



# Insulin Dependent Diabetes Trust

July 2002 Newsletter



## Support And Openness - An Unreal Expectation!

The Novo Nordisk takeover of Biobras has caused concerns *amongst* people with diabetes around the world – the people that need animal insulin to manage their diabetes. It has also caused concerns *for* people all over the world, the people in developing countries who need our support to access the cheaper animal insulin. Without this many will die and not for lack of insulin but for lack of affordable insulin – a situation that is indefensible and disgraceful.

As well as producing animal insulin, Biobras has been the major world source of insulin crystals needed for the production of animal insulin. As Novo Nordisk have publicly stated their intention to discontinue production of all their animal insulins, we have good reason to be

concerned. Not only do Novo Nordisk now control their own supply of crystals but they also control the supplies to other animal insulin manufacturers. CP Pharmaceuticals are committed to the ongoing production of animal insulin but they and people that need animal insulin, are in a very vulnerable position.

### **We are not asking very much!**

We have won the battle for recognition that some people are not suited to treatment with 'human' insulin, if nothing else because the UK Department of Health says so! What we have not achieved is the acceptance of this by medical and healthcare professionals. Neither have we achieved support of people that are in a position to influence the pharmaceutical companies to continue to produce the ongoing supplies of the animal insulin we need. So what good is recognition of the problem, if no one is prepared to help to maintain our supplies of animal insulin? What do they imagine will happen to us? Even worse is

the thought that they might not even care! Who are these people that could influence such decisions?

The answer is simple – they are the people that pharmaceutical companies rely on to sell the products that make their undeniably huge profits. This is not you or me, the patients, it is the people that supposedly look after our welfare – diabetes associations both nationally and internationally, government health departments, the medical experts in diabetes.....

Most of these people know or should know, just we know, that the introduction of ‘human’ insulin took place without any evidence of benefit for patients and that there were known problems with hypoglycaemia *BEFORE* it even went on the market. They also know that it is prescribed now as first choice insulin but without any evidence of benefit over animal insulin.

Then there are others that are doing little to support us on a day to day basis – the healthcare professionals, the doctors and the pharmacists that frequently supply patients with misinformation – the most common *“human’ insulin is better than animal insulin”*. There is absolutely no scientific evidence for this statement and we have a right to expect the information we receive from healthcare professionals to be evidence based. *“Animal insulin is no longer available”* – another statement frequently made and totally untrue in the UK. Do we need more examples? I think not!

### **We are not asking for very much!**

We are not asking for the condemnation of ‘human’ insulin or for it to be withdrawn and we have no wish to sue for the adverse effects that we have suffered. We recognise that the vast majority of people with diabetes are happily treated with ‘human’ insulin, despite the fact that there is no evidence to support this prescribing practice. We just want help to influence the pharmaceutical companies and governments to ensure that animal insulin remains available for us. Without it, the group of people they themselves acknowledge need animal insulin, will suffer unnecessarily and so will their families.

**It seems inconceivable** that we are not receiving support from the very people whose life, work and aims are directed towards the welfare of people with diabetes. Perhaps these people that do not have diabetes cannot imagine how it feels to fear the discontinuation of the insulin that keeps you alive, well and gives you the best quality of life. To them I would say, just imagine how you would really feel if your supply of water was going to be discontinued and no one did anything to help you. Just imagine how your family would feel watching you suffer unnecessarily and unable to do anything to help, because your needs were being ignored for only one reason, profit.

### **IDDT seeks help from the International Diabetes Federation**

The takeover of Biobras prompted us once again to approach the International Diabetes Federation [IDF] to ask for their help and support. This is the body that represents people with diabetes in countries throughout the world. We put a submission to the April 2002 Executive Board meeting of the IDF [published in IDDT’s Spring 2002 Newsletter]. Here is the summary of our submission:

The IDF should make recommendations to support the needs of patients and these should be put in the public domain and also sent to diabetes associations and organisations of the medical and nursing professions:

- condemning the dominant position of the major insulin producers whereby people with diabetes are suffering and dying as a result of their commercial decisions.
- expressing the view that patients’ needs are paramount and patients’ right to an informed choice of treatment is an essential and integral part of best practice.
- that animal insulins should remain available throughout the world for the people that need them for whatever reason whether these be on the grounds of economics or clinical need.

IDF Response:

In May, IDDT was informed that the response to our submission and the IDF position was stated in their magazine, Diabetes Voice, March

2002 –interesting in itself because the response was published before the April meeting of the IDF Executive Board had taken place! Was our submission ever actually discussed by the Executive Board? We don't know but obviously their view was not expected to influence any formal IDF statement by the President!

The statement in Diabetes Voice was made by their President, Professor Sir George Alberti, President of the Royal College of Physicians in the UK and Professor of Medicine, at the University of Newcastle upon Tyne .

Here are his relevant points:

- A huge challenge remains: to have substantial supplies of affordable insulin available worldwide both for day to day use and for emergency situations.
- Colleagues in some developing countries report that there is considerable pressure to transfer people to the more expensive human insulin.
- There is also increasing worry about supplies of animal insulin. It is currently cheaper than human insulin, and is the main reason for continuing its availability.
- Furthermore, a small number of people react better to and/or prefer to use this form of insulin.
- One of the producers of animal insulin, Biobras has just been bought out by a major international company, Novo Nordisk, leading to concerns that animal insulin may be phased out. I have been assured that this will not happen.

### **So is this the reassurance we need?**

I think not! People in most European countries, Australia, Canada and the USA know this is not true because Novo Nordisk have already 'phased out' animal insulin! Equally, Novo Nordisk UK informed IDDT about 2 years ago that they intend discontinuing their animal insulin range. So Professor Alberti's assurances are hardly credible and appear to contradict the reality. But what Professor Alberti has done is publicly acknowledge that 'a small group of people react better and/or prefer animal insulin'. While we may think that this underestimates the

seriousness of the adverse effects and the numbers of people needing animal insulin, it does acknowledge our existence!

In responding to the IDF, IDDT pointed out the contradictions and expressed some surprise that neither the President of the IDF nor the IDF itself were aware of this situation. We suggested that Novo Nordisk may have been able to give this bland assurance because they now own Biobras where animal insulin is still being produced. Producing it in Brazil, while at the same time discontinuing it in countries around the world is of little help to us!

We expressed our disappointment with the President's statement:

- if the IDF is truly unaware of the actual lack of availability of animal insulin, then they are not in a position to properly represent the best interests of ALL people with diabetes.
- if the IDF is aware of the true position but is prepared to publicly accept the assurances from Novo Nordisk while at the same time watching them systematically withdrawal of animal insulin, then Professor Alberti's statement is misleading people with diabetes. People who can no longer obtain animal insulin know it to be untrue and this reduces the credibility of the IDF.
- It is saddening that the IDF cannot publicly state that they are taking action to ensure that animal insulin will be available. This appears to display little care on the part of the IDF for the 'small' number of people that they acknowledge need animal insulin.

So in the light of Professor Alberti's assurances, IDDT wrote to Novo Nordisk UK to see if they had indeed changed their policy.

We received a very honest response:

- Their long-term strategy to discontinue animal insulin remains unchanged. They will give 18 months advance notice of discontinuation.
- In the short-term there are no plans to terminate animal insulin production at Biobras but they expect the existing production of animal insulin at Biobras will gradually be converted to the

production of semi-synthetic human insulin\*. Thus, they will continue to produce insulin from animal source at Biobras, but it will be modified to become human insulin, in line with their strategy to discontinue animal insulin.

\*What this means is that they will make 'human' insulin from animal insulin, hence the name semi-synthetic. This is how human insulin was first made in the 1980s.

### **Conclusions?**

It is hard to believe that Novo Nordisk are quite prepared to be open and honest with IDDT but not with the IDF President - we are a small organisation of 'ordinary' people, the IDF is a large international organisation with many experts in diabetes involved! The President's statement is at best naïve and at worst, misleading in being economical with the truth. Did he hope that people like IDDT would just accept his assurances and disappear along with the animal insulin we need? That really is naïve!

But IDDT is not naïve, we realise that the IDF relies on drug company funding and has to strike a balance with their 'corporate partners' [their words not mine] but it appears that this balance is failing people who need animal insulin. It seems the IDF find it difficult to oppose the policies of their corporate partners and the penalty is that they and their President risk losing their credibility.

Is it so hard to argue the case on the basis of evidence of risk/benefit/cost?

There is no evidence of benefit from using 'human' insulin rather than animal insulin and 'human' insulin is more expensive and unaffordable in poor countries, so the IDF could easily make a strong case to oppose the global discontinuation of animal insulin.

If they need evidence, they need look no further than our very own NICE – the National Institute for Clinical Excellence. The final draft guideline on Type 2 diabetes – glycaemic control, is currently on the NICE website [downloaded April 2002]. Page 59 in the section on the

use of insulin in the treatment of Type 2 states the following:

*“Despite the lack of an evidence-base to support current practice, the group recognised that usual insulin therapy both for people with diabetes starting and continuing insulin now utilised human species insulin rather than beef or pork. However the purified forms of these latter species of insulin are appropriate options for clinical and patient choice.”*

Perhaps we need to translate this into plain English! It says that although doctors presently prescribe human insulin rather than pork or beef, there is no evidence [or reason] why they should because beef and pork insulins are appropriate options and gives the patient choice.

### **So now we know!**

We realise that the IDF Insulin Task Force is working hard for the masses of people in the developing world and we wholeheartedly support them in this. However it is an international organisation and as such, surely should concern itself with the needs of all people with diabetes, even those in rich countries. Quality of life, and indeed life itself, is equally important to each person with diabetes whether they live in a rich or poor country. Failure to support us, the group of people the IDF acknowledge need animal insulin, is a failure to recognise this and we have the right to expect more, especially from the experts in diabetes. But perhaps not, when Professor Alberti ends with the following statement:

“Personally I care less about what sort of insulin is available, and more that it is accessible, affordable, of reasonable quality – and works”.

- We know that Novo Nordisk intend globally withdrawing animal insulin and that we will have 18 months notice of this.
- We know that in the UK we have CP Pharmaceuticals that are committed to making beef and pork insulin and so we have an alternative source of the animal insulin we need. But we don't know how long Biobras ie Novo Nordisk, will go on supplying insulin crystals to other manufacturers.
- We also know that we are likely to receive little help from the IDF!

IDDT has no option to continue to try to ensure that animal insulin remains available for the people that need it both now and in the future. We have no alternative but to resist the discontinuation of the insulin we need especially when there is no reason other than commercial gain.

***Finally a point from Dr Matthew Kiln:***

*Novo Nordisk have clearly stated that they will modify animal insulin to become 'human' insulin. Clearly the IDF do not appear to know this simple point or appreciate that this will significantly increase the price of this insulin – with absolutely no benefit. However, it will mean that unless Novo Nordisk supply this 'human' insulin at the same price as animal insulin, their action will deprive many vulnerable patients in developing countries of affordable insulin. This is likely to lead to patients using less insulin than they need with sustained poor control or possible death in the poorest countries.*

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## Research - The Future Perhaps?

### Vaccines may prevent Type 1 diabetes

- UK scientists have found strong evidence that Type 1 diabetes might be caused by a common virus, Coxsackie B4 [CVB4]. It has been believed that the cause is a virus that triggers destruction of the insulin producing cells in genetically susceptible people but this is the first evidence of a specific virus. The scientists used the virus's genetic code to reproduce key parts of its structure to see how it affected the immune system of 40 young people with Type 1 diabetes. The immune system of those with diabetes was very sensitive to the CVB4 virus and the response was different in those with diabetes from healthy people suggesting recent or repeated exposure to the virus.
- Researchers in the North Carolina have developed DNA vaccines

that have been tested on mice and the majority of the mice injected remained free from diabetes for over a year. The vaccines balance the two immune cells involved in Type 1 diabetes, one vaccine activates the insulin producing cells and the other stops the action of the cells that kill off the insulin producing cells. They worked by selectively suppressing the body's auto-immune response while leaving the remainder of the immune system in tact. If this is a possibility in man, the researchers say that people may only require DNA vaccines every one or two years.

- In Sweden a vaccine called Diamyd is about to undergo Phase II clinical trials in man. This vaccine is designed to protect the insulin-producing cells from being destroyed and it only affects the auto-immune process that leads to diabetes.
- Reseachers at the University of Colorado have developed a vaccine that elicited immune responses and reduced the incidence of Type 1 diabetes. 1000 adults and adolescents with new onset diabetes have been enrolled into early trials to assess the vaccines safety and efficacy and whether or not repeated doses of the vaccine will preserve the body's own insulin production.

Not a vaccine but a drug that may prevent Type 1 diabetes

Published May 30 2002 in The New England Journal of Medicine

A new 'high-tech' drug has been shown to decrease the need for insulin in people with newly diagnosed Type 1 diabetes. The drug protects the insulin producing beta cells and preserves insulin production. It is an antibody that works against the body's own antibodies that attack the beta cells in Type 1 diabetes.

In the first human study, 12 people between the ages of 7 and 27 with Type 1 diabetes received daily injections of the new drug for 2 weeks within 6 weeks of diagnosis. A year later they were still producing the same amount of insulin allowing them to reduce the number of injections with no severe side effects from the drug. 10 of the 12 people used for comparison who did not receive the drug had a dramatic drop in their own insulin production after a year.

The most common side effects were fever, rash and anaemia. There have been other drugs developed in the past that have had similar effects but there has been unacceptable and dangerous side effects of shutting down the whole immune system, leaving the person vulnerable to life threatening infections and cancer.

One of the problems with the development of Type 1 diabetes is that the process of the beta cells being attacked starts years before symptoms appear. So we have to hope that if this drug is shown to be safe and effective, it could be given to people who are known to be at risk.

### **Insulin Pill trial offers some hope**

- Researchers in Israel have developed an insulin pill. They gave the pill to 12 volunteers without diabetes to see if it worked in principle. They found that it delivered insulin into the blood stream and liver within 30 minutes. A second phase of trials is planned with a small group of people with diabetes to find out if the amount of insulin reaching the blood stream is sufficient. At this stage the pill is being aimed at people with Type 2 diabetes and if successful it will then be tested on people with Type 1 diabetes. There is still a long way to go...
- GlaxoSmithKline plc has signed a \$283million agreement with Nobex, a tiny US company that developed oral insulin, and in exchange Glaxo will get world-wide rights to sell this new insulin. Nobex oral insulin uses polymer technology that resists degradation by the enzymes in the body but it has only been tested in small numbers of people over short periods and is some years away from being on the market.

### **Latest on inhaled insulin**

May 2nd – Inhale Therapeutic Systems announced that results of a new study confirm that inhaled insulin controls blood sugars as well as injected insulin but again inhaled insulin diminished lung function. This breathing difficulty has resulted in a delay in the application for marketing approval until other studies conclusively prove it is safe.

### **Drinkable insulin comes step nearer**

Insulin has to be injected because it is broken down by the acidic conditions of the stomach. Biochemists in Scotland have developed a liquid emulsion, called APSET, that is stable in acidic conditions such as the stomach, and this could be used to carry substances through the stomach to the gut. They have already used it to transport insulin, growth hormone and Vitamin E through a simulated gut. We have heard of this sort of thing in the past without success but if APSET works as effectively as injected insulin, then in years to come we might see the end of injections, pumps and pens! The researchers have set up their own company to market it and according to the Scottish Sunday Mail, one expert said that they could write their own cheque for the product!

### **Prevention theory doesn't work**

We reported some time ago on a US large scale study designed to find out if Type 1 diabetes could be prevented in people at high risk of developing diabetes by injecting low doses of insulin. The answer is no. The first stage of the study involving 339 young people at high risk of Type 1 diabetes has shown that the progression to diabetes was the same whether or not they were given insulin -15.1% per year in the insulin treated group compared to 14.6% in the untreated group.

Presented at the ADA Conference, June 2001

### **Transplant of pig pancreas cells to a baboon**

Researchers in the US have transplanted coated insulin-producing cells from the pancreas of the pig into a diabetic baboon and the baboon has been able to produce its own insulin for 9 months without any insulin injections. The cells were coated with a complex carbohydrate before being injected into the abdominal cavity of the baboon. The coating ensured that the baboon's immune system did not attack them but glucose was still able to enter the cells and insulin could get out through the special membrane. The researchers are hopeful that this technique could eventually be used on humans. Unlike transplants of islet cells that require human donors, there would be no shortage of donor islet cells from the world's pigs already involved in food production, so this research has the potential to revolutionise the lives of millions of people with diabetes.

## Pig cell transplants under debate in New Zealand

A research company based in Auckland hopes that it will soon be able to start clinical trials involving the transplantation of pig insulin-producing cells to humans [called xenotransplantation]. Initial approval was granted by the cabinet of the Cook Islands after the Ministry of Health in New Zealand refused plans to hold them in New Zealand because of the risk of pig retroviruses being transmitted to the human population. The Cook Islands are in the South Pacific with independent government, have a population of 20,000 people and one of the highest rates of diabetes in the world. The people are citizens of New Zealand and can travel to New Zealand for their healthcare.

With a great deal of press coverage in New Zealand, strong feelings have been expressed on both sides of the argument.

Professor Bob Elliott who heads Diatranz, the company wanting to carry out the research, said that a few of the Cook Islanders have expressed opposition and they do not have diabetes. He expected no major obstacles to arise from the public consultation on the Cook Islands. He was dismissive of the International Xenotransplantation Association [IXA] view suggesting that the reason the trials were being carried out in the Cook Islands is because such countries do not have the sophisticated virology facilities needed for monitoring pig viruses and bacteria. Professor Elliott said that all this work would be carried out in New Zealand.

There was public debate in 1994 when the initial trials took place. One recipient of pig-insulin producing cells in 1994 pointed out, the Ministry of Health is not consistent in it's attitude because they have never contacted her to check her health or to do blood tests to find out if she had developed a retrovirus.

While calling for greater public debate, the Ministry of Health in New Zealand decided to reject this research. However, this decision is to be reviewed by medicines review committee appointed by the Minister of Health.

## Pre-Meal Injection Timing

### Most of us don't do as we are told, but does it make a difference?

For as long as most of us can remember, we have always been told to inject short-acting insulin 20 to 30 minutes before a meal, but for as long as we can remember, many of us have not done this! The reasons for this 'non-compliance' are no doubt numerous but mainly amount to the inconvenience or lack of time to inject half an hour before eating. Then, of course, there is the justified reason of having low blood sugars before a meal and the half-hour between injecting and eating can be enough to cause a hypo. However, research has now looked at this and we can all stop beating ourselves with guilt over our 'non-compliance'!

Research carried out at Newcastle University [ref1] studied 179 'human' insulin-treated people who had been advised to inject 20 minutes or more before meals. These people were asked one question about the timing of their injections and their doctors provided information about their medical and diabetes history and their blood glucose control.

### What did the people report?

- 27% reported doing their injection 0-5minutes before meals
- 31% 6-10 minutes before meals
- 24% 11-20 minutes before meals
- 18% reported following the recommendations and injecting 20minutes or more before meals.

So 82% of the people in this study did not follow the clinic's advice they were given!

### What was the difference in their control?

Using the HbA1c as a measure of their diabetic control, the results showed that the pre-meal timing of the injection did not affect the HbA1c results. In fact the HbA1c did not differ with pre-meal injection interval nor did it differ with age, sex, body mass index or duration of diabetes.

The researchers concluded that the majority of people do not follow

the recommendations regarding pre-meal timing of injections but that blood glucose control is not affected by this. So if you don't follow the timing injection advice, maybe you don't need to feel guilty anymore!

**The results of this study have various ramifications:**

**The doctor/patient relationship** - clearly advice about having a long interval between injections and meals is not followed by most people and this has implications for the doctor/patient relationship. Perhaps it appears to the patient that the doctor doesn't really understand some of the day to day difficulties of living with diabetes - for instance that it is often not practical to have a 30 minute interval, or is not always easy to remember to inject with this interval.

**The use of the new insulin analogues** - this study must make us wonder about the use of the very fast-acting insulins, Humalog and NovoRapid. One of the main advertised advantages of these insulins has always been that they can be conveniently injected immediately before meals. It was also pointed out to patients that because they acted quickly the post prandial [after meal] blood sugars would be lower, presumably resulting in better overall control. But this research seems to muddy this picture even more.

The people who injected as advised, 20-30minutes before a meal, may well produce lower post prandial blood sugars. Indeed, surely this was the basis for the advice in the first place, but this research shows that HbA1cs were not any better in people who injected 20-30 minutes before eating than the group that didn't. So does this mean that perhaps lower post prandial blood glucose levels do not significantly improve overall blood glucose control as measured by the HbA1c results?

So logic dictates that we must ask what exactly are the benefits of rapid-acting insulins, such as Humalog and NovoRapid, if 'ordinary' insulin can be injected close to a meal without producing higher HbA1cs? What are the benefits for patients? It has been shown that they can reduce the risk of night hypos. But as we all know, this is because as well as being very fast-acting they are also very short-acting and basically they 'run out' sooner and there is a consequent rise in blood

sugars at other times. So one wonders what the advantages of these newer insulins really are? Time will tell and let us hope that this is sooner than the 19 years it has taken to show that 'human' insulins have NO advantages over their predecessors!

Ref1 Pract Diab March 2001, Vol18 No 2

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## More On Meters

### Warning! Accu-chek Advantage II

Glucose test strips. When you open a new container of test strips, don't just throw away the Patient Information Leaflet because you have read it before! If the manufacturers make changes or issue new warnings, the information will be in the Patient Information Leaflet, so it is important to read it.

Here is an example of why:

Roche Diagnostics have issued new information that although the result displayed on the Accu-Chek Advantage II meter is correct, it is possible that not more than once every

7 days the result may be incorrectly recorded in the memory.

- If the time and date on your meter is set correctly then this will only apply if you do a blood glucose test between 12.00 midnight and 12.10am
- If the time and date is not set on the meter then one blood glucose test every 7 days could be incorrectly stored in your meter memory.

This warning is particularly important if you or your doctor use the blood glucose results stored in your meter's memory to make adjustments to your insulin regime.

## **The Soft Sense**

This is the new blood glucose testing device made by Medisense which enables blood to be taken from the forearm, upper arm and the base of the thumb. It is said to be virtually pain free and of course gives the finger tips a rest. The meter and lancet are enclosed in a casing so the needle cannot be seen and the process starts with one click of a button. The blood is automatically put on the strip and the reading given 20seconds later.

The bad news is that the Soft Sense costs £225, although there are vouchers available to reduce the cost to £195. The lancets are available on prescription and until the strips become available on prescription [expected June 2002] Medisense is supplying them free of charge.

If this meter could incorporate some talking mechanism it would be ideal for blind and visually impaired people because the difficulty of actually getting the blood on the strip is removed.

**Note:** there is research that shows that blood tests taken from other parts of the body may be less accurate, especially with lower blood sugars. A study published by the ADA showed differences as great as around 5mmols/l in tests with blood from the forearm compared to the finger tips although the researchers did not rub the arm first before testing as the manufacturers recommend. In the US the FDA has decided to let the manufacturers of the meters do their own research to prescribe whether or not arm testing should be used and companies are advising that people avoid using alternative sites when testing for low blood glucose levels. [This is OK if you already expect the blood sugars to be low, but what people without warnings who do not know they are low?]

## **Problems with Lifescan's One Touch Profile Meters**

Lifescan has issued a letter in the US and Canada warning that One Touch Profile meters show a higher than expected number of display problems as they age. It appears that the visual display that forms the letters and numbers begins to fail so that it might present a test result or a calibration code that is unrecognisable. Apparently the problems tend to peak at two and a half years after the meter was manufactured.

While IDDT picked up these warnings for the US and Canada, if you have a One Touch Profile that is two years old, it may be sensible to regularly check that these problems have not occurred in your meter. You should carefully check that all the parts of the display are present each time you turn on your meter. If you need more time you can press the power button again to turn off the meter, then repeat the process by pressing and holding the power button. If you find that there are problems with the display, then you should contact the manufacturers, Lifescan.

## **Queen's Award for international trade goes to two biotechnology companies involved in monitoring blood glucose levels.**

### **April 22 2002**

The Financial Times reported news that the global rise in people with diabetes by about 3 million a year [mainly Type 2 diabetes], has not escaped the notice of biotechnology companies! This trend may not be healthy for the global population, but it provides healthy business opportunities for them!

Two such companies, Medisense UK and Inverness Medical have both won Queen's awards for international trade for blood glucose monitoring supplies. However, both have grown so fast that they have been snapped up by US giants of the pharmaceutical industry. Medisense increased annual sales by 140% to £150million and now are part of Abbott Laboratories. Inverness Medical won its award for booking a 3 year 400% increase in sales to £50million and they have been bought by Johnson and Johnson. This is yet another example of the pharmaceutical giants in diabetes gaining control and power which will enable them to control supplies and dictate prices.

## **Blood Glucose meters at low temperatures**

By Paul Murphy, United States

I spend a considerable amount of early mornings out stalking in the woods, from before dawn until late morning. It gets pretty cold in Michigan, during November and December. Many times it's -10° and some mornings as cold as -16°.

I've been a Type I diabetic since 1962, and while my hypoglycaemic awareness is much better on beef insulin - it's not perfect. I have greatly variable anti-regulatory hormones in the early morning and it's especially important for me to check my blood glucose level two hours after my morning injection. When I'm out in the woods I'm usually sitting fifteen feet up in a tree ladderstand which could be very dangerous if I was to experience a hypo. I always have a pint bottle of Quik chocolate milk in my pocket - in case my exercise and the cold weather make my blood sugar go lower than normal.

The problem is that many meters will not even boot up below 14°. This was the case with my Lifescan Profile, Fastake (Pocketscan in UK) and my Accucheck Advantage. The new Lifescan Ultra will now start up as low as 6°. This isn't good enough when it's colder, so I keep the Ultra in it's case in my flannel lined jeans front pocket inside of my hunting suit.

This last season I found the bottom line for when the strip's chemical reaction will still work. At -9° not only is it difficult to get a drop of blood from ones finger, but I found also the meter will start immediately out of one's warmth in pocket, but it will not give a result. It comes up with a reading of low, which at first led me to believe it was below 1.3 mmol. But what it really means is that the meter is working but it's too damn cold for readings – or for stalking!

As B. B King says in the Ultra advertisements, 'Test often' and keep safe!

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## Animal insulin Availability

### In the UK

- Novo Nordisk are still supplying pork insulins but only in vials and not cartridges for pens.
- CP Pharmaceuticals in Wrexham produce beef and pork insulins

in both vials and cartridges for pens. They are committed to the ongoing supply of their Hypurin range of beef and pork insulins.

Earlier this year there was a shortage of Novo Nordisk pork Mixtard and we received calls from people who could not get their Mixtard. Not only were they told that it was no longer available but they were even told that the CP equivalent Hypurin porcine 30/70 Mix was no longer available either. It was true that there was a shortage of Novo's Mixtard but NOT true that it had been withdrawn or that there was any difficulty in obtaining CP Hypurin 30/70. Unfortunately the message here is clear, do not accept without question that your insulin has been discontinued even if this information comes from a professional source. Always check before panicking! If the situation with supplies changes, IDDT will send out a special mailing to members to let you know the position.

### In Germany

Novo Nordisk discontinued their range of animal insulins in Germany at the end of 2001 and almost immediately IDDT was contacted by people in Germany desperate to obtain pork insulin. There has been pressure from within Germany to obtain supplies for this group of people. So it is good news that CP Pharmaceuticals, UK, have arranged with Novo Nordisk that they will promote CP pork insulin in Germany. Novo Nordisk representatives are communicating this message to all diabetes centres using CP product information and the information is to be on the websites of both Novo Nordisk and CP Pharmaceuticals. Our thanks to CP for making this arrangement to answer the needs of all people requiring insulin.

### In the US - availability of Lilly Iletin II, pork insulin

Increasing numbers of people are contacting IDDT-US not only because they cannot obtain supplies of Iletin II from their pharmacies but also because again, they are being misinformed and told that Iletin II insulin has been discontinued. Lilly Iletin II pork insulins have NOT been discontinued. This has been confirmed to IDDT from the FDA and the FDA website gives information about insulin availability, confirming that pork insulin is available. It also says that beef insulin is

not available but provides a section about how to import beef insulin. Visit the FDA website at [www.fda.gov/diabetes](http://www.fda.gov/diabetes)

- If you live in the US and are having difficulty obtaining your supplies, you should contact Eli Lilly on their toll free number 1-800-545-5979 and your insulin should be sent to your pharmacy.
- If the problems continue, then you should report this to the FDA. If you need help with this, please contact Pam Maples on toll free direct lines 1-800-276-2091 and 1-800-276-3531 e-mail address [IDDTUS@msn.com](mailto:IDDTUS@msn.com)

#### **IDDT- US advice to people whose pharmacy is unwilling to supply Iletin II:**

- Tell them that you know it is available and you would like to order it.
- If they still refuse to supply you, inform them that you will make a complaint to the FDA.
- If this fails to achieve your supplies, then take the details of the pharmacist, the date and time and report the matter to the FDA. Contact Pam if you need help with this.
- And if you can obtain it the price might be a problem!
- We recently received the following communication from one of our members that uses pork Iletin II:
- Last Tuesday I ordered 4 bottles pork Iletin II regular [www.americarx.com](http://www.americarx.com)

Cost \$198.36 plus \$32.99 [delivery]      Grand total \$231.35

- Last Wednesday I ordered 10 bottles of regular from [www.onlineinsulin.com](http://www.onlineinsulin.com)

Cost \$199.59 plus \$7.85 [delivery]      Grand total \$207.35

Both companies supplied within a few days and both supplied in cool containers but 4 bottles of regular pork Iletin II from America RX cost MORE than 10 bottles of the same insulin from Online Insulin.com!!!!

OnLine.com is a Canadian company.

#### **In Finland**

As with other countries Novo Nordisk have discontinued supplies of some animal insulin but after pressure there has been a breakthrough and the present situation is:

- CP Hypurin Bovine Lente is fully registered with an approved price in Finland.
- 'Temporary approval' has also been granted to import CP Hypurin Bovine Neutral if required.
- Novo Nordisk have confirmed that they will supply their pork insulins until 2005

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## **Novo Nordisk Shares Suffer As Sales Are Less Than Expected**

### **Financial Times – April 11 2002**

Shares in Novo Nordisk plunged 21% after the company announced that its operating profit would grow by only 5-10% when its February prediction was 15% higher than this. Sales growth has averaged 20% over the past 3 years but is expected to be between 7 and 10% for 2002. Novo's sales in the first 3 months of 2002 grew by only 2% and they blamed the downturn on several factors but mainly a slowdown in European diabetes care sales as customers were less willing than anticipated to switch from traditional insulin and injection devices to Novo's new generation of rapid acting analogue, Novorapid. The sales of Prandin, their oral drug for Type 2 diabetes, also declined in the US.

Both Novo and investors admitted that they are puzzled by the slow down in insulin sales as the incidence of diabetes is expanding rapidly and according to analysts, the slowdown in insulin sales seemed specific to Novo rather than the market as a whole.

Could the downturn in expected sales be that there is more caution about new insulins, than in the past? Could it be that lessons have been learnt from the experience of the introduction of 'human' insulin without evidence of benefit and the subsequent reported adverse effects? Could it be that those to whom Novo Nordisk sell their new insulins, now require evidence of benefit and long term safety for their patients and that the heavy sales pitch of a new insulin is no longer quite as convincing? Let us hope so, because simply producing new insulins is of little use to us, the patients, unless there are real gains for us – better control, less hypos, better HbA1cs and a better quality of life.

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## Exercise - What's It All About?

Physical activity is good for your heart. This message is one that must have reached almost everyone but is it a message that many of us choose to ignore? Maybe we hear it so often that it just washes over us and we ignore it, as was the case with the early heavy advertising about AIDS and safe sex. It may simply be that for those of us that are couch potatoes, the very thought of 'physical activity' is quite off-putting! Or for many of us with busy lives, just the thought of trying to fit in time for 'exercise' is exhausting!

Maybe it's the words 'exercise' and 'physical activity' that put us off because they conjure up visions of fit, lithe people visiting a rather expensive gym three times a week! Perhaps the messages would be more effective if they excluded the words 'physical activity' and 'exercise' and simply encouraged us to introduce more activity into our existing lives so we actually achieve greater activity and the health benefits almost without realising it!

According to the British Heart Foundation, 7 out of 10 adults in the UK do not take enough regular exercise to achieve health benefits to protect their heart but 8 out of 10 adults actually think that they are fit.

### **So what are the benefits for you from taking more exercise?**

Physical activity halves the risk of developing coronary heart disease.

In people that have already had heart attacks, those who have been physically active are twice as likely to survive the heart attack compared to those people who have not been active.

Physical activity reduces the risk of having a stroke and helps to lower blood pressure.

It reduces the risk of Type 2 diabetes and osteoporosis.

It helps to reduce weight in people that are overweight or obese.

It can help to relieve stress, make you feel better and it can be enjoyable.

### **Facts:**

- There is no level of activity that has to be achieved to gain health benefits.
- The largest gain in health benefits from increasing physical activity levels, is in people who are inactive and who start to take regular exercise or physical activity eg walking, cycling, dancing or swimming.

### **The major risk factors for coronary heart disease are:**

- Smoking
- High blood pressure
- High cholesterol levels
- Lack of exercise

### **Other factors that may affect your risks of having a heart attack:**

- Too much alcohol
- Excessive salt intake

- Obesity

### **The science**

A review, published in the Annals of Internal Medicine [April 2002], of 54 clinical trials involving 2,419 previously sedentary adults concluded that regular exercise reduced the systolic blood pressure [the top number] by an average of 4 and diastolic blood pressure [the lower number] by an average of 2.6mm Hg. The results add to the evidence that exercise is important for treating high blood pressure and for preventing it occurring in healthy people.

While the study did not show what level of activity was ideal for lowering blood pressure, results of various types of aerobic exercise at all frequencies were beneficial to people who were previously sedentary – in other words any activity is better than none. US officials are advising that people should have at least 30 minutes of moderate exercise on 5 or more days of the week.

### **The cause of coronary heart disease**

It is caused when the arteries that supply blood to the heart become narrowed due to a gradual build up of fatty tissue [atheroma] within the walls of these arteries – this condition is called atherosclerosis. A heart attack is caused if a blood clot forms over the atheroma.

The development of this fatty tissue, or atheroma, is caused by the cells in the coronary artery walls taking up cholesterol and this is the beginning of the narrowing of the arteries. As we all know, cholesterol is formed from the fats in the food we eat but it is important to remember that there are two types of cholesterol – the good and the bad!

### **LDL cholesterol [bad] forms the atheroma**

**HDL cholesterol** [good] removes cholesterol from the circulation and appears to have a protective effect on the heart.

So ideally we should have a lower levels of LDL cholesterol and higher levels of HDL.

## **Why Is Physical Activity Important For Your Heart?**

Research indicates the following:

- Physical activity appears to raise HDL [good] cholesterol levels but does not affect LDL cholesterol levels.
- It helps to prevent blood clotting and so reduces the risk of a heart attack.
- It helps to lower blood pressure and also to prevent high blood pressure from developing.
- It helps to reach and maintain a healthy weight.

### **Physical activity and diabetes**

#### **Facts:**

- Men that have diabetes are 2 to 3 times more likely to develop coronary heart disease than men without diabetes.
- Women with diabetes are 4 to 5 times more likely to develop it than women without diabetes
- In people that already have diabetes, physical activity can reduce the amount of medications needed or reduce the insulin dose.
- Moderate, rhythmic exercise seems to reduce the risk of people developing Type 2 diabetes in middle age.

### **Types of activity**

There are two main types of exercise.

**Aerobic activity** – this type of exercise benefits your heart. It is any activity that is rhythmic and repetitive eg walking, swimming, cycling, dancing which increase the body's demand for oxygen so making the heart and lungs work harder and more efficiently.

**Isometric exercise** - this increases muscle tension without moving

a joint eg pushing against a wall. Isometric exercise does not help the heart and circulation. It should be avoided by people with heart disease or high blood pressure because it can increase blood pressure so putting the heart under stress.

### Is it safe to start exercising?

- If you already have had a heart attack or any other heart condition such as angina or you have high blood pressure, you should always discuss with your doctor how much and what sort of exercise you should do. There are certain heart conditions where exercise may not be advisable.
- Always stop exercising if you get any pain or feel dizzy, sick or unwell. If the symptoms don't go away or come back later, see your doctor.
- It is unsafe to exercise when you have a viral infection such as a sore throat.
- It is always sensible to gradually build up your physical activity in terms of both the time spent and the intensity. A sudden increase in exercise, especially vigorous exercise can be dangerous especially in middle aged people.

### Just a note about fats!

Benecol has been on the supermarket shelves for some time now and the makers claim that it reduces cholesterol. This product may well be tempting to people with diabetes as they are at greater risk of heart disease and keeping the cholesterol levels down reduces that risk. Many of us may remember that the Advertising Standards upheld a complaint that the adverts for Benecol were misleading. Their claims of how much Benecol reduces cholesterol in the first 3 weeks were misleading – in order to achieve the claimed 15% cholesterol people would have to eat far more than they normally would or could eat.

Benecol margarine and cream cheese contain high levels of chemicals called plant stanol esters. These reduce blood cholesterol by inhibiting its absorption into the body. The science of this is not in doubt but the experts have concerns about it. There are other concerns

about Benecol:

- The British Heart Foundation warns that people might see it as an answer to their cholesterol problems but it is NOT a substitute for other well-established methods of reducing the risks of heart disease.
- The British Nutrition Foundation says that Benecol only addresses one risk factor for heart disease and it should not be seen as an alternative to healthy eating and a healthy lifestyle.

A further concern is the cholesterol lowering effects of Benecol on adults and children with low cholesterol levels. According to 'Health Which?' there is no research that shows the effects of lowering healthy levels of cholesterol in children and they say that the British National Formulary is cautious about Benecol becoming a margarine for all the family. The government's Food Advisory Committee advise that young children, pregnant women and breast feeding mothers should not seek to lower their cholesterol.

The manufacturers say that it has been on sale in Finland since 1995 and over 140,000 people regularly eat it with no reported ill effects but it appears that this is not supported by evidence from research.

Finally, Benecol is also considerably more expensive than other low fat spreads and therefore unaffordable by many, especially those on low incomes who are the very people that are more at risk of heart disease.



## Most Doctors Who Set Guidelines Have Industry Ties

A study [Ref 1] Has shown that the vast majority of doctors involved in establishing national guidelines on disease treatment have financial ties to the pharmaceutical industry that could potentially sway their

recommendations and inappropriately influence thousands of other physicians.

- 87% of guideline authors had some type of relationship with drug companies, yet these often were not disclosed, according to survey responses from 100 authors of guidelines published from 1991 to 1999 for common conditions such as **diabetes**, high blood pressure and asthma.
- 38% of respondents said they had served as employees or consultants for pharmaceutical companies
- 58% had received financial support for medical research.
- 59% had links with drug companies whose medications were considered in the particular guidelines they authored.

The researchers said that these figures may underestimate the problem because only 52% of the authors contacted for the survey responded.

The researchers say that these findings show that people on committees that write practice guidelines have lots of financial relationships with companies whose products they're assessing and this is a potential problem because of conflict of interest. To make matters worse, when respondents were asked whether relationships with drug companies influenced guideline recommendations:

- 19% said they thought their co-authors' recommendations were swayed by their relationships
- 7% said they thought their own relationships influenced recommendations.

How much industry involvement should disqualify a doctor from participation in clinical guidelines? Unless there is zero involvement, this will always be a problem but the researchers specifically recommended the disqualification of authors who own equity in a company whose products are being reviewed in the guidelines. However all they said beyond that was that each group that sets guidelines should devise their own ways for identifying and dealing

with potential conflicts of interests and they should prevent conflicts of interest from harming the patient/consumer.

Ref 1 JAMA February 6, 2002;287:612-617



Apologies For Error!

The Spring 2002 Newsletter – information about the blood glucose levels for diagnosis were out of date. Perhaps it is sufficient to say that if the fasting blood glucose is 7.0mmols/l or above, then diabetes is diagnosed.



## Correction

Our Spring Newsletter contained details of Sweet Success, the Pancreas Transplant Support Group. Unfortunately Sweet Success is in the process of moving and there has been some difficulty in contacting them. The latest details are:

Pancreas Transplant Support Group, PO Box 429, Oxford OX2 0WH  
tel 01865 725146.

If you should have any difficulty getting through by phone, please let IDDT know as Jo Tomlinson the founder of the Group is happy to call you. If you have internet access, her e-mail address is [enquiries@sweetsuccess.org.uk](mailto:enquiries@sweetsuccess.org.uk)

# IDDT Opposes Direct To Consumer Advertising Of Drugs

In IDDT's October 2001 Newsletter we reported on the campaign to oppose any relaxation in the existing regulations that prevent direct to consumer advertising of drugs [DTCA] by the pharmaceutical industry. IDDT supports this campaign because we believe that patient information should not be supplied by drug companies who can hardly be unbiased or independent when their future depends on promoting their name and their products.

## The EU Proposals

In July 2001 the European Commission proposed changes in EU law to allow drug manufacturers to have 'disease awareness campaigns' for a 5 year period in 3 disease areas - AIDS, asthma and diabetes. Clearly this is the nearest thing to DTCA without actually allowing advertising. These proposals originated with the Commission's division with responsibility for promoting business but they were said to be as a result of demand from patients' groups. However, the Commission has been unable to say which groups made the demand, why these 3 health areas were 'chosen' or what form the review at the end of the 5 years will take. It doesn't really take a great deal of imagination to work out why diabetes, asthma and AIDS were chosen. They all affect large numbers of people, they all require ongoing costly medication or medical devices and there is a lot of money to be made by industry especially if they can tell patients directly about their wonderful new and usually more expensive products! As we go to print, the European Parliament is due to debate the Commission's proposals later in the year.

We are convinced that our opposition is the right stance – just look at the evidence!

**A study [The Lancet vol 358, Oct 6 2001] carried out from 1998-1999**

This study looked at the content of drug advertisements in 10 magazines in the US, one of the only two countries where DTCA is allowed. The results showed:

- 67 adverts appeared a total of 211 times during the year of the study
- 133 [63%] were drugs for symptom relief eg allergies, menopause
- 54 [26%] were to treat a diagnosed disease eg Alzheimer's, diabetes, blood pressure
- 23 [11%] to prevent illness eg osteoporosis, high cholesterol

## The promotional techniques were used as follows:

- 45 [67%] used emotional appeals
- 26 [39%] used encouragement to consumers to consider medical causes for their experiences

## How the benefits were described:

- 58 [87%] used vague qualitative terms such as "If your diabetes is uncontrolled.....Glucophage can help"
- 66 [98%] specified the adverse reactions in accordance with the regulations but about 50% went further and described less common side effects accompanied by statements like "Each of these side effects occurred in less than 2% of patients"
- only 9 [13%] used evidence to support their claims of benefit

This study showed that few adverts contained factual evidence to support claims of benefit. This may not be too important for drugs that are supposed to relieve symptoms because patients can judge for themselves whether or not the drug works, but it does matter with drugs that are supposed to treat a disease. The authors recommend that provision of complete information about the benefit of prescription drugs in advertisements would serve the best interests of physicians and the public.

## Health Action International [HAI]

This is a network of consumer health groups and is a leading opponent of DTCA. According to HAI:

- drug companies in the US spent over 95% of their DTCA budgets on just 50 drugs which produced retail sales of US\$41.3 billion, yes billion dollars!
- The 50 advertised drugs accounted for \$9.94 billion of the increase in prescription drug spending from 1999 to 2000 and this is almost half of the total spend!
- DTCA is very effective for the drug companies as every dollar spent on a TV advert returns \$1.69 in sales; every dollar spent on a magazine advert returns \$2.51

## Consumers Association

On June 2nd the Consumers Association in the UK released the results of an opinion survey showing that the public wants to retain the ban on advertising of prescription drugs.

- More than 60% of the public believe that if advertising were allowed, drug companies would try to convince people they had illnesses they didn't have.
- More than 80% believe that the companies would focus on advertising their most profitable products
- Over 66% were concerned that companies would not provide enough information about possible side-effects.
- Only 25% believe that companies can be trusted to provide unbiased comprehensive information, including non-pharmaceutical alternatives.

## IDDT has joined the campaign against any relaxation in the ban on DTCA

HAI has organised a campaign and petition that IDDT has signed. It is surprising that at the time of writing IDDT is the only diabetes organisation to have raised objections to these proposals – or perhaps not surprising as we are probably the only national diabetes organisation [maybe in the world] that does not accept pharmaceutical

industry money!

We also contacted about 50 other small patient health groups to ask for their support and thankfully some have signed the petition. At the moment it is clear from the experiences in the USA that the disadvantages of DTCA far outweigh any potential advantages. It is disappointing that organisations such as the Long-term Medical Conditions Alliance and the large charities either do not recognise that this proposal could be the thin end of the wedge that leads to full blown direct to consumer advertising of drugs or they do not recognise that changes of this magnitude would increase our national drugs budget in an already cash strapped NHS. It is equally sad that they do not recognise that changes of this magnitude should be based on sound evidence from risk/benefit and cost analysis. Maybe these organisations have gone too far down the road of being sponsored/funded by pharmaceutical companies to be in a position to object but we expect better of organisations that are supposed to represent patients' best interests.

To see our position statement and for more information about the HAI campaign visit [www.haiweb.org](http://www.haiweb.org)

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## From Our Own Correspondents

### Utter amazement!

Dear Jenny,

I have just read the Spring 2002 Newsletter, with many thanks for all the good works on our behalf. I read "Trapped in my house without a pen" with utter amazement!

I was diagnosed with Type 1 diabetes over 30 years ago, as a rock climber living in Scotland. It frightened the life out of me but with the help of my girl friend, I soon found that life was still possible, climbing

the Munroes carefully soon after my release.

I have been very lucky to have escaped the bad side effects of diabetes but I am beginning to find the hills are getting bigger and the miles are longer now I am in my 60s. However, I have recently toured Estonia and into Moscow on my bike.

I use an ordinary syringe for porcine insulin and visibly check my blood glucose levels since I believe it is FAR more important to know HOW FAST I am going UP and DOWN, rather than the accurate value at that instant – especially when using energy fast, such as cycle touring.

I have never found injections difficult, they just require some careful discretion. So a pen may make life a bit easier, but even that has its problems: my experience with pens was that it was TOO EASY to chase blood sugar peaks with a drop of insulin, which got me into serious trouble, oh what an imperfect world we inhabit!

I have NEVER gone seriously low when doing energetic activities, since any low tendency becomes obvious and is easily corrected. My biggest danger time is when sitting waiting for a meal that is late – I can easily fail to recognise the approaching hypo then.

So a 'pipe and slipper' existence is NOT obligatory with a syringe!

Mr H.D.  
N Yorks

**Jenny's comments:** thanks to Mr H.D. firstly for reminding us all that the importance of blood testing is to enable us to live life as we want to and to be able to make the necessary dose adjustment. Mr H.D. highlights somethings that many people became aware of when pens first came on the market – it is just too easy to chase blood sugars, this means giving extra insulin to bring the blood sugars down afterwards rather than establishing the right dose initially to prevent the high. It leads to a vicious circle of chasing blood sugars. Another drawback to the pen that people recognised in the early days was that it made

it all too easy to eat extra and just give extra insulin, result – weight gain! As Mr H.D points out, we are not perfect and the temptation to eat and add a bit more insulin with the so convenient pen is too great for some people.

### **Transition to 'human' insulin fairly smooth**

Dear Jenny,

I have just found your website. I am a teacher in Saudi Arabia and I have been asked to talk to some senior school students about my diabetes. I thought I would just get up to date on all current issues and research and was delighted to find your site - it is extremely informative and easy to use. I am disappointed by the lack of relevant information presented by other leading groups, please keep up the good work it is very much appreciated. My mum subscribes to the IDDT Newsletter in the UK which is always read upon my return but I will certainly be logging onto this site on a regular basis.

To add to your debate on animal versus human insulin, I was horrified when I first arrived in this country six years ago to be told that since pork insulin is obviously not available here that I had no option but to use human insulin. I am pleased to say that the transition was fairly smooth however, I do experience the odd hypo with lack of warning symptoms. As I am responsible for very small children I do have to be organized but thankfully I have had no problems to date.

Ms M.N.  
Saudi Arabia

**Jenny's comments:** many thanks to Ms M.N. for telling us that she managed to change from pork insulin to 'human' insulin when forced to do so by lack of availability of the insulin she was used to. It is reassuring to know that she has been able to cope but concerning that she has loss of warnings of hypos sometimes and has to be more careful.

Continued withdrawals of animal insulins around the world mean that

people are having to change from an insulin that suits them for no good medical reason but some people are not coping as well as Ms M.N.. Should Ms M.N. or anyone else have to put up with lack of warnings that did not happen when using pork insulin, simply because the drug companies make commercial decisions that are only in their own best interests?

### **The doctors do not believe!**

Dear Jenny,

Toxical reactions against human insulin were diagnosed in my case 12 years ago. I went into hospital for a condition not related to my diabetes, the doctors ignored the warnings of my good informed friend and my son and they ignored the lot of animal insulin my friend gave to them. I had an anaphylactic shock after an infusion with human insulin.

I fight against stopping selling animal insulin in Germany for a long time but the government answer is a catastrophe for me! I go on fighting.

Name withheld  
Germany

**Jenny's comment:** why is it easy to believe people when they say they react badly to penicillin but so difficult to believe people when they say they react badly to 'human' insulin? Are we all classed as natural fibbers?

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## **Disability Living Allowance [DLA]**

We have published articles in previous newsletters about Disability Living Allowance [DLA] because it can be a difficult process to understand and how you fill in the forms or how your doctor fills in

the forms can affect your claim. If your claim is not accepted then the Appeal process can be even harder to deal with. Our advice has always been to seek the assistance of someone that is used to helping people with their claims. However, Barton Hill Advice Service [BHAS] has an excellent website that not only explains the complex system in a user-friendly way but also provides 2 minute tests to help you decide if you might be eligible to claim DLA. In addition there are details of how to make a claim and how to prepare for a home medical visit from a doctor sent by the Benefits Agency. IDDT is well aware that not everyone has access to the internet [or even wants it!] so you can write to BHAS for information. Please note that they cannot respond to or even acknowledge individual benefit queries. If you prefer, you can contact IDDT for the information on 01604 622837 and we will download it from their website for you. Here are the details of BHAS:

### **Barton Hill Advice Service**

Unit 32

Easton Business Centre

Felix Road

Easton Bristol BS5 0HE

e-mail: [info@bhas.org.uk](mailto:info@bhas.org.uk) Website address is [www.bhas.org.uk](http://www.bhas.org.uk)

### **What is Disability Living Allowance?**

It is a Social Security benefit that you may be able to claim if you are under 65 and have long term health problems, mental or physical, that affect everyday activities.

Facts [printed with permission of BHAS]

Many people are given the wrong information about whether or not they are eligible for DLA so no matter what you have been told there are some things that will not affect your right to claim – here they are:

### **12 things that won't affect your right to claim DLA:**

1. You're getting other benefits – DLA will be paid on top.
2. You're working.

3. Your partner works.
4. You have savings.
5. You have not paid any national insurance contributions.
6. You don't consider yourself to be disabled – DLA is for long term health problems that affect your everyday life.
7. You've been told by a doctor, nurse or other care worker that you won't get DLA. Eligibility for DLA is a legal question, not a matter of medical, or any other opinion.
8. You live alone and no one is providing care for you.
9. You already have someone, eg a partner, providing care for you.
10. You don't want anyone to provide care for you.
11. You've been turned down before. Once you have looked at the information in the guides, you may decide you could put forward a stronger case if you applied again.
12. You do not want to spend money on personal care: you can spend Disability Living Allowance on anything you wish.

So if we can help, please give IDDT a call on 01604 622837

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## News

### **Vacuum therapy devices for impotence available on the NHS**

Impotence [erectile dysfunction] can be caused by diabetes. It can be treated with drugs eg Viagra, available on the NHS. However, some men may not be able to use these drugs because of interactions with other medications they are taking. The Dept of Health has recently announced that vacuum therapy devices [VCTs] can be prescribed on the NHS.

## Update For People With Visual Impairment

### **Newcastle upon Tyne - new group for people with retinopathy**

A new support group has formed for people with diabetic retinopathy in the Newcastle upon Tyne. It is open to anyone that is interested either because they have retinopathy or because someone close to them has. If you would like further details phone:

Northumbria Sight Services on 0191 273 9009 or

Newcastle Disability Forum on 0191 285 4556

Using the internet - a tip for people who find the print on websites too small

The print on the internet websites is often small and too small for people with visual impairment. Increasing the print size on website pages can be done by the user's own computer browser settings. Internet Explorer users should click on 'View' in the menu and then click on 'Text size' and click on a size of print that is suitable for their needs.

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## 'Seeing Things Clearly'

### **By Jackie Banks**

This is an interesting little book in large print for people that are visually impaired. The author, Jackie, has had diabetes for 42 years and retinopathy for 25 years. She describes her personal experiences of retinopathy and laser treatment but also talks readers through screening procedures, effective laser treatment and the after effects. She discusses driving with the retinopathy. In addition she discusses nutritional supplements and how to choose them.

Seeing Things Clearly costs £4.95 and its ISBN No is: 0 948706 13 9 or it is available from Brent Publications, Fleet House, Armstrong Road, South Benfleet SS7 4FH for £5.95 incl p&p

### **Visual field assessment for driving important information**

Jackie's book raises some important issues for people that have lost their driving licence because of visual field difficulties and for those that are about to be tested.

During the 1990s as a result of EU guidelines the DVLA implemented more stringent standards for visual field assessment and this has resulted in greater numbers of people losing their driving licences.

The instruments used for checking visual fields are called perimeters and there are two types:

- An automated perimeter that uses static flashing lights and automatically prints out the results. This is widely used and can, and often is, not operated by a qualified optician in many high street opticians.
- A manually operated perimeter eg Goldmann using a system on moving lights. This is operated by an optician

The manually operated Goldmann type is often easier to use for the person being checked and may well give better results. Clearly your results could be different according to which perimeter is used. Apparently there has been a great deal of campaigning about this issue that has resulted in the DVLA agreeing to review their guidelines and carry out research into finding a more appropriate method of checking visual fields. IDDT will be writing to the DVLA for more information. If you are about to have a field check or indeed have recently lost your driving licence, we would advise you to request a test on a hand held perimeter such as the Goldmann.

We will keep you posted...

REMINDER – IDDT Newsletter is available on Tape or in large print. If

you would like to receive either of these, contact Beverley Sharpe on 01604 622837 or IDDT, PO Box 294, Northampton NN1 4XS

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## **Thanks Are Due To You!**

**From Jenny Hirst**

### **IDDT Questionnaire**

We have had a tremendous response from you to our questionnaire about what activities you are prepared to undertake for our plan of action. I thank you all for the time and effort put into this, your experiences and willingness to take action in whatever form this may be, are central to any activities we undertake. Your experiences from all over the UK mirror each other and the evidence from you will be hard to deny. It is reminiscent of the BDA unpublished report that assessed the experiences of the people that first reported the adverse effects – there is a clearly defined category of symptoms that affect some people when using 'human' insulin. It is powerful stuff, but whether anyone has greater power than the pharmaceutical companies remains to be seen. But be assured, we shall try!

### **Insulin for life**

We would like to thank everyone who has sent in date unwanted insulin and other diabetes supplies to help people in poor countries. The response to our appeal has been tremendous and is much appreciated by the doctors in clinics in developing countries. So to members friends and to all the diabetes specialist nurses that are taking the time and trouble to send unwanted supplies to us – a very big thank you!

At the time of going to print IDDT has sent the following supplies to help people in need:

- Insulin - 427 vials, 977 cartridges, 429 pre-filled pens

- 36 blood glucose meters and 39 packs of blood glucose reagent strips
- Large quantities of finger prickers, pen needles and syringes.

Our Appeal continues, so we would be grateful for your continued help.

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## Pen Cartridges - Correction For Balance Readers

Readers of Balance May-June 2002 may have noticed that the article on insulin pens [pages 40-41] referred to 'LP Pharmaceuticals' insulins being available in 3ml pen cartridges. We assume that it actually means CP Pharmaceuticals' insulin but CP do not make 3ml cartridges. They make 1.5ml for both beef and pork insulins.

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## Interesting Quotes!

### **POLICY ON PRESCRIBING ANIMAL INSULIN – rare but fair!**

#### **From University College London Hospitals NHS Trust:**

*“Much controversy surrounds the reported hypoglycaemic unawareness on human insulin.*

*Our policy is to start patients on human insulin unless they request otherwise. They may change to porcine or bovine insulin at any time.*

*For patients on insulin already – if they wish to have animal insulin there should be absolutely no objection to this.”*

Who could ask for anything more?

## At Last!

### **A statement from Diabetes UK**

Diabetes UK [formally the British Diabetic Association] go further than ever before about the problems with 'human' insulin! In the January 2002 issue of their magazine Balance, there is a statement about the adverse effects of 'human' insulin that goes further than they have ever gone before in admitting that some people are unable to use 'human' insulin.

Diabetes UK states:

*“Unfortunately, and we don't know why, some people cannot control their diabetes using human insulin. This is why Diabetes UK campaigns to ensure that animal insulin is still available in the UK. In addition, Diabetes UK also recommends that people experiencing difficulties with their insulin discuss the options with their healthcare team – remembering that an animal insulin may, at times, be more appropriate or even essential.”*

While their campaigning on this issue appears to have a very low profile, we welcome this statement although we also deplore the fact that it is so late in coming. Indeed it could well be too late now that Novo Nordisk control the major global source of insulin crystals.

However in their leaflet 'The facts about insulin', they are not so accurate! Page 10 says “...some animal insulins remain available for those who already use them.” Pork and beef insulin have marketing licences like any other medicine and can be prescribed for anyone – they are NOT restricted just to people that are already using them!

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## Date For Your Diary - IDDT's Annual Meeting

**Date** - Weekend of October 12th/13th 2002

**Venue** – The Comfort Inn, Hagley Road, Birmingham

**Cost** – Saturday/Sunday overnight stay all meals included £22.50 each, Saturday and/or Sunday day delegate fee £10.50 each per day.

**Our guest speakers** - Dr Stanley Shortt, M.D., F.R.C.S.(C), an ophthalmologist from Canada speaking about Eyes and Diabetes and Alison Blackburn and Michael Gibbons speaking from a patient perspective about the help that is available to people with diabetic eye disease. There will also be panel discussions and plenty of time to chat to other people who live with diabetes.

**Applications** – the details and application forms will be sent to members in August but if you would like to make a provisional booking then contact IDDT, PO Box 294, Northampton NN1 4XS, tel 01604 622837 or e-mail [meeting@iddtinternational.org](mailto:meeting@iddtinternational.org)

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## IDDT Responds To Your Requests

There has been much press coverage given to Type 2 diabetes and our look at the press cuttings shows that people with Type 1 diabetes have been prompted to write to their local papers. They have been angered or upset by misinformation and confusion that has arisen. All too often the messages the public is picking up is that diabetes of both types is caused by obesity and lifestyle. The repercussions are that people with Type 1 diabetes are being accused of causing their diabetes by over eating and/or eating loads of sweet stuff! As well as failing to make clear the differences between Type 1 and Type 2 diabetes, many articles about Type 2 diabetes have actually interviewed and showed photos of people who quite obviously Type 1 diabetes!

### Clear messages

A photo of someone injecting, especially a young child, is emotive and

attracts press coverage for diabetes, but as many of you have pointed out, this should not be presented as the image for Type 2 diabetes. Publicity aimed to raise awareness and influence people's behaviour should carry messages that are clear, simple and not misleading. Indeed to portray Type 2 diabetes with a photo of someone injecting could well be counterproductive. Typically Type 2 diabetes affects people over forty and is treated with diet only, diet and tablets and if these treatments fail to control blood glucose levels, then insulin injections are necessary. Most people, especially the elderly, are likely to be frightened by the thought of injections, so articles showing people injecting are likely to be counterproductive and may well discourage undiagnosed people and those at risk of Type 2 from seeking early diagnosis. Finally it is important to recognise that publicity should not upset, anger or make life more difficult for people who already have diabetes.

### IDDT reacts to your requests

Whenever possible IDDT is responding to confusing press articles with a letter to the editor to clarify the differences between Type 1 and Type 2 diabetes and to act as a reminder that the seriousness of Type 1 diabetes should not be overlooked by healthcare systems and research workers.

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## Did You Know?

- Diabetes was first recorded in Egyptian hieroglyphics in 1500 BC and the treatment was four days of taking a mixture of ground earth, ground bones, wheat, lead and water.
- Identification of the pancreas as the origin of diabetes by von Mehriag and Minowski did not occur until 1889.

## Tit Bits

**Non-invasive eye test for blood glucose** - The Bio Design Group, UK, has developed a non invasive eye test to measure blood glucose levels in people with diabetes with the intention that this could replace the need for finger prick tests. This test involves the use of chemical sensors in the eye and a reading device for the detection of glucose in the lachrymal fluid [tears]. The chemical sensor is introduced into the cavity between the eyelid and the sclera [the outer part of the eye]. The changes that occur are then measured with a hand held device called a fluorimeter.

**Progress in the transplant world** - in July 2002, the University of Alberta announced that they had successfully carried out islet transplants in 7 people. Now 31 people have been transplanted and the rate of insulin independence remains high – 80% after one year and 71% after two years.

Safety syringes in the US - as a result of increasing accidents and attacks, a federal edict came into force last August that syringes must be safety syringes. This can only take effect as soon as capacity allows but only one company, Retractable Technologies, currently makes them. They have recently found a marketing partner and they expect annual sales to be worth £100million.

**Symlin [pramlintide]** - a new drug made by Amylin to be used in addition to insulin to treat diabetes and it has appeared in journals for several years. However, it has failed to receive FDA approval in the US because during the first four weeks of the trials there were 2 or 3 times more hypos in the group taking Symlin compared to those taking a placebo [dummy]. This persisted after the first 4 weeks although not to the same extent and the FDA was also concerned that the drug would prevent people from recognising hypo symptoms. In addition HbA1cs were only slightly improved. The FDA also criticised the study design because participants were not allowed to change their insulin dose as they would in normal life.

Charity donations - the total amount donated to charities in the UK in 2001 rose to £5.76bn, the highest for 7 years in real terms but smaller numbers of people are actually giving. According to NOP and NCVO research, one in three people gave nothing at all whereas in 1994 only one in five did not donate. Women give more than men and also give a larger donation with medical research and children's charities being the most popular causes. The research also showed that donors tend to give more if they believe that a higher proportion of their donation will go to the cause itself. [IDDT ought to do well on this one then, we are all volunteers with a bit of admin assistance!]

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## Coeliac Disease And Type 1 Diabetes

Research [ref1] has shown that in 491 people with Type 1 diabetes there was a high presence of undiagnosed coeliac disease [5.9%] and it was also higher than normal in their first degree relatives [1.9%]. The study also looked at 4000 healthy people and their rate of undiagnosed coeliac disease was only 0.25%. This confirms other studies that have shown similar findings and adds weight to the suggestions that there should be routine screening for coeliac disease in children and adults with Type 1 diabetes because it can remain undiagnosed. There was also a higher rate of other autoimmune disorders in people with Type 1 diabetes and coeliac disease. This is supported by other published research [ref 2]

Coeliac disease may be the cause of vague abdominal symptoms or hypoglycaemia caused by impaired carbohydrate absorption. Research shows the prevalence of coeliac disease in children with diabetes is between 1% and 16% and in adults between 1% and 6% [ref1].

### Facts

- Coeliac disease is highly prevalent in the UK and affects 1 in 300 people.
- Most coeliac disease is finally diagnosed in adulthood usually in the

30-45 age group.

- Many other cases may remain undiagnosed or may be falsely diagnosed as irritable bowel syndrome and only a third of cases are ever diagnosed as coeliac disease and treated with a gluten free diet.
- Certain groups are at greater risk of developing coeliac disease – people with Type 1 diabetes, Downs syndrome, thyroid disease and osteoporosis.

Recently developed blood test for the diagnosis of coeliac disease

Until recently coeliac disease could only be detected after years of symptoms an intestinal biopsy. The new test measures antibodies in the blood to gluten and gliaden in the diet and damaged endomysial muscle in the bowel. The anti-gliaden antibodies disappear with a gluten free diet but the endomysial antibodies persist in all people with untreated and treated coeliac disease and so it is an excellent screening test although not 100% accurate.

**Web site** - more information on coeliac disease can be found by visiting [www.allergy.co.uk/coeliac\\_disease.htm](http://www.allergy.co.uk/coeliac_disease.htm)

Ref 1 Diabetolgia [2001;44:151-155]

Ref 2 Coeliac disease and Type 1 diabetes – the case for screening, Diab Med 2001;19

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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