therapy and 'human' insulin is safe and does provide an absence of harm?
- Will they remember that 'human' insulin has no clinical advantages for patients and also recognise that there are no clinical reasons for prescribing it? Will they recognise that if some people with diabetes are put at risk of not having the necessary mental responsibility for their actions due to hypoglycaemia and/or intensive therapy, that this can only adversely affect the lives of people with diabetes and their families? Can they see that this will lead to fears amongst the

general public and discriminations against people with diabetes in many different ways?

I hope that out of this very sad case some good can come otherwise we will all fear that this is not going to be the unique case that the lawyers and police have suggested.

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## More Of The Same!

A report in the Stafford Express and Star February 4th 2000, describes how a lady was killed in a motor accident caused by the collapse of her son-in-law at the wheel of his car. He was diagnosed with diabetes 15 years ago but the court heard how 2 years ago his doctor had changed his insulin to a type that 'gave him little warning that his blood sugar level was falling'. The man said afterwards when interviewed by police 'I didn't get any warning. I was devastated afterwards that this had happened. I've lost my mother-in-law.' He was unable to remember swerving, ploughing across a roundabout at speed and shunting another car 20 metres along a grass verge. Only after the car came to rest and he took glucose tablets did he realise what had happened.

He has voluntarily given up his driving licence. The coroner recorded a verdict of accidental death. This poor man will suffer guilt for the rest of his life, but there are others that should feel this guilt. Do they, I wonder?

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## Monitoring Insulin Pork Insulin Supplies From Novo Nordisk

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 but they admitted that they had no idea how long this would be. The removal from the US earlier this year is bound to make us feel concerned about when it will happen in the UK. As you know we are keeping track of possible changes with your help by recording expiry dates and are doing this on a regular basis. It is 6 months since we included 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.

## What Irritates Me...

- Why is it that when I prick my finger for a blood test, the blood only seems to come out with pressure and squirt all over me when I am wearing white?
- When out for a meal with friends and the service is poor, I have to eat the bread to keep me going and I feel full when the meal comes but my friends have been able to just sip the wine and then eat the meal with great gusto.

Let me know the annoyances that irritate you about having diabetes. Write to Jenny Hirst, PO Box 294, Northampton NN1 4 XS

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## The Campaign Trail

### Importance Treatment - GP's Clinical Judgement

As readers are well aware, we have made known our feelings about the restriction of all impotence treatments to once a week for men with diabetes following the introduction of Viagra. We believe that it is wrong that the various treatments should be restricted, especially for those who had unlimited access to treatment before the introduction of Viagra.

IDDT wrote in January to Alan Milburn on this matter and we have now received a detailed reply from Lord Hunt, Parliamentary Under Secretary of State for Health. It appears that the position of once a week treatment is based on evidence that the average frequency of sexual intercourse in the 40-60 age range is once a week. We have, of course already pointed out to the DoH that impotence in men with diabetes can affect them at a younger age than 40-60 and therefore more frequent treatment, whether Viagra or other methods, may be necessary especially for those wanting a family. The good news is that Lord Hunt has pointed out that the DoH advice to doctors is:

- The frequency of treatment will need to be considered on a case by case basis.
- One treatment per week will be appropriate for most patients treated for impotence. If the GP in exercising his clinical judgement considers that more than one treatment a week appropriate he should prescribe that amount on the NHS.

It therefore appears that the decision about the frequency of impotence treatment really rests with your GP and if he/she considers in his/her clinical judgement you would benefit from more frequent treatment than once a week then you are entitled to it under the NHS.

The restrictions are due to be reviewed after a year, June 2000, and therefore we can only hope at that time the following research will taken into account for people with diabetes.

- A letter in Diabetic Medicine from specialists at Leeds general Infirmary, pointing out that when they carried out a Cochrane review of the three different types of treatment for impotence, the response rates for all treatments were about the same. However, in men with diabetes the response is less, 46-64% compared to 85% in non-diabetic men. The letter points out that because only about 50% of men benefit from treatment, the long term cost may not be as significant as initially thought.
- A study published in the February 3 1999 issue of the Journal of the American Medical Association [JAMA] adds weight to this argument. 268 men with diabetes for an average duration of 12 years and impotence for an average of 5.6 years were given Viagra or a placebo [dummy pill]. 136 men received Viagra and 132 the placebo once a day one hour before sexual activity for 12 weeks. The results showed improved erectile function in 56% of the men taking Viagra but in only 10% of the men taking the placebo [dummy]. The study also showed that Viagra was well tolerated and safe. 16% of the men reported side effects including headaches, indigestion and sinus congestion. Cardiovascular events were similar for those taking Viagra and those taking the placebo.

## Talking Meters - The Situation Gets Worse!

IDDT has written innumerable letters to many people – we started with Frank Dobson when he was at the Health Department and it has gone from there. We will continue to do his to point out just how unfair and unreasonable it is that blind and visually impaired people can no longer obtain ‘talking’ meters to maintain their health and independence. Some people in this situation have looked after their old Hypocount meters well so that the problem of being unable to obtain a new one has not hit them yet. However, the latest information we have received is that Roche has now withdrawn the test strips that are suitable for use with this meter, so making the meter redundant. Once more that hard face of business ignores the needs of minority groups and functions like shoe manufacturers – if brown shoes are not fashionable, they don’t produce them. But drugs and medical devices are not or should not be treated in the same way.

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

**IDDT**

PO Box 294  
Northampton  
NN1 4XS

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Postcode: \_\_\_\_\_

Tel No: \_\_\_\_\_

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## From Your Editor – Jenny Hirst

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